Environmental Management System ISO 14001:2004

Handbook of Transition with CD-ROM

Syed Imtiaz Haider, Ph.D.



CRC Press is an imprint of the Taylor & Francis Group, an **informa** business

CRC Press Taylor & Francis Group 6000 Broken Sound Parkway NW, Suite 300 Boca Raton, FL 33487-2742

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Printed in the United States of America on acid-free paper 10 9 8 7 6 5 4 3 2 1

International Standard Book Number: 978-1-4398-2939-4 (Hardback)

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Library of Congress Cataloging-in-Publication Data

Haider, Sved Imtiaz.

Environmental management system ISO 14001:2004: handbook of transition with CD-ROM / author, Syed Imtiaz Haider.

p. cm.

"A CRC title."

Includes bibliographical references and index.

ISBN 978-1-4398-2939-4 (hardcover : alk. paper)

- 1. Sustainable engineering--Standards. 2. Environmental engineering--Standards.
- ${\it 3. \,\, Environmental \,\, protection--Standards. \,\, 4. \,\, Environmental \,\, management--Standards. \,\, I. \,\, Title.}$

2010029755

TA170.H35 2011

658.4'083--dc22

Visit the Taylor & Francis Web site at http://www.taylorandfrancis.com

and the CRC Press Web site at http://www.crcpress.com

This book is dedicated to my loving father Syed Mohsin Raza and my late mother Khursheed-un-Nisan. I am also thankful to my wife Shazia Fatima, son Syed Zeeshan Haider, and daughter Syeda Mehreen Fatima for their patience and for providing a professional environment. I also thank my colleague Hima Vatee, who agreed to assist in the proofreading of this book.

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Preface

On November 15, 2004, the International Organization for Standardization (ISO) issued the second editions of ISO 14001 and ISO 14004. This revision to the standards is part of ISO's commitment to periodically review and update each standard and concludes more than three years' work by the ISO Technical Committee (TC207) responsible for their development and maintenance.

According to the introduction to ISO 14001, "The second edition of this International Standard is focused on clarification of the first edition, and has taken due consideration of the provisions of ISO 9001 to enhance the compatibility of the two standards for the benefit of the user community." Although every clause and subclause of the 1996 version have undergone some level of revision, most of the changes are minor adjustments in terminology for clarification purposes. In most cases, a system correctly implemented and in conformance with the certification requirements will need only minor changes to conform to the new version of the standard.

The first general change is that, throughout the document, the phrase "establish and maintain a procedure" has been changed to "establish, implement and maintain a procedure." Organizations that have sought certification of their Environmental Management System (EMS) have always had to demonstrate implementation of their systems in order to become certified, and this will not result in any change in the audit's approach. This change in wording will likely have little impact in any case, except possibly where an organization has self-declared the existence of an EMS and where actual implementation of the system may be weak.

Another general change is the elimination of almost all specific requirements for a "documented procedure." In fact, the only place where this requirement is still stated is in clause 4.4.6 (operational control) and even there it is modified by "... to control situations where their absence could lead to deviation from the environmental policy, objectives and targets," as it did in the 1996 version. Another remaining reference to procedural documentation exists in the definition of internal audit (3.14), which states that an audit is a "... documented process" Even with this elimination of references to the documented procedures, however, documentation remains important to the establishment and maintenance of the EMS. This is evident in clause 4.1, which requires that the organization "... establish, document, implement, maintain and continually improve an environmental management system ..." where "document" is an addition to this clause since the 1996 version. Generally, though, the new wording of the requirements allows the organization greater flexibility in determining

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where and at what level documentation should be developed. Despite these changes in language, the position of auditors will change little. While we can no longer require documented procedures as defined in some of the elements of the 1996 standard, we will continue to expect documentation, in one form or another, wherever it is necessary to ensure consistent structure and implementation of the EMS.

All audits conducted after May 15, 2005 are in accordance to the 2004 version of the standard.

After May 15, 2006, the 1996 version of the ISO 14001 became obsolete, and no certifications to that version of the standard are maintained.

The compliance to the international environmental standards is essential to be in harmony with Mother Nature. The development, implementation, and maintenance of key standard operating procedures (SOPs) are essential to an EMS and are a requirement of the ISO 14001:2004. The revised ISO 14001:2004 standard assures that the shareholders, customers, and the employees of corporations have much to gain from EMS as we owe it to our future generation. Writing SOPs can be time consuming for those new to the EMS. Moreover, the EMS does not specify how the SOPs are to be written, what format they should be in, or how many are enough. Those new to ISO 14001:2004 compliance may have difficulty knowing the best route to take. Generally, companies new to the EMS are allowed an adequate amount of time for remedial action and demonstration of their commitment to environmental compliance and continuous improvement. Documentation management, however, can minimize the number of adverse findings for incomplete or missing SOPs and prevent repeated adverse findings by making the development of SOPs a top priority. The first step is to develop an adequate set of SOPs for the EMS activities and the overall program. The CD-ROM provides template of EMS manual and a set of SOPs in hard copy and in electronic form that address the most important elements of an EMS program. These SOPs can readily be adapted to a facility's needs and style. This manual should greatly facilitate understanding of the ISO 14001:2004 and how best to develop an environmental compliance program to derive the benefits such as

- No international trade barriers
- · Zero accidents
- Regulatory compliance local and international
- · Operational cost saving
- Healthy and safe work environment at the site
- Reduction of penalties due to local legislations
- Reduction of waste generation and disposal cost
- Energy conservation

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- Reduction of raw material/resource usage
- Marketing edge over competitors
- Improved company credibility
- Reduction in insurance premiums
- Uninterrupted operations
- Good public opinion
- Improved process efficiency
- Proactive environmental insurance provisions
- Motivating employees

The EMS manual and SOPs on the included CD-ROM are valuable tools for companies in the process of developing or transitioning to achieve the ISO 14001:2004 certification/registration. The documentation package is especially relevant to quality assurance personnel, engineers, field engineers, utilities engineers, computer engineers, validation designers, internal and external auditors, or to anyone interested in developing an EMS.

The book contains information from the ABB practical guide, ISO 14001 issue date January 2000. The author is deeply grateful to ABB and Curt Hericson for granting permission for reprinting requested text.

The author believes that by following these generic examples of the manual and procedures, both new and experienced companies can benefit by enhancing their existing documentation to meet ISO 14001:2004 requirements and other legal requirements. Currently, no document specifically describes the format of the EMS manual and SOPs.

Syed Imtiaz Haider, PhD

About the Book

This book takes into account the documentation of environmental management system (EMS) and applicable procedures based on the elements described in the second edition of international standard ISO 14001:2004. No other manual in print deals exclusively with the key elements of EMS and provides hands-on templates tailored to achieve a smooth transition and registration/certification.

The ISO 14001:2004 EMS manual, together with 22 standard operating procedures, examples of policies, objectives, targets, and programs with a practical help section provide explicit instructions on how to achieve the standard for anyone, especially those individuals responsible for writing and executing the EMS manual and applicable procedures. Included herein is a ready-to-use template, on a CD-ROM that one can immediately use as his own without "reinventing the wheel," thus saving time and money without missing any critical quality elements.

The book and CD-ROM provide a complete, single-source reference, with practical help based on EMS elements described in the ISO 14001:2004 international standard.

This manual offers instant answers for professional auditors, environmental managers, engineers, field engineers, EMS coordinators, auditors, and protocol writers regarding what should be included in the EMS manual and ISO 14001:2004 standard operating procedures to achieve compliance.

Introduction

- Objective
- Definitions
- Correspondence between ISO 14001:1996 and ISO 14001:2004
- Correspondence between ISO 9001:2008 and ISO 14001:2004
- Correspondence between ISO 14001:2004 and ISO 9001:2008
- Certification

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Environmental Management and Systems Manual

• ISO 14001:2004 Compliance Manual

Standard Operating Procedures

- General requirements
- Environmental policy
- Planning
- Environmental aspects
- Legal and other requirements
- Objectives and targets
- Environmental management program(s)
- Implementation and operation
- Resources, roles, responsibility, and authority
- Competence, awareness, and training
- Communication
- Documentation
- · Control of documents
- Operational control
- Emergency preparedness and response
- · Checking and corrective action
- Monitoring and measurement
- Evaluation of compliance
- Nonconformity, corrective action, and preventive action
- · Control of records
- Internal audit
- Management review
- Examples of environmental policy statements
- EMS examples
- Practical help
- · Recommended readings

Acknowledgments

The author thanks his friends and colleagues for their encouragement and for creating a professional environment. Special thanks to the staff of the CRC Press, particularly, for their patience and diligence in the production of this book.

Last but not least, I am sincerely thankful to Dr. Ayman Sahli, the general manager of Julphar, Gulf Pharmaceutical Industries, United Arab Emirates, for providing continuous support to the development of my professional skills, which resulted in consolidation of my experience into practical applicable handbooks.

Author

Syed Imtiaz Haider earned his PhD in chemistry and is a quality assurance and environmental specialist with over 20 years of experience in aseptic and nonaseptic pharmaceutical processes, equipment validation, and in-process control and auditing. Dr. Haider is currently involved in several major biotechnology-based tasks, which include cell line qualification, process validation, bio-analytical method validation, biosimilars comparative studies, organizing preclinical studies, and preparation of files as per Central Technical Dossier (CTD) format for regulatory submission. Dr. Haider is the author and coauthor of more than 20 research publications in international refereed journals dealing with products of pharmaceutical interest, their isolation, and structure development. A professional technical writer, Dr. Haider has authored more than 2000 standard operating procedures based on the Food and Drug Administration (FDA) regulations, ISO 9001:2000, and ISO 14001:2004 standards. He is a certified QMS auditor of the International Register of Certified Auditors (IRCA) and a registered associate environmental auditor of EARA. He has written more than 10 quality system manuals for multidisciplinary industries and provided consultancy to the Ministry of Health, United Arab Emirates, Drug Control Laboratory, in developing a quality management system based on the ISO 9003 and later transition to ISO 9001:2000.

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Dr. Haider is also involved in organizing cGMP conferences in the region and resourcing competitive speakers from Europe, Canada, and the United States.

Introduction

Environmental Management System ISO 14001:2004: Handbook of Transition with CD-ROM is comprised of the manual and applicable procedures fully updated to meet the new requirements of ISO 14001:2004.

The book provides administrative solutions for management in both text and software for successful transition in the shortest possible time frame. The contents of the book address the following:

- Introduction
- Definitions
- Correspondence between ISO 14001:1996 and ISO 14001:2004
- Correspondence between ISO 9001:2008 and ISO 14001:2004
- Correspondence between ISO 14001:2004 and ISO 9001:2008
- Certification
- Documented Environmental Management System Manual ISO 14001:2004
- Twenty-two documented standard operating procedures based on the elements defined in the ISO 14001:2004 series of standard
- Examples of policies
- Examples of EMS objectives, targets, and programs
- Practical help

The environmental system manual and standard operating procedures in text and on the CD-ROM are valuable tools for those companies that are in a process of adopting and incorporating the requirements of ISO 14001:2004 published in November 2004 in their existing system or planning to apply for registration in future. The documentation package is especially relevant to EMS coordinators, management representatives, engineers, field engineers, designers, internal auditors, external auditors, or to anyone interested in developing a documented system.

The EMS manual and standard operating procedures are provided both in text and in an electronic form on CD-ROM for customers' convenience. The book and CD-ROM EMS manual based on the ISO 14001:2004 series of standard with samples of policy statements, objectives, targets, and programs will enable the users to amend or adopt them without reinventing the wheel and losing time.

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The CD-ROM also includes standard operating procedures; they are made available so that customers can input them into their computer and use their own Microsoft Word® program to edit and print these documents. The contents of the procedures are written in simple and precise language to be in compliance with the elements of the amended ISO 14001:1996 standard to the ISO 14001:2004 series of standards in November 2004. The book aims to minimize the number of documents and to avoid the nightmare of management representative at the time of certification. The standard operating procedures refer exclusively to the documents especially required for compliance; however, specific formats are included to ensure that the soft copy can be easily used worldwide with a diversified range of industries and organizations.

Environmental Management System ISO 14001:2004: Handbook of Transition with CD-ROM is primarily written in a global context and can be applied to any process-related industry or organization interested in environmental compliance. The documents provided in the text, however, can be applied to any regulated or nonregulated industry. Some of the reasons for purchasing this book would be as follows:

- Reducing the difficulty of translating the revised ISO 14001:1996 standard to ISO 14001:2004 requirements into action.
- Provides readers and frontline management all the information they need to know to make a successful documented EMS based on the ISO 14001:2004 series of standards implemented from November 2004, which has acquired global acceptance to overcome international trade barriers.
- Simple, concise, and easy-to-use reference tool covering the basic concepts and elements described in the applicable ISO 14001:2004 series of standard.
- The text and the software are valuable time-savers for those companies that are in a process of writing and organizing the documentation for certification and the purpose of further improvement.
- The manual and procedures provided in the CD-ROM can be easily tailored to incorporate changes to add organizational requirements.
- The manual and procedures provide stepwise guidance on how to develop and implement the system.
- Explicit working formats are provided to execute impact analysis and management review, identify aspects of significant environmental impacts based on applicable international and local legislations, provide priority rating to aspects of significant impacts,

Introduction xix

define policies, objective and targets, develop programs, and establish emergency preparedness, thus reducing the anxiety of middle management to defining EMS-related terminologies.

- Examples of EMS polices, targets, objectives, and programs.
- A practical help chapter is provided with virtually filled forms for customer convenience as to how to use the attachment.

Below is a list of potential primary and secondary users who may benefit from the handbook of EMS:

- Pharmaceutical industry
- Medical device industry
- All consumer products manufacturers
- All process-related industries
- · Packaging material manufacturers
- Bulk raw materials manufacturers
- Electronic component manufacturers
- Food items manufacturers
- · Healthcare management organizations
- Pharmacies
- Mechanical equipment manufacturers
- Hi-tech equipment manufacturers
- · Tourism industry
- Servicing organizations
- R&D laboratories
- Hospitals
- Inspection and testing laboratories
- Chemical manufacturers
- Nuclear facilities

Objectives: This section describes the background of the ISO series of standards and their development and basic changes in the ISO 14001:2004 international standard. It also provides a timeline chart and documentation and describes the registration/certification process.

EMS Manuals: Templates of the EMS manual provided as a model can be directly adopted by a company planning for the first time for registration/certification to an international standard ISO

xx Introduction

14001:2004 or planning for transition to an ISO 14001:2004 company in possession of the ISO 14001:1996 registration/certification that intends to revise its EMS manual.

- **Standard Operating Procedures:** This provides 22 template procedures that can be adopted after minor changes suitable to each company's operations.
- **The Practical Help:** Provides 28 explicit attachments to be used as a guide and 31 examples of attachments filled in for customers' convenience.

Manual Format

- **Your Company Name:** At the top of each page of the quality manual, space is provided to enter the company name.
- **EMS System Manual:** The EMS manual assigns a space to indicate the standard used to document the quality management system.
- **Manual Serial Number:** The EMS manual is assigned a unique number that appears at the upper right-hand corner of each page.
- **Revision Number:** At the right-hand corner of each page is the revision number box, which is provided to document the revision number.
- **Written by:** The EMS manual provides space for the author name, title, and the department with signatures and the date.
- **Checked by:** The EMS manual is assigned a space to provide the name of the person responsible for the verification of the contents of the manual, the title, and the department with signatures and the date.
- **Approved by:** Each page of the EMS manual has a space to provide the name, title, and department of the person in the quality assurance unit or the management representative approving the manual with signatures and the date.
- **Date Supersedes:** Each page of the EMS manual allocates a space to indicate the issue date of the manual superseded.
- **Date Issued:** Each page of the EMS manual is provided with a space to provide the manual's issue date.
- **Distributed to:** Each top page of the EMS manual has a space bar to indicate the recipients of the manual.

Controlled Copy Number: Each front page of the EMS manual is assigned a space to provide the copy number assigned to the manual for distribution.

- **Section Clauses:** Each page of the EMS manual has a box to indicate the section and the applicable clause.
- **Reasons for Revision:** On the top page of the EMS manual, space is provided to describe the reasons for revision of the procedure with the date.
- **Reference SOP Number:** On the last page of each clause described in the EMS manual, space is provided to write the applicable SOP number.

SOP Format

All SOPs have been designed and formatted to have the same look, and similar information is located in the same place on all SOPs. Information common to all SOPs is described below.

- **Your Company Name:** At the top of each page of an SOP, space is provided to enter the company name.
- **Subject:** The subject of each SOP appears at the upper left-hand corner of the SOP and describes the quality element described in the SOP.
- **SOP Number:** Each SOP is assigned a unique number that appears at the upper right-hand corner of the SOP based on the reference clause of the ISO 14001:2004 series of standard.
- **Corresponding Clause:** All SOPs are provided with a space in the second line of the SOP's header to provide reference to the corresponding clause of international standard ISO 14001:2004.
- **Distributed to:** Each SOP has a space to list the recipients of the SOP.
- **Based on:** Each SOP is provided with a space to list the applicable ISO14001:2004 series of standard.
- **Revision Number:** At the right-hand corner of each page is the revision number box. The box is provided to document the revision number.
- **Written by:** Each SOP has dedicated space to provide the author's name, title, and department with signatures and the date.

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Checked by: Each SOP is provided with a space to provide the name of the person responsible for the verification of the procedure, title, and department with signatures and the date.

- **Approved by:** Each page of the SOP has a space to provide the name, title, and department of the person in the quality assurance unit or the management representative approving the SOP with signatures and the date.
- **Date Supersedes:** Each page of the SOP has space to indicate the issue date of the SOP superseded.
- **Date Issued:** Each page of the SOP has a space to provide the SOP issue date.
- **Page Number:** Each SOP page is numbered.
- **Purpose:** Each SOP is supported with reasons, describing the purpose of that SOP.
- **Responsibility:** Each SOP is supported with responsibility, describing the department and the employee responsible for implementing the procedure.
- **Definition:** Where necessary, definitions are provided in the SOP for better understanding.
- **Procedure:** Following the responsibility statement are the individual steps of the SOP. These are arranged in a logical order and numbered on the ISO 14001:2004 series of standards.
- **Reasons for Revision:** At the end of each SOP, space is provided to describe the reasons for the revision of the procedure with the date.
- **CD-ROM**: An electronic copy of the EMS manual and SOPs are provided.

Disclaimer

Every effort has been made to ensure that the contents of the ISO 14001:2004 EMS Manual are accurate and that the recommendations are appropriate and made in good faith. The author accepts no responsibility for inaccuracies or actions taken by companies subsequent to these recommendations.

The similarity in the contents with a particular reference may be incidental due to likenesses in principle.

100.10-1

Objective

ISO 14001:

After the series of avoidable environmental catastrophes such as Bhopal, Chernobyl, and Exxon, there has been a continuous increase in public anxiety as it is really difficult to define all of the factors promoting change in the environment. However, it is clear that the solution to control the environment is only possible at the corporate level and public awareness.

As the public and regulatory concern grows for maintaining and improving the quality of the environment and protecting human health, organizations of all sizes are increasingly focusing their attention to the significant environmental impacts of their activities, products, or services. The environmental performance of an organization is of increasing importance to internal and external interested parties. The sound environmental performance achievement requires organizational commitment to a structured approach and to continual improvement of the Environmental Management System (EMS) ISO 14000:2004.

The ISO 14001:2004 is the only standard, which contains requirements that may be objectively audited for certification registration purpose or for self-declaration purposes. An EMS provides order and consistency for an organization to address environmental concerns through the allocation of resources, assignment of responsibilities, and ongoing evaluation of practices, procedures, and processes.

Following the global recognition of ISO 9000 in 1993, the European committee for standardization and the International Standard Organization made an agreement for the development of standards for environmental management and performance. The task was begun with the initiation of standards ISO 14000, ISO 14001, and ISO 14040 in 1996. The ISO 14000 series of standards include:

EMS specification with guidance for use

150 11001.	Livio specification with guidance for use
ISO 14001:	Environmental Management System—General
	guidance on principles, systems, and supporting
	technique
ISO 1410-12:	Guidelines for environmental auditing
ISO 14010:	General principles of environmental auditing
ISO 14011:	Auditing procedures
ISO 14012:	Qualification criteria for environmental auditors

ISO 14020:	Labeling standards
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ISO 14030: Environmental performance standards

ISO 14040: Life cycle assessment standards

ISO 14050: Environmental management vocabulary

ISO 9000:2000: Quality management systems—Fundamental

and vocabulary

ISO 9001:2000: Quality management systems—Requirements

ISO 14004:2004: Environmental management systems—General

guidelines on principles, systems, and support

techniques

ISO 19011:2002: Guidelines for quality and/or environmental

management systems auditing

ISO 9001:2008: Revised quality management system

On November 15, 2004, the International Organization for Standardization (ISO) issued the second editions of ISO 14001 and ISO 14004. This revision to the standards is part of ISO's commitment to periodically review and update each standard and concludes more than three years' work by the ISO Technical Committee (TC207) responsible for their development and maintenance.

According to the introduction to ISO 14001, "The second edition of this International Standard is focused on clarification of the first edition, and has taken due consideration of the provisions of ISO 9001 to enhance the compatibility of the two standards for the benefit of the user community." Although every clause and sub-clause of the 1996 version has undergone some level of revision, most of the changes are minor adjustments in terminology for clarification purposes. In most cases, a system correctly implemented and in conformance with the certification requirements will need only minor changes to conform to the new version of the standard.

The first general change is that, throughout the document, the phrase "establish and maintain a procedure" has been changed to "establish, implement and maintain a procedure." Organizations that have sought certification of their EMS have always had to demonstrate implementation of their systems in order to become certified and this will not result in any change to the auditor's approach. This change in wording will likely have little impact in any case, except possibly where an organization has self-declared the existence of an EMS and where actual implementation of the system may be weak.

Another general change is the elimination of almost all specific requirements for a "documented procedure." In fact, the only place where this requirement is still stated is in clause 4.4.6 (operational control) and even there it is modified by "... to control situations where their absence could

Objective 3

lead to deviation from the environmental policy, objectives and targets," as it did in the 1996 version. Another remaining reference to procedural documentation exists in the definition of internal audit (3.14), which states that an audit is a "...documented process...." Even with this elimination of references to documented procedures, however, documentation remains important to the establishment and maintenance of the EMS. This is evident in 4.1, which requires that the organization "... establish, document, implement, maintain and continually improve an environmental management system..." where "document" is an addition to this clause since the 1996 version. Generally though, the new wording of the requirements allows the organization greater flexibility in determining where and at what level documentation should be developed. Despite these changes in language, the position of auditors will change little. Although we can no longer require documented procedures as defined in some of the elements of the 1996 standard, we will continue to expect documentation, in one form or another, wherever it is necessary to ensure consistent structure and implementation of the EMS.

It is true that over the past 100 years there has been significant pollution of the environment by many industrial units and has led to the pollution in several ways such as:

- Air pollution
- Ozone depletion
- Soil pollution
- Increase level of CO₂
- Underground water pollution
- Global warming
- · Acid rain
- Noise pollution
- Excretion of toxic waste

The answer to adoption of the industrial units to ISO 14001:2004 EMS can be simply explained as prevention of population besides many other benefits such as:

- No international trade barriers
- · Zero accidents
- Regulatory compliance local and international
- Operational cost saving
- Healthy and safe work environment at the site
- Reduction of penalties due to local legislations

- Reduction of waste generation and disposal cost
- Energy conservation
- Reduction of raw material/resource usage
- Marketing edge over the competitors
- Improved company credibility
- Reduction in insurance premiums
- Uninterrupted operations
- Good public opinion
- Improved process efficiency

The standard operating procedures (SOPs) became very popular in the late 1970s with the development of good laboratory practices (GLPs) regulations, and since then the US Environmental Protection Agency (EPA) also considers SOPs as an essential tool to demonstrate the documented procedures that lead to subjective environmental compliance evidence. SOPs help management evaluate adequacy through

- · Historical records
- Audits from environmental agencies
- · Internal audits

Development of EMS and applicable SOPs is an enormous task, and the staff often experience difficulty with certain ISO 14001:2004 requirement, especially those concerning the establishment and assigning a numerical value to an aspect of major environmental concern within an organization development of complete set of SOPs and data record keeping.

The Environmental Management System (EMS) Manual and Standard Operating Procedures formats based on ISO 14001: 2004 series of standard provide explicit 22 essential information, which can be tailored to make it your own system without reinventing the wheel, paying heavy consultation fees, and going through enormous painstaking job of using selective language to describe your system.

Your company can personalize your own documentation system. The documentation is provided on a CD-ROM (ISO 14001:2004 COMPLIANCE MANUAL), which can be opened on your personal computer.

Herein is the electronic documentation CD-ROM required to help comply with ISO 14001:2004 series of standard. The CD includes template *Environmental Management System Manual* based on the ISO 14001:2004 standard and 21 SOPs describing the elements to be in compliance with the EMS requirements.

Environmental Management Systems Manual and Standard Operating Procedures on the CD (ISO 14001:2004 COMPLIANCE PACK) are valuable tools for a company intending to improve documentation control and getting certified. The Manual and SOPs are especially relevant to environmental personnel and documenting managers, operational personnel, designers, engineers, field engineers, and anyone interested in developing or improving environmental documentation practices.

The Environmental Management System Manual and Standard Operating Procedures are provided in an electronic form on a CD for convenience. These are made available so that one can import them into a computer and use Microsoft Word program to incorporate changes and print these documents.

We are convinced that you will find these electronic *Environmental Management System Manual and Standard Operating Procedures* a valuable time and money saver.

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Definitions Used

Without normative references, environment is defined as surrounding in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation.

The definition of surrounding in the context may be extended from within an organization to the global system. There are no references present; however, the following definitions include seven new definitions marked "N" and a number of changes to the existing definitions. The definitions changed from ISO 14001:1996 to ISO 14001:2004 are marked "C" within parentheses.

Continual improvement (C)

A process of enhancing the environmental management system to achieve improvements in overall environmental performance in line with the organization's environmental policy.

Corrective action (N)

Action to eliminate the cause of a detected nonconformity.

Document (N)

Information and its supporting medium.

Environment

Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation.

Environmental aspect

Element of an organization's activities, products, or services that can interact with environment.

Environmental impact

Any change to the environment, whether adverse or beneficial, wholly or partially, resulting from an organization's activities, products, or services.

Environmental management system (C)

The part of the overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, achieving, reviewing, and maintaining the environmental policy.

Environmental management system audit

A systematic and documented verification process of objectively obtaining and evaluating evidence to determine whether an organization's environmental management system conforms to the environmental management system audit criteria set by the organization and for communication of the results of this process to management.

Environmental objectives (C)

The overall environmental goal, arising from the environmental policy, that an organization sets itself to achieve and which is quantified where practicable.

Environmental performance (C)

Measurable results of the environmental management system, related to an organization of its environmental aspects based on its environmental policy objective and targets.

Environmental policy

Statement by the organization of its intentions and principles in relation to its overall environmental performance, which provides a framework for action and for the setting of its environmental objectives and targets.

Environmental target

Detailed performance requirement quantified where practicable, applicable to the organization or parts thereof, that arises from the environmental objectives and that needs to be set and met in order to achieve those objectives.

Internal audit (N)

Systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the environmental management system audit criteria set by the organization are fulfilled.

Interested party

Individual or group concerned with or affected by the environmental performance of an organization.

Nonconformity (N)

Nonfulfillment of a requirement.

Organization

Company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether in corporate or not, public or private, that has its own functions and administration.

Preventive action

An action to eliminate the cause of a potential nonconformity.

Procedure

A specified way to carry out an activity or a process.

Record

Document stating results achieved or providing evidence of activities performed.

Prevention of pollution (C)

Use of processes, practices, materials, or products that avoid, reduce, or control pollution, which may include recycling, treatment, process changes, control mechanisms, efficient use of resources and material substitution.

100.10-3

Correspondence between ISO 14001:1996 and ISO 14001:2004

On November 15, 2004, the International Organization for Standardization (ISO) issued the second editions of ISO 14001 and ISO 14004. This revision to the standards is part of ISO's commitment to periodically review and update each standard and concludes more than three years work by the ISO Technical Committee (TC207) responsible for their development and maintenance.

According to the introduction to ISO 14001, "The second edition (ISO 14001:2004) of this International Standard is focused on clarification of the first edition, and has taken due consideration of the provisions of ISO 9001 to enhance the compatibility of the two standards for the benefit of the user community." Although every clause and subclause of the 1996 version has undergone some level of revision, most of the changes are minor adjustments in terminology for clarification purposes. In most cases, a system correctly implemented and in conformance with the certification's requirements will need only minor changes to conform to the new version of the standard.

Although the majority of the changes to the standard are very minor, there are a few places where the shift in meaning may be more significant, depending on the organization and management system involved. A summary of these follows.

Significant Changes to the Standard and What They Mean

Section 3 of the standard includes seven new definitions and a number of changes to the existing definitions. The seven new definitions include:

Corrective action

Document

Internal audit

Nonconformity

Preventive action

Procedure

Record

The definitions that have changed include:

Continual improvement
Environmental management system
Environmental objective

Environmental performance

Prevention of pollution

Of the changed and new definitions, two are significant:

Internal audit—The definition of internal audit is significant in two aspects. The definition specifically states that this is an "independent and documented" process. Independence is always a good idea in an audit program but previously this was not emphasized for internal audits of an EMS. In conjunction with the requirement in clause 4.5.5 that "selection of auditors and conduct of audits shall ensure objectivity and the impartiality of the audit process," this represents one of the most significant changes to the requirements of the standard. The inclusion of the requirement for the process to be documented is a departure from the general elimination of any specific requirement for "documented procedures" from the standard. Although this documented process may not be considered a formal "procedure" within the EMS, we will be looking for essentially the same thing.

Environmental performance—This term is now much more clearly defined as "measurable results of an organization's management of its environmental aspects." This is particularly important in enhancing clauses 4.4.1.b with respect to the responsibilities of the management representative, 4.5.1 with respect to the monitoring of performance, and 4.6 in defining information to be considered during management review.

- 4.1 The addition to 4.1 requiring the organization to "... define and document the scope of its environmental management system" will help organizations clearly understand the boundaries of their EMS. All organizations seeking to have their EMS certified have had to identify the scope of the EMS, often in cooperation with their certification body. This requirement may help organizations be better prepared initially and better able to maintain focus as they improve their system.
- 4.2 The policy commitment to comply with "environmental legislation and regulations" has been clarified to read "a commitment to comply with applicable legal requirements ... which relate to its environmental aspects." This should help to define specifically which legal requirements fall within the scope of the EMS. Although this clarification will not substantially change the way in which the auditors will assess the issue, organizations may find it easier to be prepared.

- 4.3.1.a The clarification "... within the defined scope of the environmental management system ..." will help organizations and auditors to focus on identifying aspects only within the defined scope of the EMS. While this has always been the interpretation, the better definition of the scope required in 4.1 will help to reduce the confusion regarding the inclusion of environmental aspects at the margins of the organization, facility, or EMS.
- 4.3.1.a The requirement for an organization to identify its environmental aspects has been strengthened by the addition of the phrase "... taking into account planned or new developments, or new or modified activities, products and services" Although this has always been implied, the lack of clarity has led to some weaknesses in EMS implementation. While this will not alter the way in which the auditors perform the audit, it does give them more justification when identifying weaknesses in this area.
- 4.3.2 A requirement has been added to 4.3.2 stating that the organization must "determine how [legal and other] requirements apply to its environmental aspects." Not only will this help organizations to understand how legal requirements relate to their system, but it will also help to align these requirements with operational controls and performance monitoring. This will not have any significant impact on how this clause is audited.
- 4.4.1.b In refining the role and responsibility of the management representative, 4.4.1.b has added the specific responsibility for "reporting to top management on ... recommendations for improvement." This means auditors will now be looking for the management representative to be active in developing and/or gathering recommendations for improvement. Whereas ideas for improvement of the system may still come from virtually any source and may have multiple points of entry into the system, this establishes an important link between the day-to-day operation of the management system and management review, which has been strengthened in 4.6.
- 4.4.2 The addition of the phrase "person(s) performing tasks for it *or on its behalf*" strengthens and broadens the requirements for competence, training, and awareness to include contractors, service providers, and other parties that may operate on the organization's behalf. Previously, this clause of the standard was often interpreted as applying only to employees of the organization, with the activities of other parties controlled only under 4.4.6, operational controls. The auditors will expect to see the organization better identify those individuals or organizations operating on its behalf, whose work can have a significant impact on the environment, and describe how their competence is ensured.
- 4.4.4 The management system documentation clause now describes in more detail the minimum documentation expected in the system. Of particular interest are the description of the scope of the EMS and the requirement for "documents including records, determined by the organization to be necessary to ensure the effective planning, operation and control of processes that relate to its significant environmental aspects."

The term "core elements" has been replaced by "main elements," which may not provide much in the way of clarification. However, the Annex (A.4.4) now provides better assistance in determining the appropriate level of documentation. These changes will not alter the way in which the auditors will assess this element.

- 4.4.5 The changes to clause 4.4.5 have brought clearer and more practical wording. The only significant changes are the clarification of the relationship between documents and records and the addition of 4.4.5.f, concerning documents of external origin. Both of these issues, however, were implied in the 1996 version of the standard and this will not result in any significant change to the way auditors assess document control.
- 4.5.2.1 The requirement for the organization to monitor its compliance with applicable legal requirements has been moved into its own subclause to add emphasis and now further requires the organization to "... keep records of the results of the periodic compliance evaluations." While the auditors have always sought these records, this clarification will give them a stronger foundation for doing so.
- 4.5.2.2 The 1996 version of the standard required a policy commitment to "... other requirements to which the organization subscribes," but there was no clear indication of how this commitment would be supported in the other requirements of the standard. The inclusion of clause 4.5.2.2 in the 2004 version corrects this oversight with the requirement that the organization "evaluate compliance with other requirements to which it subscribes." The auditors will now seek evidence of a periodic evaluation of compliance with these "other requirements" and appropriate follow-up and corrective action whenever a nonconformity is identified.
- 4.5.3, 4.5.4, and 4.5.5 are all renumbered from the original 4.5.2, 4.5.3, and 4.5.4, respectively, as a result of the addition of the new 4.5.2 for evaluation of compliance. Although this change has no technical significance, it may result in misalignment of some manuals and other system documents modeled on the 1996 version.
- 4.5.3 Changes to the clause for nonconformity, corrective action, and preventive action include specific requirements for (d) "recording the results of corrective action(s) and preventive action(s) taken," and (e) "reviewing the effectiveness of corrective action(s) and preventive action(s) taken." In order to demonstrate sufficient evidence to support certification, these requirements have always been implied so there will be no significant change in the way these clauses are audited.
- 4.5.4 Within the records requirements, the addition of the requirement to "... maintain records as necessary to demonstrate ... the results achieved" is a change in keeping with the overall shift toward performance-based management of the system. This change will be of particular interest to auditors in association with the revised definition of environ-

mental performance, where we will be looking for records of the results of the organization's management of its environmental aspects.

- 4.5.5 The most significant change to the internal audit requirements is the addition of the requirement that "selection of auditors and conduct of audits shall ensure objectivity and the impartiality of the audit process." As noted above, in association with the new definition of "internal audit," this new requirement for independence of internal auditors is one of the most significant changes to the specific requirements of the standard. The auditors will now be looking for this independence in the planning and execution of internal audits.
- 4.6 Of the revised clauses of ISO 14001, one of the most significantly changed is the management review clause, 4.6. While the framework and stated intent of the management review have remained the same, the standard now identifies specific inputs and outputs. The specific inputs now additionally include:

Communications from external interested parties

Environmental performance

Complaints

Follow-up from previous reviews

Recommendations for improvement

Developments in legal requirements

Among the most significant of these additions are environmental performance and recommendations for improvement. The organization will now need to be able to identify specific measures of environmental performance, maintain records, and make a judgment as to whether the existing levels of performance are acceptable. Together with the requirement for recommendations for improvement, management review should, in many cases, become much more productive.

Revisions to this clause also include more clearly defined outputs, including specifically "... decision and actions related to possible changes ..." the auditors will expect to see these decisions and actions in response to the reported levels of environmental performance and the recommendations for improvement, as well as in response to other inputs, as appropriate.

Annex A It has also been revised and now provides much better direction, clarification, and guidance for organizations implementing and maintaining their environmental management systems. Of particular interest are the sections on the environmental review (A1), identification of aspects (A.3.1), objectives, targets, and programs (A.3.3), documentation (A.4.4), and monitoring and measurement (A.5.1).

100.10-4

Correspondence between ISO 9001:2008 and ISO 14001:2004

ISO 9001:2008			ISO 14001:2004
Introduction (title only)			Introduction
General	0.1		
Process approach	0.2		
Relationship with ISO 9004	0.3		
Compatibility with other management system	0.4		
Scope (title only)	1	1	Scope
General	1.1		
Application	1.2		
Normative references	2	2	Normative references
Terms and definitions	3	3	Terms and definitions
Quality management system (title only)	4	4	Environmental management system requirements (title only)
General requirements	4.1	4.1	General requirements
Documentation requirements (title only)	4.2		
General	4.2.1	4.4.4	Documentation
Quality manual	4.2.2		
Control of documents	4.2.3	4.4.5	Control of documents
Control of records	4.2.4	4.5.4	Control of records
Management responsibility (title only)	5		
Management commitment	5.1	4.2	Environmental policy
		4.4.1	Resources, roles, responsibility, and authority
Management representative	5.5.2	4.4.1	Resources, roles, responsibility, and authority
Customer focus	5.2	4.3.1	Environmental aspects
		4.3.2	Legal and other requirements
		4.6	Management review
Quality policy	5.3	4.2	Environmental policy
Planning (title only)	5.4	4.3	Planning (title only)

continued

ISO 9001:2008			ISO 14001:2004
Quality objectives	5.4.1	4.3.3	Objectives, targets, and program(s)
QMS planning	5.4.2	4.3.3	Objectives, targets, and program(s)
Responsibility, authority, and communication (title only)	5.5		
Responsibility and authority	5.5.1	4.1	General requirements
		4.4.1	Resources, roles, responsibility, and authority
Management representative	5.5.2	4.4.1	Resources, roles, responsibility, and authority resources, role
Internal communication	5.5.3	4.4.3	Communication
Management review (title only)	5.6	4.6	Management review
General	5.6.1	4.6	Management review
Review input	5.6.2	4.6	Management review
Review output	5.6.3	4.6	Management review
Resource management (title only)	6		
Provision of resources	6.1	4.4.1	Resources, roles, responsibility, and authority
Human resources (title only)	6.2		
General	6.2.1	4.4.2	Competence, training, and awareness
Competence, training, and awareness	6.2.2	4.4.2	Competence, training, and awareness
Infrastructure	6.3	4.4.1	Resources, roles, responsibility, and authority
Work environment	6.4		
Product realization (title only)	7	4.4	Implementation and operation (title only)
Planning of product realization	7.1	4.4.6	Operational control
Customer-related processes (title only)	7.2		
Determination of requirements related to the product	7.2.1	4.3.1 4.3.2 4.4.6	Environmental aspects Legal and other requirements Operational control
Review of requirements related to the product	7.2.2	4.3.1 4.4.6	Environmental aspects Operational control
Customer communication	7.2.3	4.4.3	Communication
Design and development (title only)	7.3		
Design and development planning	7.3.1	4.4.6	Operational control
Design and development inputs	7.3.2	4.4.6	Operational control
J 1	-		1

continued

ISO 9001:2008			ISO 14001:2004
Design and development outputs	7.3.3	4.4.6	Operational control
Design and development review	7.3.4	4.4.6	Operational control
Design and development verification	7.3.5	4.4.6	Operational control
Design and development validation	7.3.6	4.4.6	Operational control
Control of design and development changes	7.3.7	4.4.6	Operational control
Purchasing (title only)	7.4		
Purchasing process	7.4.1	4.4.6	Operational control
Purchasing information	7.4.2	4.4.6	Operational control
Verification of purchased product	7.4.3	4.4.6	Operational control
Production and service provision (title only)	7.5		
Control of production and service provision	7.5.1	4.4.6	Operational control
Validation of processes for production and service provision	7.5.2	4.4.6	Operational control
Identification and traceability	7.5.3		
Customer property	7.5.4		
Preservation of product	7.5.5	4.4.6	Operational control
Control of monitoring and measuring equipment	7.6	4.5.1	Monitoring and measurement
Measurement, analysis, and improvement (title only)	8	4.5	Checking (title only)
General	8.1	4.5.1	Monitoring and measurement
Monitoring and measurement (title only)	8.2		
Customer satisfaction	8.2.1		
Internal audit	8.2.2	4.5.5	Internal audit
Monitoring and measurement of processes	8.2.3	4.5.1	Monitoring and measurement
		4.5.2	Evaluation of compliance
Monitoring and measurement of product	8.2.4	4.5.1	Monitoring and measurement
		4.5.2	Evaluation of compliance
Control of nonconforming product	8.3	4.4.7	Emergency preparedness and response
		4.5.3	Nonconformity, corrective action, and preventive action
Analysis of data	8.4	4.5.1	Monitoring and measuremen
Improvement (title only)	8.5		

ISO 9001:2008		ISO 14001:2004	
Continual improvement	8.5.1	4.2	Environmental policy
		4.3.3	Objectives, targets, and program(s)
		4.6	Management review
Corrective action	8.5.2	4.5.3	Nonconformity, corrective action, and preventive action
Preventive action	8.5.3	4.5.3	Nonconformity, corrective action, and preventive action

100.10-5

Correspondence between ISO 14001:2004 and ISO 9001:2008

ISO 14001:2004			ISO 9001:2008
Introduction			Introduction (title only)
		0.1	General
		0.2	Process approach
		0.3	Relationship with ISO 9004
		0.4	Compatibility with other management systems
Scope	1	1	Scope (title only)
		1.1	General
		1.2	Application
Normative references	2	2	Normative references
Terms and definitions	3	3	Terms and definitions
Environmental management system requirements (title only)	4	4	Quality management system (title only)
General requirements	4.1	4.1	General requirements
		5.5	Responsibility, authority and communication (title only)
		5.5.1	Responsibility and authority
Environmental policy	4.2	5.1	Management commitment
		5.3	Quality policy
		8.5.1	Continual improvement
Planning (title only)	4.3	5.4	Planning (title only)
Environmental aspects	4.3.1	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
Legal and other requirements	4.3.2	5.2	Customer focus
		7.2.1	Determination of requirements related to the product

continued

ISO 14001:2004		ISO 9001:2008		
Objectives, targets, and	4.3.3	5.4.1	Quality objectives	
program(s)		5.4.2	Quality management system planning	
		8.5.1	Continual improvement	
Implementation and operation (title only)	4.4	7	Product realization (title only)	
Resources, roles, responsibility, and authority	4.4.1	5.1	Management commitment	
		5.5.1	Responsibility and authority	
		5.5.2	Management representative	
		6.1	Provision of resources	
		6.3	Infrastructure	
Competence, training, and	4.4.2	6.2.1	(Human resources) General	
awareness		6.2.2	Competence, training, and awareness	
Communication	4.4.3	5.5.3	Internal communication	
		7.2.3	Customer communication	
Documentation	4.4.4	4.2.1	(Documentation requirements) Genera	
Control documents	4.4.5	4.2.3	Control of documents	
Operational control	4.4.6	7.1	Planning of product realization	
		7.2	Customer-related processes (title only)	
		7.2.1	Determination of requirements related to the product	
		7.2.2	Review of requirements related to the product	
		7.3.1	Design and development planning	
		7.3.2	Design and development inputs	
		7.3.3	Design and development outputs	
		7.3.4	Design and development review	
		7.3.5	Design and development verification	
		7.3.6	Design and development validation	
		7.3.7	Control of design and development changes	
		7.4.1	Purchasing process	
		7.4.2	Purchasing information	
		7.4.3	Verification of purchased product	
		7.5	Production and service provision (title only)	
		7.5.1	Control of production and service provision	
		7.5.2	Validation of processes for production and service provision	

ISO 14001:2004			ISO 9001:2008
		7.5.5	Preservation of product
Emergency preparedness and response	4.4.7	8.3	Control of nonconforming product
Checking (title only)	4.5	8	Measurement, analysis, and improvement (title only)
Monitoring and measurement	4.5.1	7.6	Control of monitoring and measuring equipment
		8.1	(Measurement, analysis, and improvement) General
		8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
		8.4	Analysis of data
Evaluation of compliance	4.5.2	8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
Nonconformity, corrective action, and preventive action	4.5.3	8.3	Control of nonconforming product
		8.4	Analysis of data
		8.5.2	Corrective action
		8.5.3	Preventive action
Control of records	4.5.4	4.2.4	Control of records
Internal audit	4.5.5	8.2.2	Internal audit
Management review	4.6	5.1	Management commitment
		5.6	Management review (title only)
		5.6.1	General
		5.6.2	Review input
		5.6.3	Review output
		8.5.1	Continual improvement

100.10-6

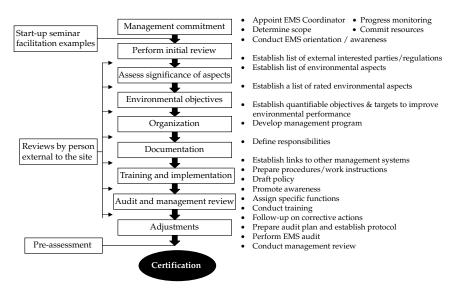
Certification

The key steps involved in the development of the Environmental Management System (EMS) for certification involves the following steps:

- Environmental impact analysis/management review
- Identify the aspect of significant adverse impact on environment
- Set improvement objectives/set targets
- Implement improvement program
- Implement control procedures that may generate positive aspects
- Conduct education and training
- Implement monitoring system
- Review your progress

The general implementation process is as follows:

General Implementation Process



The most difficult, expensive, and time-consuming part is the development of the EMS manual and the applicable standard operating procedures (SOPs). Enormous efforts are needed to establish the following:

- Policy
- Identification of aspects/impacts
- Regulatory requirements
- Setting objectives
- Identifying roles and responsibilities
- Training
- Communication
- Documentation

- Document control
- Operational control
- Emergency procedure
- Monitoring
- Nonconformance
- Records
- Audits
- Management review

Among others, the most time-consuming part is the study of significant aspects and their impacts on the environment defining objectives and targets and the program to monitor and control the EMS. The formats provided in the applicable SOPs can be used directly after entering the applicable legislation and your own process-related requirements and the results of the environmental impact analysis performed in house or by the outside agencies. The key documents involved are the local legislation requirements, which can be obtained from the regulatory agency of the concerned country.

The certification is a two-step process.

Step One

- Management review/impact analysis
- Develop environmental policy
- Writing EMS manual
- Writing of SOPs

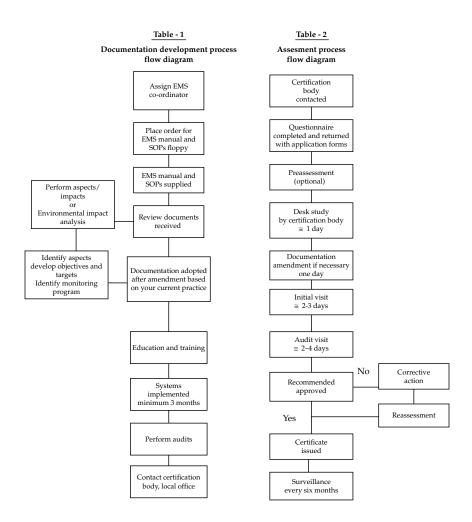
Step Two

- Implementation of procedures (SOPs)
- Certification
- Surveillance

The total time involved in accomplishing steps one and two varies from company to company; however, the most time-consuming and expensive step is the writing of the EMS manual and SOPs, which might take from 9 to 12 months, followed by implementation and training of staff, which as a rule requires a minimum of three months, to invite any certification body for assessment of your system. For the life cycle of documents development and certification, refer Tables 1 and 2, respectively.

All audits must be carried out referring to the new standard and all existing certificates must be transitioned to the new standard.

The assessment to comply with the new version can be arranged, either through preliminary assessment work or by adding time to the existing planned audits.



If you already have a certified management system For most organizations, the revisions will require one to carry out some reviews of the system documentation and processes, verify the ongoing compliance in those areas subject to change and clarification, and make changes as necessary to align the EMS to the new standard.

Follow these steps to upgrade the EMS:

- 1. Identify gaps and needed changes. To assist in this process, follow the checklist provided under Section 100.10.3, which should be useful to assess the changes and review the need to take any action.
- 2. Define the transition team.
- 3. Establish the transition schedule.
- 4. Train the transition team and internal auditors.
- 5. Upgrade the EMS.
- 6. Run one cycle of internal audits, corrective actions, and management review.
- 7. Conduct preaudit.
- 8. Proceed with the certification against ISO 14001:2004.

If you are working toward first certificate For companies seeking certification of an EMS for the first time, the EMS should be developed based on the ISO 14001:2004. If the EMS has already been largely developed according to the 1996 edition, the new requirements should be implemented in the EMS by following the steps as described above. A well-implemented EMS should meet the key requirements of both versions, since the fundamental requirements are the same.

ISO 14001:2004 Compliance Manual

200.20-1

Environmental Management Systems Manual

QUALITY ASSURANCE DEPARTMENT ISO 14001:2004

Prepared and Maintained in Accordance with EN ISO 14001: 2004

Written by	Checked by	Approved by
Date supersedes	Date issued	Manual serial no.
mm/dd/yyyy	mm/dd/yyyy	EMS-1
		Revision no.: 0

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4.	Environmental coordinator	Copy-3

5.

6.

Reasons for Revision

mm/dd/yyyy 1. First time issued for "Your Company Name."

Environmental Management Systems Manual			
GENERAL REQUIREMENTS	Section-1, Clause-4.1	Revision no.: 0	
Written by:	Checked by:	Approved by:	
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: 1 of 1	

General Requirements

The "Your Company Name" has established and maintained an environmental management system, the requirements of which are established and documented.

The Environmental Management System (EMS) provided the company: a structured process for the achievement of continual improvement in the long term.

- Provide your company profile.
- Explain the type of activities, processes, and products involved.
- Provide organization chart.

Although immediate reduction of adverse environmental impacts may not result, systems have enabled the organization to

- Establish an environmental policy appropriate to itself.
- Identify the environmental aspects arising from the organization's past, existing or planned activities, products or services to determine the environmental impacts of significance.
- Identify the relevant legislative and regulatory requirements.
- Identify priorities and set appropriate environmental objectives and targets.
- Establish a structure and (a) program(s) to implement the policy and achieve objectives and targets.

Environmental Management Systems Manual			
GENERAL REQUIREMENTS Section-1, Clause-4.1 Revision no.: 0			
Written by:	Checked by:	Approved by:	
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: 1 of 1	

- Facilitate planning, control, monitoring, corrective action, auditing, and review activities to ensure both that the policy are complied with and that the environmental management system remains appropriate.
- Be capable of adapting to changing circumstances.
- Indicate continuous improvement of the EMS.
- State how the organization will define the scope of the EMS.

Reference SOP—[Number—ESM-4.1, dated mm-dd-yyyy].

Environmental Management Systems Manual			
ENVIRONMENTAL POLICY	Section-1, Clause-4.2	Revision no.: 0	
Written by:	Checked by:	Approved by:	
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: 1 of 4	

Environmental Policy

[Environmental policy statement here]

[Should be by top management]

The management has defined the organizations environmental policy and has ensured that it includes a commitment to continual improvement and prevention of pollution is appropriate to the nature, scale, and environmental aspects and impacts of its activities, products, or services.

Includes a commitment to comply with applicable, relevant environmental legislations and legal regulations, which relate to its environmental aspects and with other requirements to which the organization is associated which provides the framework for setting and reviewing environmental objectives and targets:

The Environmental Management System (EMS) is documented, implemented, maintained, and communicated to all employees and is available to the public for information.

The environmental policy recognizes all activities, products, or services causing impacts on the environment. The "Your Company Name" is committed to

- Minimize any significant adverse environmental impacts of new developments through the use of the integrated environmental management procedures and planning.
- Development of environmental performance evaluation procedures and associated indicators.
- Embody life cycle thinking.

Environmental Management Systems Manual			
ENVIRONMENTAL POLICY Section-1, Clause-4.2 Revision no.: 0			
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- Design products in such a way to minimize their environmental impacts in production, use, and disposal.
- Prevent pollution, reduce waste and the consumption of resources (materials, fuel, and energy), and commit to recovery and recycling, as opposed to disposal where feasible.
- Education and training.
- Sharing environmental experience.
- Involvement of and communication with interested parties, inhouse employees, contractors, trainees, and external personnels associated with the EMS.
- Work toward sustainable development.
- Encourage the use of EMS by suppliers and contractors.

Signature

Designation of the Head of the Company/Date

Three more additional examples are quoted. Adopt or amend the one applicable to the activities, processes, or products of your company.

Environmental Management Systems Manual			
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Environmental Policy

EXAMPLE-1

Manufacturing Company

- All present and future operations will, as a minimum, comply with relevant environmental legislation and standards so as to prevent pollution.
- We will develop manufacturing processes with minimum environmental impact, particularly the production.
- We will educate, train, and motivate our employees, contractors (external persons), trainees and so forth to carry out their tasks in an environmentally responsible manner.
- An important long-term aim in our business development is to protect the environment during the whole of our product life cycle. We will do this by limiting negative environmental impact as far as practicable, and by maximizing the recyclability of components.
- We will periodically conduct environmental audits in order to continually improve our environmental performance.

Signature

Designation of the Head of the Company/Date

Environmental Management Systems Manual			
ENVIRONMENTAL POLICY Section-1, Clause-4.2 Revision no.: 0			
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Environmental Policy

EXAMPLE-2

Manufacturing Company

Our business is about design and manufacture of air filtration systems for indoor climate control. Our competitive edge comes from the market's awareness of the environmental performance of our products.

An important strategy in the long-term development of our business is protection of the environment during all stages of product life cycle including design, manufacture, use, and disposal. This means working to minimize negative environmental impact and to achieve as much as possible with limited environmental resources.

Therefore, we shall

- Comply with and follow up on the requirements of relevant laws and standards for environmental protection.
- Choose raw materials, materials, and processes with small negative environmental impact, to economize with resources and to decrease emissions and waste amounts.
- The air filtration units are made mainly of best technology available sheet, and we aim at decreasing the spill during manufacture. At least 90.0% of the materials used should be recyclable when the products are disposed off.
- Educate and motivate our staff, "external" persons to work with and assume responsibility for environmental issues.
- Perform environmental assessments when a process is changed.

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- Have an open dialogue on environmental issues with our staff, customers, suppliers, and other stakeholders.
- Follow up on and set new targets for our environmental work on a regular basis to ensure a continuous decrease in environmental impacts.

The legal responsibility for the environmental impact of the operations lies with the general manager; each department manager, production manager and foreman is responsible within his/her scope of operation for the implementation of the environmental system.

Signature

Designation of the Head of the Company/Date

Environmental Management Systems Manual		
ENVIRONMENTAL POLICY	Section-1, Clause-4.2	Revision no.: 0
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Environmental Policy

EXAMPLE-3

Transport Company

- We will consider the environment as a factor in every business decision we make, and continually improve our performance.
- We will comply with all applicable regulations and laws.
- We will establish environmental management systems to keep us informed about the impact of all our operations, allowing us to achieve the most effective and cost-efficient improvements in performance.
- We are committed to publishing targets for continual improvement in performance, and will work toward these with annual action plans.
- We will reduce the impact of our transport operations by maximizing the efficiency of our routes and vehicles, reviewing our selection of fuels and vehicles, and thinking flexible about delivery methods.
- We will consider the environmental impacts of our suppliers, alongside quality and cost. We will set environmental standards for our suppliers, and work with them to achieve these.
- We will reduce the amount of waste we create: We will minimize our use of materials, design and modify our operations to minimize waste production, use materials longer where practicable, and always investigate recycling opportunities for used materials.

Environmental Management Systems Manual		
ENVIRONMENTAL POLICY	Section-1, Clause-4.2	Revision no.: 0
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- We will invite opinions and feedback on our methods and goals from inside and outside the company, and publish our ideas for furthering best environmental practice in the transport sector.
- We will communicate our policy to persons working in house on our behalf, for example, contractors and trainees.

Signature

Designation of the Head of the Company/Date

Reference SOP—[Number—ESM-4.2, dated mm-dd-yyyy].

Environmental Management Systems Manual		
PLANNING	Section-1, Clause-4.3	Revision no.: 0
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Planning

The "Your Company Name" has developed and maintained structured plan to be in compliance environmental management system ISO 14001:2004. The environmental management system coordinator is responsible to develop plans.

Reference SOP—[Number—ESM-4.3, dated mm-dd-yyyy].

Environmental Management Systems Manual		
ENVIRONMENTAL ASPECTS	Section-3.1, Clause-4.3.1	Revision no.: 0
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Environmental Aspects

The "Your Company Name Here" has established and maintained (a) procedure(s) to identify the environmental aspects of its activities, products, or services that it can control and over which it can be expected to have an influence, in order to determine those which have or can have significant impacts on the environment. The organization has ensured that the aspects related to these significant impacts are considered in setting its environmental objectives.

The review of aspects includes planned or new developments and new or modified activities, products, and services within the aspects process.

Significant aspects are considered during establishing, maintaining, and developing the EMS programs as a basis to set EMS objectives.

The organization keeps this information up-to-date.

Reference SOP—[Number—ESM-4.3.1, dated mm-dd-yyyy].

Environmental Management Systems Manual		
DEFINITIONS	Section-3.1, Clause-4.3.1	Revision no.: 0
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Definitions

Following are the definitions applicable to ISO 14001:2004 Environmental Standard.

Without normative references environment is defined as surrounding in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelationship.

The definition of surrounding in the context may be extended from within an organization to the global system. There are no references present, however, following definitions include seven new definitions (marked "N") and a number of changes to the existing definitions. The definitions changed from ISO 14001:1996 to ISO 14001:2004 are marked "C" in bracket.

Continual Improvement (C)

Process of enhancing the environmental management system to achieve improvements in overall environmental performance in line with the organization's environmental policy.

Corrective Action (N)

Action to eliminate the cause of a detected nonconformity.

Document (N)

Information and its supporting medium.

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Environment

Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelationship.

Environmental Aspect

Element of an organization's activities, products, or services that can interact with the environment.

Environmental Impact

Any change to the environment, whether adverse or beneficial, wholly or partially resulting from an organization's activities, products, or services.

Environmental Management System (C)

The part of the overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes and resources for developing, implementing, achieving, reviewing, and maintaining the environmental policy.

Environmental Management System Audit

A systematic and documented verification process of objectively obtaining and evaluating evidence to determine whether an organization's environmental management system conforms to the environmental management system audit criteria set by the organization and for communication of the results of this process to management.

Environmental Management Systems Manual		
DEFINITIONS	Section-3.1, Clause-4.3.1	Revision no.: 0
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Environmental Objectives (C)

Overall environmental goal, arising from the environmental policy, that an organization sets itself to achieve and which is quantified where practicable.

Environmental Performance (C)

Measurable results of the environmental management system, related to an organization's environmental aspects based on its environmental policy objectives and targets.

Environmental Policy

Statement by the organization of its intentions and principles in relation to its overall environmental performance, which provides a framework for action and for the setting of its environmental objectives and targets.

Environmental Target

Detailed performance requirement quantified where practicable, applicable to the organization or parts thereof, that arises from the environmental objectives and that needs to be set and met in order to achieve those objectives.

Internal Audit (N)

Systematic, independent, and documented process for obtaining audit evidence and evaluation to objectively determine the extent to which the environmental management system audit criteria set by the organization are fulfilled.

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DEFINITIONS Section-3.1, Clause-4.3.1 Revision no.: 0			
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Interested Party

Individual or group concerned with or affected by the environmental performance of an organization.

Nonconformity (N)

Nonfulfillment of a requirement.

Organization

Company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether in corporate or not, public or private, that has its own functions and administration.

Preventive Action

Action to eliminate the cause of a potential nonconformity.

Procedure

Specified way to carry out an activity or a process.

Record

Document stating results achieved or providing evidence of activities performed.

Prevention of Pollution (C)

Use of processes, practices, materials, or products that avoid, reduce, or control pollution. Which may include recycling, treatment, process

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DEFINITIONS	Section-3.1, Clause-4.3.1	Revision no.: 0
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changes, control mechanisms, efficient use of resources, and material substitution.

Reference SOP—[Number—ESM-4.3.1, dated mm-dd-yyyy].

Environmental Management Systems Manual		
LEGAL AND OTHER REQUIREMENTS	Section-3.2, Clause-4.3.2	Revision no.: 0
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Legal and Other Requirements

The organizational management has established and maintained a procedure to identify and have access to legal and other requirements to which the organization subscribes, that is, applicable to the environmental aspects of its activities, products or services in developing, implementing, and maintaining EMS.

Reference SOP—[Number-ESM-4.3.2, dated mm-dd-yyyy].

Environmental Management Systems Manual		
OBJECTIVES AND TARGETS	Section-3.3, Clause-4.3.3	Revision no.: 0
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Objectives and Targets

The "Your Company Name" has established and maintained documented environmental objectives and targets, at each relevant function and level within the organization.

When establishing and reviewing the objectives, due consideration is given to the legal and other requirements, its significant environmental aspects, its technological options and its financial, operational and business requirements, and the views of interested parties.

The objectives and targets are consistent with the environmental policy, including the commitment to continual prevention of pollution and improvement.

Reference SOP—[Number—ESM-4.3.3, dated mm-dd-yyyy].

Environmental Management Systems Manual		
ENVIRONMENTAL MANAGEMENT PROGRAM(S)	Section-3.4, Clause-4.3.4	Revision no.: 0
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Environmental Management Program(s)

The program has been established and maintained (a) for achieving the objectives and targets includes:

Designation of responsibility for achieving objectives and targets at each relevant function and level of the organization.

The means and time frame by which they are to be achieved.

If a project relates to new developments and new or modified activities, products or services, program(s) are amended where relevant to ensure that environmental management applies to such projects.

Reference SOP—[Number—ESM-4.3.4, dated mm-dd-yyyy].

Environmental Management Systems Manual				
IMPLEMENTATION AND OPERATION Section-4, Clause-4.4 Revision no.: 0				
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Implementation and Operation

The organization has defined roles, responsibilities, and authorities to facilitate effective environmental management system. The resources provided include personnel, specialized skills, technology, and financial.

Reference SOP—[Number—EMS-4.4, dated mm-dd-yyyy].

Environmental Management Systems Manual				
RESOURCES, ROLES, RESPONSIBILITIES, AND AUTHORITIES	Section-4.1, Clause-4.4.1	Revision no.: 0		
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Resources, Roles, Responsibilities, and Authorities

Roles, responsibilities, and authorities are defined, documented, and communicated in order to facilitate effective environmental management. For executive summary refer to Table 1.

Management provides resources essential to the establishment, implementation, maintaining, control, and improving of the environmental management system. Resources include human resources and specialized skills, technology and financial resources, contractors, temporary staff, and so on.

The organization's top management has appointed management representative who, irrespective of other responsibilities, has defined roles, responsibilities, and authorities for:

Ensuring that environmental management system requirements are established, implemented, and maintained in accordance with this International Standard:

The environmental management system coordinator (management representative) is responsible for the performance of the environmental management system to top management for review and as a basis for improvement of the environmental management system.

Describe brief responsibilities of the key personnel identified in the organization chart in Table 1.

Reference SOP—[Number—EMS-4.4.1, dated mm-dd-yyyy].

Environmental Management Systems Manual					
RESOURCES, ROLES, RESPONSIBILITIES, AND AUTHORITIES	Section-4.1, Clause-4.4.1	Revision no.: 0			
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mm/dd/yyyy	mm/dd/y	ууу	y									
					•							
TABLE 1												
Element in the Environmental Sy	ystem			tify onsi								
ISO 14001:2004 CLAUSE	A	В	С	D	Е	F	G	Н	I	J	K	L
4.1 General requirements												
4.2 Environmental policy												
4.3 Planning												
4.3.1 Environmental aspects												
4.3.2 Legal and other requirement	its											
4.3.3 Objectives and targets												
4.3.4 Environmental managemen	it program(s)											
4.4 Implementation and operation												
4.4.1 Resources, roles, responsibilities, and												
authorities												
4.4.2 Competence, awareness, and training												
4.4.3 Communication												
4.4.4 Environmental managemen documentation	ıt system											
4.4.5 Control of document												
4.4.6 Operational control												
4.4.7 Emergency preparedness and response												
4.5 Checking and corrective action												
4.5.1 Monitoring and measurement												
4.5.2 Evaluation of compliance												
4.5.3 Nonconformity, corrective a	ection, and											
preventive action	•											
4.5.4 Control of records												
4.5.5 Internal audit												

X RESPONSIBLE FUNCTIONS, *FUNCTIONS CONCERNED, -NOT APPLICABLE. A–L Department responsible or function concerned.

4.6

Management review

Environmental Management Systems Manual				
COMPETENCE, AWARENESS, AND TRAINING	Section-4.2, Clause-4.4.2	Revision no.: 0		
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Competence, Awareness, and Training

The company has identified training needs. It is ensured that all personnel (for, or on behalf of the organization) whose work may create a significant impact upon the environment, have received appropriate training, contractors, temporary staff, and so on.

Procedure is established and maintained to make the employees or external person at each relevant function and level aware of:

- Their roles and responsibilities in achieving conformance with the environmental policy and procedures and with the requirements of the environmental management system, including emergency preparedness and response requirements.
- The importance of conformance with the environmental policy and procedures and with the requirements of the environmental management system.
- The significant environmental impacts, actual or potential, of their work activities and the environmental benefits of improved personal performance.
- The potential consequences of departure from specified operating procedures.
- Personnel performing the tasks, which can cause significant environmental impacts, are competent on the basis of appropriate education, training, and/or experience.

Reference Procedure—[Number—EMS-4.4.2, dated mm-dd-yyyy].

Environmental Management Systems Manual					
COMMUNICATION Section-4.3, Clause-4.4.3 Revision no.: 0					
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Communication

The procedure established and maintained with regard to environmental aspects and environmental management system of the organization for:

Internal communication between the various levels and functions of the organization.

Receiving, documenting, and responding to relevant communication from external interested parties.

The organization communicates pro-actively its significant aspects.

The companies consider the processes for external communication on its significant environmental aspects and record its decision.

Reference SOP—[Number—EMS-4.4.3, dated mm-dd-yyyy].

Environmental Management Systems Manual					
DOCUMENTATION	Section-4.4, Clause-4.4.4 Revision no.: 0				
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Documentation

The "Your Company Name" has established and maintained information, in paper and electronic form, to describe the core elements of the management system and their interaction. Provide direction to related documentation. Describe the scope of the EMS in the system documentation.

Documents describing scope of EMS, effective planning, operation, and control of processes that relate to the significant aspects.

Reference SOP—[Number—EMS-4.4.4, dated mm-dd-yyyy].

Environmental Management Systems Manual					
CONTROL OF DOCUMENT	CUMENT Section-4.5, Clause-4.4.5 Revision no.: 0				
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Control of Document

The procedure has been established and maintained for controlling all documents in-house and external documents required by this International Standard to ensure that

They can be located.

They are periodically reviewed, revised as necessary, and approved for adequacy by authorized personnel.

The current versions of relevant documents are available at all locations where operations essential to the effective functioning of the environmental management system are performed.

Obsolete documents are promptly removed from all points of issue and points of use, or otherwise assured against unintended use.

Any obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified.

Documentation is legible, dated (with dates of revision) and readily identifiable, maintained in an orderly manner and retained for a specified period. Procedures and responsibilities are established and maintained concerning the creation and modification of the various types of document.

Reference SOP—[Number—EMS-4.4.5, dated mm-dd-yyyy].

Environmental Management Systems Manual					
OPERATIONAL CONTROL	Section-4.6, Clause-4.4.6	Revision no.: 0			
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Operational Control

The operations and activities that are associated with the identified significant environmental aspects in line with its policy, objectives, and targets have been identified. The organization plans these activities, including maintenance, in order to ensure that they are carried out under specified conditions by

Establishing and maintaining documented procedures to cover situations where their absence could lead to deviations from the environmental policy and the objectives and targets

Stipulating operating criteria in the procedures

Establishing and maintaining procedures related to the identified significant environmental aspects of goods and services used by the organization and communicating relevant procedures and requirements to suppliers and contractors

Reference SOP—[Number—EMS-4.4.6, dated mm-dd-yyyy]

Environmental Management Systems Manual				
EMERGENCY PREPAREDNESS AND RESPONSE	Section-4.7, Clause-4.4.7	Revision no.: 0		
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Emergency Preparedness and Response

The procedures are established and maintained to identify potential for and respond to accidents and emergency situations, and for preventing and mitigating the environmental impacts that may be associated with them.

The management reviews and revises, where necessary, its emergency preparedness and response procedures, in particular, after the occurrence of accidents or emergency situations.

The company also tests such procedures periodically where practicable.

Reference SOP—[Number—ISO 4.4.7, dated mm-dd-yyyy].

Environmental Management Systems Manual				
CHECKING AND Section-5, Clause-4.5 Revision no.: 0				
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Checking and Corrective Action

The company has established, documented, and maintained the procedures to initiate necessary corrective actions and preventive measures resulted from the findings, conclusions, and recommendations reached as a result of measuring, monitoring, audits, and other reviews of environmental management systems.

Reference SOP—[Number—EMS-4.5, dated mm-dd-yyyy].

Environmental Management Systems Manual			
MONITORING AND Section-5.1, Clause-4.5.1 Revision no.: 0			
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Monitoring and Measurement

The procedure is established, documented, and maintained to monitor and measure, on a regular basis, the key characteristics of operations and activities that can have a significant impact on the environment. This includes the recording of information to track performance, relevant operational controls, and conformance with the organization's environmental objectives and targets.

Monitoring equipments are calibrated and maintained, and records are retained according to the procedures.

The company has established and maintained a documented procedure for periodically evaluating compliance with relevant environmental legislation and regulations. The procedures are available describing how to document information required to monitor performance, applicable operational controls, and conformity with objectives and targets.

Reference SOP—[Number—EMS-4.5.1, dated mm-dd-yyyy].

Environmental Management Systems Manual			
EVALUATION OF COMPLIANCE Section-R, Clause-4.5.2 Revision no.: 0			
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Evaluation of Compliance

The organizational evaluation of compliance includes both legal environmental requirements and other requirements to which an organization subscribes. The records of evaluation are maintained.

Reference SOP—[Number—EMS-4.5.2, dated mm-dd-yyyy].

Environmental Management Systems Manual				
NONCONFORMANCE, CORRECTIVE ACTION, AND PREVENTIVE ACTION Section-5.2, Clause-4.5.3 Revision no.: 0				
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Nonconformance, Corrective Action, and Preventive Action

Procedures have been established and maintained for evaluating the need for actions defining responsibility and authority for handling and investigating potential nonconformance, taking action to mitigate any impacts caused and for initiating and completing corrective and preventive action to avoid recurrence.

The corrective or preventive action taken to eliminate the causes of actual and potential nonconformances are appropriate to the magnitude of problems and commensurate with the environmental impact encountered.

The management, reviews, implements, and records any changes in the documented procedures resulting from corrective and preventive action.

Reference SOP—[Number—EMS-4.5.3, dated mm-dd-yyyy].

Environmental Management Systems Manual			
CONTROL OF RECORDS Section-5.3, Clause-4.5.4 Revision no.: 0			
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Control of Records

Reference SOP—[Number—EMS-4.5.4, dated mm-dd-yyyy].

Environmental Management Systems Manual				
INTERNAL AUDIT Section-5.4, Clause-4.5.5 Revision no.: 0				
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Internal Audit

The program and procedure have been established and maintained for periodic environmental management system audits to be carried out, in order to:

Determine whether or not the environmental management system

- 1. Conforms to planned arrangements for environmental management including the requirements of this International Standard
- 2. Has been properly implemented and maintained
- 3. Provide information on the results of audits to the management

The audit program and schedule is based on the environmental importance of the activity concerned and the results of previous audits. In order to be comprehensive, the audit procedures shall cover the audit scope, frequency, and methodologies, as well as the responsibilities and requirements for conducting audits and reporting results. The audit records are maintained. The selection of auditors ensures objectivity and the impartiality of the audit process.

Reference SOP—[Number—ESM-4.5.5, dated mm-dd-yyyy].

Environmental Management Systems Manual				
MANAGEMENT REVIEW Section-6, Clause-4.6 Revision no.: 0				
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Management Review

The "Your Company Name" management, at intervals determines, reviews the environmental management system, to ensure its continuing suitability, adequacy, and effectiveness. The management review process ensures that the necessary information is collected to allow management to carry out this evaluation. This review is documented.

The management review address the possible need for changes to policy, objectives, and other elements of the environmental management system, in the light of environmental management system audit results changing circumstances and the commitment to continual improvement.

The management review includes specific inputs and outputs.

Each management review addresses an agenda in accordance with the requirement of ISO 14001:2004 international standard.

Reference SOP—[Number—ESM-4.6, dated mm-dd-yyyy].

List of Referenced SOP's

SECTION-7

Section	Subject	SOP no.	Revision no.	Issued on
1	General requirements	EMS-4.1	New	mm/dd/yy
2	Environmental policy	EMS-4.2	New	mm/dd/yy
3	Planning	EMS-4.3	New	mm/dd/yy
3.1	Environmental aspects	EMS-4.3.1	New	mm/dd/yy
3.2	Legal and other requirements	EMS-4.3.2	New	mm/dd/yy
3.3	Objectives and targets	EMS-4.3.3	New	mm/dd/yy
3.4	Environmental management program(s)	EMS-4.3.4	New	mm/dd/yy
4	Implementation and operation	EMS-4.4	New	mm/dd/yy
4.1	Resources, roles, responsibilities, and authorities	EMS-4.4.1	New	mm/dd/yy
4.2	Competence, awareness and training	EMS-4.4.2	New	mm/dd/yy
4.3	Communication	EMS-4.4.3	New	mm/dd/yy
4.4	Documentation	EMS-4.4.4	New	mm/dd/yy
4.5	Control of document	EMS-4.4.5	New	mm/dd/yy
4.6	Operational control	EMS-4.4.6	New	mm/dd/yy
4.7	Emergency preparedness and response	EMS-4.4.7	New	mm/dd/yy
5	Checking and corrective action	EMS-4.5	New	mm/dd/yy
5.1	Monitoring and measurement	EMS-4.5.1	New	mm/dd/yy
5.2	Evaluation of compliance	EMS-4.5.2	New	mm/dd/yy
5.3	Nonconformity, corrective action, and preventive action	EMS-4.5.3	New	mm/dd/yy
5.4	Control of records	EMS-4.5.4	New	mm/dd/yy
5.5	Internal audit	EMS-4.5.5	New	mm/dd/yy
6	Management review	EMS-4.6	New	mm/dd/yy

300.30

Standard Operating Procedure

300.30-1

General Requirements

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: General Requirements		SOP no.: EMS-4.1
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe general requirements in accordance with the clause 4.1 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

1. To define environmental policy, the following departmental managers are responsible to review, which may have major impact on

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the environment. For details, refer to SOP EMS-4.2, Attachment no. 4.2 (1).

- e.g. Production manager or supervisors as the case may be
 Packaging manager or supervisors as the case may be
 Stores managers or supervisors as the case may be
 Shipping manager or supervisors as the case may be
 Purchase manager or supervisors as the case may be
 Quality assurance manager or supervisors as the case may be
 Environmental management system coordinator
- 2. The review committee is headed by the management representative made responsible to develop and implement the environmental management system (environmental management system coordinator).
- 3. Initially the review is focused on regulatory compliance (refer local requirement), areas where liabilities are involved and efficient use of materials.
- 4. The environmental policy defined by the committee is approved by the general manager after the review and shall refer to include the following guidelines as applicable according to the type of industry.
 - Identification of legislative and regulatory requirements
 - Identification of environmental aspects of its activities, products, or services so as to determine those that have or can have significant environmental impacts and liabilities

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- Evaluation of performance compared with relevant internal criteria, external standards, regulations, codes of practice, and sets of principles and guidelines
- Existing environmental management practices and procedures
- Identification of the existing policies and procedures dealing with procurement and contracting activities
- Feedback from the investigation of previous incidents of noncompliance
- Opportunities for competitive advantage
- The views of interested parties
- Functions or activities of other organizational systems that can enable or improve environmental performance
- 5. In all cases, consideration is given to the full range of operating conditions, including possible incidents and emergency situations.
- 6. The EMS system developed shall demonstrate continual improvement.
- 7. The EMS system developed shall have defined scope.
- 8. The process and results of the initial environmental review are documented and opportunities for EMS development are identified. The following techniques are used or as appropriate.
 - Ouestionnaires
 - Interviews
 - Checklists
 - Direct inspection and measurement

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- Record review
- Bench marking
- List of sensitive sites
- 9. Consultation with a number of outside sources such as
 - Government agencies in relation to laws and permits
 - Local or regional libraries or databases
 - Other organizations for exchange of information
 - Industry associations
 - Larger customer organizations
 - Manufacturers of equipment in use
 - Business relations (e.g., with those who transport and dispose of waste)
- 10. For detailed description of aspect identification, refer to SOP no. EMS-4.3.2.

Documentation

- 1. List of activities, products and services and quantities involved, refer to Attachment no. 4.1 (1).
- 2. List of significant environmental aspects identified, refer to Attachment no. 4.1 (2).
- 3. Internal and external legal requirements review, refer to Attachment no. 4.1 (3).

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- 4. Historical review (list of previous incidents over the last ten years), refer to Attachment no. 4.1 (4).
- 5. Customers feedback (interested parties), refer to Attachment no. 4.1 (4).
- 6. For general overview of the aspects identification process, refer to Attachment no. 4.1 (6).
- 7. Examples of legal requirements, refer to Attachment no. 4.1 (7).
- 8. Examples of product aspects, refer to Attachment no. 4.1 (8).
- 9. Examples of supplier aspects, refer to Attachment no. 4.1 (9).
- 10. Interrelation of ISO 14001:2004 clauses, refer to Attachment no. 4.1 (10).
- 11. For alternative initial internal review, refer to Attachment nos. 4.1 (10), 4.1 (11), 4.1 (12), 4.2 (13), and 4.1 (14).

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.1 Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (1)

Activities/Products and Services

Activities	Prepared by (Concerned Manager)	Aspect	Impact	Annual Quantities	Annual Value
Aspect	_				
Products					
Services					

Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (2)

Significant Aspects (List)

Aspects	Prepared by (Concerned Manager)	Technique Used	Significant, Impact on Environment
Activities			
1) 2) 3) 4) 5) 6) 7) 8)		 Questioner Interview Checklist Direct Inspections Measurements Record Review Benchmarking 	
Products 1) 2) 3) 4) 5) 6) 7)		 Questioner Interview Checklist Direct Inspections Measurements Record Review Benchmarking 	
Services 1) 2) 3) 4) 5) 6) 7)		 Questioner Interview Checklist Direct Inspections Measurements Record Review Benchmarking 	

Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (3)

Internal and External Legal Requirements Review

Aspects	Reviewed by (Concerned Manager)	Current Practice	Internal Requirement	External Legal Requirements	Remarks
Activities					
Products					
Services					

Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (4)

Historical Review

Incidents Effecting Environment	Prepared by (Concerned Manager)	Year	Impact	Remarks
			•	

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.1 Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (5)

Customers Feedback

Aspects	Customer Concerned	Remarks (Concerned Manager)
Activities		
1) 2) 3) 4) 5)		
Products		
1) 2) 3) 4) 5)		
Services		
1) 2) 3) 4) 5)		

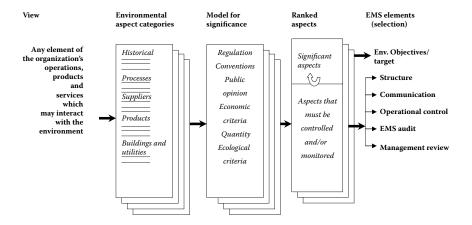
Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (6)

General Overview of the Aspects Identification Process



Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (7)

Examples of Legal Requirements List

Regulation	Application	Procedure
Air		xxx
Environmental Protection Act 1990	Solvents to atmosphere	xxx
Environmental Protection Regulation 1991	Solvents to atmosphere	
Environmental Protection Regulation 1993	Solvents to atmosphere	
Water		
Surface Waters Regulations	Discharge to water course	xyz
Water Resource Act	Discharge to cooling water to sewer	ууу
Control of Pollution Act	Discharge to cooling water to sewer	
Waste		
Environmental Protection Act	Waste management	zzz, xy, yz

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (8)

Examples of Product Aspects

Product	Aspect	Amount	Comment
Motors	Energy loss Recyclability Maintenance materials Noise	Moderate High Solvents needed High	Small improvement in energy efficiency gives large change in lifetime impact
Gas turbines	Energy loss Recyclability Maintenance chemical	Low High Solvents needed	Small improvement in energy efficiency gives large change in lifetime impact
Filters for yyy duty	Resource content Recyclability Eco-toxicity	High Nil High	Filter is special waste at end of life due to contamination
Rail vehicles, aluminum bodyshell	Resource content Energy content Energy consumption Recyclability Noise production Cd contamination from conductor wire	High High High 85% Moderate Low	Many other aspects known. Full LCA to be integrated into design process
Rail vehicles, composite bodyshell	Resource content Energy content Energy consumption Recyclability Noise production Cd contamination from conductor wire	Moderate Low Low Nil Moderate Low	Many other aspects known. Full LCA to be integrated into design process

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (9)

Example of a Supplier Aspects List

Supplier	Materials	Aspects	Notes
A company	Molded plastic components	Discharge of VOCs to atmosphere. Consumption of nonrenewable resource	Emissions likely to have significant odor
B company	Plastic-insulated power cables	Discharge of VOCs to atmosphere	Low emissions
C company	Steel forgings	Consumption of large quantities of water for steel manufacture	Looking at recycle
D company	Chromium-plated metal parts	Discharge of chromium waste to watercourse	Prosecuted twice May go out of business We need alternative
E company	Solvent-based paints	Discharge of large quantities of VOCs to atmosphere	Looking to reduce emissions
F company	Hardwood flooring	Consumption of tropical hardwoods from nonmanaged forests	Supplies from managed sources now available. We will switch at end of contract
G company	Oils and lubricants	Consumption of nonrenewable resource. Sulfur dioxide emissions	Recently prosecuted for environmental damage to protected estuary
H company	Steel castings	Dust emissions to atmosphere, energy consumption, carbon dioxide emissions	Local pressure due to dust emissions
I company	Painted bodyshells	VOC emissions to atmosphere	Largest single source of VOCs in region. Abatement plan to be considered

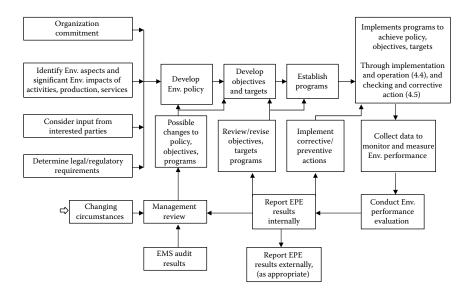
Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (10)

Inter-Relation of ISO 14001 Clauses

The flow chart shown below shows the elements of an EMS and how they relate to each other.



Environmental Management System ISO 14001:2004

SOP no.: EMS-4.1

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (11)

Initial Internal Review

Prepared by: Concerned Manager

ENVIRONMENTAL	rei	fe- nce		nit	Мо		Le	-	fo	nsible or	Obje	ctive	1	get	Moni	dure		aff .	Aud			alifi-		иs		gement	
ASPECT	PI	an	No	ise	tor	ed	Requir	ements	Moni	toring	S	et	S	et	and C	ontrol	Trai	ned	Cond	ucted	cat	ion	Prog	rams	Rev	iews	Remarks
	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
NOISE POLLUTION																											
AIR POLLUTION																											
Emissions																											
SOIL AND GROUND																											
WATER PROTECTION																											
 Hazardous materials 																											
Storage areas																											
Tanks																											
Ground water																											
Spills																											
Integrity testing																											
(Tanks)																											
 Contractors 																											

	 	 		 	 	 $\overline{}$	 	 	_	 	_	 	 	
SOLID AND														
HAZARDOUS														
WASTE														
 Solid 														
 Hazardous waste 														
 Special waste 														
 Clinical waste 														
 Waste disposal on site 														
 Hold waste 														
management														
 Waste disposed by 														
contractor														
 Underground storage 														
tanks														
 Nonhazardous waste 														
 Toxic substances 														
 Transportation 														
 Nuclear materials 														
• Other: (Please list)														

Reviewed by:	XYZ	mm/dd/yyyy
(EMS Coordinator)	Signature	Date

Y = Yes

N = No

Issue date: mm/dd/yyyy

Revision no.: New

SOP no.: EMS-4.1

Attachment no. 4.1 (12)

Initial Internal Review

Prepared by: Concerned Manager

ENVIRONMENTAL ASPECT	rei	efe- nce an	Emi Nois		Moni- tored		egal rements	fe	onsible or toring	Obje	ective et	Tar S	get	Moni	edure toring ontrol		aff ned	Au Cond			alifi-	l .	MS rams		gement iews	Remarks
	Y	N	Y	N.	Y N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
Major accidents Hazards regulations Ozone-depleting substances Poly chlorinated biphenyls Special process requirements Products controlling growth of natural Flora Fauna Promote wildlife Recreational facilities Parks																										

Reviewed by: (EMS Coordinator)

XYZ Signature mm/dd/yyyy **Date**

Y = Yes

N = No

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (13)

Initial Internal Review

Prepared by: Concerned Manager

province		fe-					_			nsible			_			edure				•••							
RESOURCE	ı	nce	ı	mit	Mo		Leg		fo			ctive				toring		aff	Au			alifi-		MS		gement	
MANAGEMENT	PI	an	N	oise	toı	red	Requir	ements	Moni	toring	S	et	S	et	and C	ontrol	Irai	ned	Cond	ucted	cat	ion	Prog	rams	Rev	iews	Remarks
	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
Water consumption																											
• Fuel																											
Electricity																											
Recycling activities																											
- Products																											
- Materials																											
- Process																											
Use of land																											
Activities leading to																											
- Odor																											
- Dust																											
- Vibrations																											
 Visual impact 																											

Reviewed by:	XYZ	mm/dd/yyyy
(EMS Coordinator)	Signature	Date

Y = Yes

N = No

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (14)

Final Management System Assesment Review (Internal) Prepared by: Concerned Manager

Management System	YES	NO	Date	Remarks
Environmental aspects identified of activities, products, or services				
Aspects of significance impact on environment determined				
The top 5 impacts determined				
Objectives and targets made				
Policy documented authorized				
Policy made available to public				
EMS integrated with Quality system Health and safety None				
Regulatory requirements listed				
Program made for EMS				
EMS responsibilities defined				
EMS coordinator appropriated				
Training provided on Communication Documentation Document control				
 Conditions considered Normal Abnormal Accidents/Emergencies 				

Reviewed by:	XYZ	mm/dd/yyyy
(EMS Coordinator)	Signature	Date
Approved by:	XYZ	mm/dd/yyyy
(General Manager)	Signature	Date

300.30-2

Environmental Policy

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Environmental Policy		SOP no.: EMS-4.2
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for the development of environmental policy in accordance with clause 4.2 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement environmental policy requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Definition

Statement by the organization of its intentions and principles in relation to its overall environmental performance which provides a framework for action and for setting of its environmental objectives and targets.

SUBJECT: Environmental Policy		SOP no.: EMS-4.2
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Procedure

Note: The environmental policy will be based on initial reviews, aspects of significant environmental impacts and will be approved by the general manager after the review of objectives and targets.

1. The environmental policy is established to provide direction and set the principles of the action for an organization

The environmental policy will be communicated to

- Company employees
- Persons working on company behalf
- Contractors will be communicated about the policy and EMS-4.4.6 using suitable forms defining rules, directives, and procedures
- 2. The responsibilities to develop overall direction, policies, and objectives and targets are defined in Attachment no. 4.2 (1). The concerned employees can follow attachments provided in SOP no. EMS-4.1.
- 3. The policies derived by the managers will be reviewed and audited by EMS coordinator, refer to Attachment no. 4.2 (2).
- 4. The EMS coordinator ensures that environmental policy has been developed based on the following considerations:
 - The organization's mission, vision, core values, and beliefs
 - Requirements of and communication with interested parties
 - Continual improvement
 - Prevention of pollution

SUBJECT: Environmental Policy		SOP no.: EMS-4.2
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
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- Guiding principles
- Coordination with other organizational policies (e.g., quality, occupational health, and safety)
- Specific local or regional conditions
- Compliance with relevant environmental regulation, laws and other criteria to which the origination subscribes
- 5. Some issues which are considered in the development of environmental policy are below
 - The organization environmental policy is relevant to its activities, products, and services.
 - The policy reflects the organization's value and guiding principles.
 - The environmental policy has been approved by top management and has someone been identified and given the authority to oversee and implement the policy.
 - The policy guides the setting of environmental objectives and targets.
 - The policy guides the organization toward monitoring appropriate technology and management practices.
 - Commitment is embodied in the environmental policy for support for continual improvement, support for the prevention of pollution, monitoring, meeting or exceeding applicable legal requirements, environmental legislation and regulations, and consideration of the exceptions of interested parties.
- 6. The EMS coordinator is responsible to get approval of the policy from the general manager.

SUBJECT: Environmental Policy		SOP no.: EMS-4.2
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
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- 7. The environmental policy is approved by the general manager of the company.
- 8. The concerned departmental managers and supervisors are responsible for implementation and provide continuous input for the modification of the policy if necessary.
- 9. Last but not the least, the policy is derived from the aspects of significant impacts over the environment and made part of the organization objectives and targets included in the program to ensure continuous improvement.

Documentation

- 1. Environmental Management System Manual, EMS 1
- 2. Responsibilities, refer to Attachment no. 4.2 (1)
- 3. Policy audit checklist, refer to Attachment no. 4.2 (2)

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.2 (1)

Responsibilities

Copy to: All Concerned

Environmental Responsibilities	Typical Person(s) Responsible		
Establish overall direction	General manager, chief executive officer (CEO), board of directors		
EMS defined with clear scope	General manager, chief executive officer (CEO), board of directors		
Develop environmental policy	President, environmental management system (EMS) coordinator		
Develop environmental objectives, targets, and programs	Relevant managers		
Monitor overall EMS performance	Chief environmental manager		
Assure regulatory compliance	Senior operating manager		
Ensure continual improvement	All managers		
Identify customers expectations	Sales and marketing staff		
Identify suppliers expectations	Purchasers, buyers		
Develop and maintain accounting procedures	Finance/accounting managers		
Comply with defined procedures	All staff		
Policy communicated to those who are involved inside and outside company operations and public	EMS coordinator, employees, contractors		
* Note: In the case of small industrial unit	ts, the person responsible can be the owner.		
Reviewed by:			
(EMS Coordinat	tor) Signature Date		

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.2 (2)

Policy Audit Checklist

To: Concerned Manager Policy No.: _____

	1		
1. Policy Statement	YES	NO	Remarks
COMMENTS			
Policy statement was made prior to identification of environmental aspect		NO	
2. No modification to the policy statement was made		NO	
3. Policy statement links to aspects		NO	
4. The policy statement is supported with objectives and targets	YES	NO	
5. Policy statements clearly define scope of EMS	YES	NO	
6. The employees at all levels of the organization are aware of the policy statement (understand and implement)	YES	NO	
7. The policy was made aware by report/display		NO	
8. The policy statement ensures that, as a minimum, regulatory and legislation compliance will be achieved (if there is any) as part of objectives and target	YES	NO	
9. The interested parties requirements are respected	YES	NO	
10. The compliance to the policy has resulted in the continual improvement in overall performance and is measurable	YES	NO	
11. The policy has resulted in the prevention of pollution by the use of processes/practices/materials or products/reduce or control pollution which may include recycling, treatment, process changes control mechanisms, efficient use of resources and materials substitution	YES	NO	

1. Policy Statement	YES	NO	Remarks
12. The policy compliance refers to best available technology where economically viable, cost effective, and judged appropriately		NO	
13. Management systems		NO	
Improved definition of responsibilities, management structure, and interfaces		NO	
Better control and dissemination of documentation/ information		NO	
Process parameters better defined and formalized		NO	
Defined management and operational practices	YES	NO	
Efficiency of corrective/preventive action systems	YES	NO	
Quality of monitoring and measurement information	YES	NO	
Effectiveness of audit and review cycle	YES	NO	
14. Training/Communication		NO	
Staff, suppliers, contractors/subcontractors, customer, and public environmental awareness programs		NO	
15. Products	YES	NO	
Reduction of material input		NO	
Selection of alternative materials with less significant environmental impacts		NO	
Improved recyclability of products	YES	NO	
The use of less/alternative packaging	YES	NO	
Increased efficiency in distribution/transport	YES	NO	
The design of products to minimize their environmental impacts during production, use, and disposal		NO	
16. Processes		NO	
The use of cleaner technologies that are more efficient in resource and material consumption		NO	
The recovery and re-use materials	YES	NO	

continued

1. Policy Statement	YES	NO	Remarks
Recyclability waste products	YES	NO	
Reduction of wastes	YES	NO	
Reduction and elimination of polluting releases to the environment	YES	NO	
Prevention of environmental accidents, mitigation of their environmental impacts, and contingency planning	YES	NO	
17. Natural resources	YES	NO	
Minimization of resource usage	YES	NO	
Use of renewable energy sources	YES	NO	
Minimization of energy consumption	YES	NO	
Recovery and reuse of energy	YES	NO	
18. Raw materials and bought-in goods	YES	NO	
Use renewable materials	YES	NO	
Use recyclable materials	YES	NO	
Pressure suppliers improvement in manufacture of raw materials	YES	NO	
Preventative measures in transport, storage, and handling	YES	NO	
19. Communication	YES	NO	
EMS policy is communicated to in-house staff	YES	NO	
EMS policy is communicated to persons indirectly involved, e.g., contractors	YES	NO	

Remarks (if any):								
Reviewed by:								
	(EMS Coordinator)	Signature	Date					

cc: General Manager

300.30-3

Planning

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Planning	SOP no.: EMS-4.3	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe procedures for performing environmental planning in accordance with clause 4.3 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

1. The environmental management system coordinator is responsible to develop a plan to enable the organization to comply with environmental policy.

SUBJECT: Planning		SOP no.: EMS-4.3
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
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- 2. The environmental management system elements include
 - Identification of environmental aspects and evaluation of associated environmental impacts
 - · Legal requirements
 - Environmental policy
 - Internal performance criteria
 - Environmental objectives and targets
 - Environmental plans and management program
- 3. The above elements are considered in the management review meetings, initial assessment, and data are generated as apart of environmental planning.
- 4. The EMS coordinator defines the tasks, responsibilities, and the time frame for the successful achievement of the EMS program.

Documentation

- 1. Environmental Management System Plan, refers to Attachment no. 4.3 (1)
- 2. EMS Certification Plan, (optional), refer to Attachment no. 4.3 (2)
- 3. Example of approach to achieving a certified EMS, refer to Attachment no. 4.3 (3)

SUBJECT: Planning	SOP no.: EMS-4.3	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.3 Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.3 (1)

Environmental Management System Plan

Copy to: Concerned Responsible

				MONTH											
S. No.	TASKS	RESPONSIBILITY	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	REMARKS
1	Review of aspects														
	Activities														
	• Product														
	Services														
2	Identification of significant aspects														
3	Development of objectives and targets														
4	Propose policy														

App	roval of policy							
E	MS program							
1	EMS program Evaluation of performance							
	Internal audit							
	Management review							
	Preinspection							
	Certification							
	Surveillance visit							

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.3

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.3 (2)

EMS Certification Plan

				Re	esult	Path	s			Codes: X = Executes work	7	Геат	Re	spo	nsi	bili	ties	;
Goal No.	Target date	Planning	Aspects	Documentation	Metrics	Training	Auditing, checking	Start up	Certification	D = Takes decision solely d = Take decision jointly R = Responsible for progress C = Must be consulted I = Must be informed A = Available to advise Goal Definitions	Team leader	Team member 1	Team member 2	Team member 3	Site manager	Quality manager	All managers	All employees
1		•								When management support has been obtained, and resources and	X	I	I	I	Ι	I	I	I
2										deliverables agreed When an initial review of the					I	Α	I	H
		•								business has been completed					1	А	1	
3		·								When a milestone plan for the EMS project has been agreed by the project team	d	d	d	d	Ι	A		
4			•							When the company's environmental aspects have been agreed	d	d	d	d		A		
5			•							When the legal requirements and other constraints have been identified	R							
6										When site policy, objectives, and targets have been agreed	X	X	X	X	D		I	I
7			`	À						When system procedures, work instructions, and controls have been designed and issued	X	X	Х	Х		С	I	
8					1					When metrics/feedback on environmental performance are in place	X	Х	Х	X	I			
9						•				When key staff have been trained an all staff are aware of the company's program	R						I	
10						,				When audit program is running	R	I	I	I		I		П
11								•		When first management review has taken place	R	I	I	I	X	X	I	П
12								\		When the EMS has been checked against the standard	R	I	I	I				
13							•			When the EMS has been checked against the significant aspects	R	I	I	I				
14										When the EMS has been checked for loop closure	R	I	I	I				
15									J	When the initial visit by the certifier has taken place	R	I	I	I	I	I		
16									•	When the audit visit has taken place	R	I	I	I	I	I	I	I
17									•	When certification has been obtained	R	I	I	I	I	Ι	I	I

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.3

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.3 (3)

Example of Approach to Achieving a Certified EMS Note: Modify the Approach for Your Company

- 1. When management support has been obtained and resources agreed.
- 2. When the **Legal Requirements** have been identified.
- When an Initial Review of the business has been completed and when the company's Environmental Aspects have been identified.
- 4. When a milestone plan for the EMS project has been agreed.
- 5. When **Policy**, **Objectives**, **Targets** have been agreed.
- When the Environmental Program has been agreed
- When System Procedures, Work Instructions, and controls have been designed and issued.
- 8. When metrics/feedback on **Environmental Performance** are in place.
- 9. When key staff have been **Trained** and all staff are **Aware** of the company's program.

- Top management agreement and active support. Resources needed include money, time, and people.
- Constraints, including regulatory, insurance, contractual, business requirements, public perceptions, views of other interested parties, etc.
- Rate and rank environmental aspects to identify most significant. Include potential liabilities from the initial.
- Plan project and agree project responsibilities. Identify and obtain support of project team.
- Agree policy, objectives, and targets. Must be relevant to the significant aspects.
- Design and agree program. Agree responsibilities. Needs to be simple and easily understood.
- Design, draft, agree, implement.

 Documentation should be as clear, easily understood and as short as possible.

 Involve employees in writing work instructions. Try to use flow diagrams, not text.
- Design, implement. Relating metrics to turnover or output will allow benchmarking against other companies.
- Train key staff. Incorporate into existing staff training program if appropriate. Implement program of staff briefings to ensure awareness of company staff.

10. When the **Audit** program is running.

11. When the first **Management Review** has taken place.

- 12. When the EMS has been checked against the standard.
- 13. When the EMS has been checked against significant aspects.
- 14. When the EMS has been checked for loop-closure.
- 15. When the **Initial Visit** by the certifier has taken place.
- 16. When the **Audit Visit** has taken place.
- 17. When Certification has been obtained.

Design audit protocols and program. Implement. Auditors and audit program must be credible.

Implement. Needs to be at least one management review to obtain certification.

Do clause trace table. Fill any missing or incomplete areas.

Confirm all significant effects managed.

Check all loops closed, e.g., corrective actions, nonconformances, communications.

Incorporate any changes required.

Close out any nonconformances. Success.

300.30-4

Environmental Aspects

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Environmental Aspects	SOP no.: EMS-4.3.1	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
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Purpose

To describe a procedure for identifying Environmental Aspects in accordance with clause 4.3.1 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system coordinator) is responsible for SOP compliance.

Definitions

Environment (3.2)
 Surroundings in this context extend from within an organization to the global system.

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Note: Surroundings in this context extend from within an organization to the global system.

• Environmental aspect (3.3)

Element of an organization's activities, products, or services which can interact with the environment.

Note: A significant environmental aspect is an environmental aspect which has or can have a significant environmental impact.

• Environmental impact (3.4)

Any change to the environment, whether adverse or beneficial, wholly or partially resulting from an organization's activities, products, or services.

Procedure

- 1. The identification of the environmental aspects of significance is a continuous process.
- The identification of aspects is based on the past, current, and potential impacts (positive or negative) of the organizations activities on the environment.
- 3. The aspect evaluation maybe conducted using the following or a combination of the following techniques.
 - Past performance review
 - Product review (LCA)

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- Site assessment
- Product/process data review
- Communications review
- · Environmental impact assessment
- Compliance audits
- Environmental audit
- Environmental performance evaluation
- 4. The aspects evaluation shall also consider
 - Inclusion of planned or new developments and new or modified activities, products, and services within the aspects process.
- 5. The clear requirements for the information from the aspects shall be documented.
- 6. Significant aspects shall also be considered where establishing and maintaining/developing the EMS in general and as a basis to set the EMS objectives.
- 7. The identification of environmental aspects and evaluation of associated environmental impacts is carried out as follows:
 - A. Source
 - B. Controlled and uncontrolled emissions to the atmosphere
 - C. Controlled and uncontrolled discharges to water
 - D. Contamination of land
 - E. Solid waste
 - F. Use of raw materials and other natural resources

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- G. Use of energy
- H. Use of water
- I. Noise, odor, dust, vibration, and visual impact
- J. Effect on the ecosystem
- K. Upstream effects
 - Energy
 - Water
 - Raw materials
- L. Downstream effects
- M. Past effects
- N. Future effects
- O. Selection test
- P. Environmental impact evaluation
- Q. Identification of level of significance
- 8. Prepare list of company's product, services, and activities.
- 9. Refer to Attachment no. 4.3.2 (1) in order to establish the initial information on significant aspects and impacts.
- 10. The other issues considered in identification of environmental aspects and evaluation of environmental impacts are as follows:
 - The environmental aspects of the organization's activities, products, and services.
 - The organization has a procedure for evaluation of the environmental impacts of new projects.

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- The location of the organization and the sensitive environmental areas.
- How will any intended changes or additions to activities, products, or services affect the environmental aspects and their associated impacts.
- The significance or sever of the potential environmental impacts which may lead to process failure.
- The frequency of the situation that could lead to the impact.
- The significant environmental impacts are local, regional, and global in scope.
- 11. The identification of significant priority environmental impacts is carried out as follows:
 - Identify as many actual and potential, positive and negative, environmental impacts, as possible associated with each identified aspect of activity, product or services as follows:

Activity, Product, or Service	Aspect	Impact
Activity—handling of hazardous materials	Potential for accidental spillage	Contamination of soil or water
Product—product refinement	Reformulation of the product to reduce its volume	Conservation of natural resources
Service—vehicle maintenance	Exhaust emissions	Reduction of air emissions

12. The significance of each of the identified environmental impacts can be different for each organization. Quantification can aid judgment.

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13. Two-step process is established to award a numerical score to each environmental effect to quantify the relative importance of different criteria. You should adjust and review the scoring system to suit the circumstances of your company and your particular site.

Step A: Normal operating conditions

For normal operating conditions, each environmental effect is awarded a score to reflect the relative importance of:

- 1. Legislation (both current and forthcoming).
- 2. Environmental damage, for example, toxicity, acidity, greenhouse gas emissions, ozone-depleting substances.
- 3. Interested parties, for example, the reaction of the local residents, environmental interest groups.
- 4. Quantity, for example, the volume of the waste stream or the frequency of occurrence at the foundry.

The matrix shown below illustrates the way in which a particular environmental effect can be scored under normal operating conditions.

The scores are multiplied by a weighting factor, which reflects the overall importance of the criteria at a particular site or within a particular company. You should adjust these as necessary to reflect your company concerns. Adding the four multiplications together produces a total score for this environmental effect under normal operating conditions. This total score is then used to rank the particular environmental effect under normal operating conditions.

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Score			W	eigh	ino			
	3	2	1	0		Fact	_	
Legislation	Existing	Impending		None	х	2	=	а
Environmental damage	Known detriment	Possible detriment	Limited detriment	No detriment	х	3	=	b
Interested parties	Considerable interest	Moderate interest	Little interest	No interest	х	2	=	С
Quantity	High	Medium	Low	Nil	х	3	=	d

Normal operating conditions total score = (a + b + c + d).

Step B: Other operating conditions

The same environmental effect is also awarded a numerical score under other operating conditions to reflect the importance of four further criteria:

- 1. Abnormal operations, for example, factory start-up after a holiday shutdown period.
- 2. Accident/emergency, for example, fire, accidental damage.
- 3. Past activities, for example, activities of former site occupant, burial of foundry waste on site.
- 4. Planned activities, for example, new product or production line, site development.

The four scores are again added to produce a total score under other operating conditions as shown below. This total score is used to rank the environmental effects under other operating conditions. For working format, refer to Attachment no. 4.3.2 (2).

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		Score				
-	12	6	3	0		
Abnormal operations		Increased environmental impact	No change	Reduced environmental impact	=	а
Accident/ Emergency		Increased environmental impact	No change	Reduced environmental impact	=	b
Past activities	Evident/requires action	Possible damage/ difficult to evaluate		No damage	=	С
Planned activities	High	Increased environmental impact	No change	Reduced environmental impact	=	d

Other operating conditions total score = (a + b + c + d).

14. After the scoring, prepare the final list with the total score. The top priority is assigned to the aspect of highest score.

Step C: Financial Scoring

However, it is subject to the final approval of the managing director and the financial scoring.

- 15. The business concerns are subdivided and assigned a number for low, medium, and high
 - Potential regulatory and legal exposure
 - Difficulty of changing the impact

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- Cost of changing the impact
- Effect of change on other activities and processes
- Concerns of interested parties
- Effect on the public image of the organization

Key to Scoring

0-37 = Insignificant

38-max. = Significant

16. Legal and other requirements

The organization has established and maintained procedures to identify and have access to and understand all legal and other requirements to which it subscribes, directly attributable to the environmental aspects of its activities, products, or services.

To maintain regulatory compliance, an organization has identified and followed regulatory requirements applicable to its activities, products, or services. Regulations exist in several forms.

- Those specific to the activity (e.g., site-operating permits)
- Those specific to the organizations products or services
- Those specific to the organizations industry
- General environmental laws
- Authorizations, licenses, and permits

Following sources are used to identify environmental regulations and ongoing changes, including:

• All levels of government

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- Industry associations or groups
- Commercial databases
- Professional services

To facilitate keeping track of legal requirements, an organization has established and maintained a list of all laws and regulations pertaining to its activities, products, or services.

- 17. Some issues considered in legal and other requirements
 - Traces and identification of relevant legal and other requirements
 - Tracking of legal and other requirements
 - Tracking of changes to legal and other requirements
 - Communication of relevant information on legal and other requirements to employees.
- 18. Internal performance criteria

Internal priorities and criteria's have been developed and implemented where external standard do not meet the needs of the organization or are nonexistent. Internal performance criteria, together with external standards, assist the organization in developing its own objectives and targets.

- 19. The areas where an organization has internal performance criteria includes
 - Management systems
 - Employee responsibilities
 - Acquisition, property management, and divestiture
 - Suppliers
 - Contractors

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- Product stewardship
- Environmental communication
- Regulatory relationships
- Environmental incident response and preparedness
- Environmental awareness and training
- Environmental measurement and improvement
- Process risk reduction
- Prevention of pollution and resource conservation
- Capital projects
- · Process change
- Hazardous material management
- Waste management
- Water management (e.g., waste, storm, ground)
- Air quality management
- Energy management
- Transportation

Documentation

- 1. Environmental aspects/significance evaluation matrix, refer to Attachment no. 4.3.1 (1) (Register of Environmental Impacts).
- 2. Aspects significance ranking list, refer to Attachment no. 4.3.1 (2).

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Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.3.1 (1)

Environmental Aspect Significance Evaluation Matrix

Prepared by: Concerned Manager

SOURCE:	ACTIVITY:	PRODUCT:	SERVICES:		
LOCATION	AREA				
ENVIRONMENTAL ASPECT	OTHER INFORMATION	IMPACT	IMPACT CODE		
Controlled and uncontrolled emissions to atmosphere					
Controlled and uncontrolled discharges to water					
Contamination of land					
Solid waste					
• Use of raw materials and other natural resources					
• Use of energy					
• Use of water					
Use of raw materials					
• Noise, odor, dust, vibration, and visual impact					

SOURCE:	ACTIVITY:	PRODUCT:	SERVICES:
LOCATION		AREA	
ENVIRONMENTAL ASPECT	OTHER INFORMATION	IMPACT	IMPACT CODE
Effects on ecosystems			
Upstream effects			
Energy, water, raw materials			
Downstream effects			
Past effects			
Future effects			
Selection test			
Environmental impact evaluation			
Identification of level of significance			
New developments			
Modified activities, products, services			
Aspects during maintaining and developing the EMS			

A: Ranking of environmental effects under normal operation conditions													
			Cond	itio	ns/Score				Weig	ghting fa	ctor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	То	tal	Remarks
Legislation	Existing		Impending				None		×	2		а	
Environmental damage	Known detriment		Possible detriment		Limited detriment		No detriment		×	3		b	
Interested parties	Considerable interest		Moderate interest		Little interest		No interest		×	2		С	
Quantity	High		Medium		Low		Nil		×	3		d	
Norn	nal operating co	ndi	tions total = (a	i + b	c+c+d)		Tota	ıl A					

B: Rai	B: Ranking of environmental effect under other operating conditions										
			Condi	tion	s/Score				То	tal	
Elements	Condition	12	Condition	6	Condition	3	Condition	0			Remarks
Abnormal operations			Increased environmental impact		No change		Reduced environmental impact			а	
Accident/emergency			Increased environmental impact		No change		Reduced environmental impact			b	
Past activities	Evident/ requires action		Possible damage/ difficult to evaluate				No damage			С	
Planned activities/Modified activities, products, and services, elements during maintaining and development of EMS			Increased environmental impact		No change		Reduced environmental impact			d	
Other operating	g conditions	total	score = (a + b + c + a)	!)	Total B						

Elements	Very high	4	High	3	Medium	2	Low	1	None	0	Total	Remarks
Cost												
F-6												
Estimated	stimated											
Cost factor Total C								Total C				

Remarks:			
Reviewed by:			
•	EMS Coordinator	Signature	Date

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.3.1 (2)

Aspects Significance Ranking List

To: All Concerned

ENVIRONMENTAL ASPECTS	PRODUCT ACTIVITY/ SERVICES	NEGATIVE IMPACE CODE NO.	SIGNIFICANCE ASPECT RANKING
	•		

Reviewed by:			
	EMS Coordinator	Signature	Date

300.30-5

Legal and Other Requirements

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Legal and Other Require	SOP no.: EMS-4.3.2	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe procedure for identifying and reviewing legal and regulatory aspects in accordance with clause 4.3.3 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

Note: The procedure describes explicit and comprehensive procedure to assign priority factor (numerical score) to the aspects of environmental concern and enables the company to scientifically

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and logically develop the EMS program. The procedure described is optional and helpful to assign priority. The procedure may provide good support to execute SOP no. EMS-4.1 and 4.3.1.

- 1. The identification of the legal and other environmental aspects is the responsibility of concerned managers.
- 2. The identification of aspects is based on the past, current, and potential impacts (positive or negative) of the organizations activities, products, and services on the environment. The data collected based on the SOP EMS-4.1 and EMS-4.3.1 can be assigned priority using the following procedure.
- 3. The aspects evaluation includes review of
 - Identification of potential regulatory requirements to an organization's environmental aspects.
 - Legal requirements to an organization's environmental aspects.
 - Impacts related to the health and safety.
 - Environmental risk assessment.
 - The EMS coordinator shall ensure that legal and other environmental requirements to which organization subscribes are considered in developing, implementing, and maintaining the EMS.
- 4. The identification of environmental aspects of significant environmental priority may be carried out as follows for your company.
- 5. Prepare a list of your company's activities, product, and services, refer to SOP EMS-4.1.
- 6. Refer to Attachment no. 4.3.2 (1) in order to establish the initial information on significant aspects and impacts.

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- 7. The other issues considered in identification of environmental aspects and evaluation of environmental impacts are as follows:
 - The environmental aspects of the organization's activities, products, and services.
 - The organization has a procedure for evaluation of the environmental impacts of new projects.
 - The location of the organization and the sensitive environmental areas.
 - How will any intended changes or additions to activities, products, or services affect the environmental aspects and their associated impacts.
 - The significance or severity of the potential environmental impacts which may lead to process failure.
 - The frequency of the situation that could lead to the impact.
 - The significant environmental impacts are local, regional, and global in scope.
- 8. The identification of significant priority environmental impacts is carried out as follows:
 - Identify as many actual and potential, positive and negative, environmental impacts, as possible associated with each identified aspect of activity, product, or services as follows:

Activity, Product, or Service	Aspect	Impact
Activity—handling of hazardous materials	Potential for accidental spillage	Contamination of soil or water
Product—product refinement	Reformulation of the product to reduce its volume	Conservation of natural resources
Service—vehicle maintenance	Exhaust emissions	Reduction of air emissions

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- 9. The significance of each of the identified environmental impacts can be different for each organization. Quantification can aid judgment.
- 10. Two-step process is established to award a numerical score to each environmental effect to quantify the relative importance of different criteria. You should adjust and review the scoring system to suit the circumstances of your company and your particular site.

Step A: Normal operating conditions

For normal operating conditions, each environmental effect is awarded a score to reflect the relative importance of:

- 1. Legislation (both current and forthcoming)
- 2. Environmental damage, for example, toxicity, acidity, greenhouse gas emissions, ozone-depleting substances
- 3. Interested parties, for example, the reaction of the local residents, environmental interest groups
- 4. Quantity, for example, the volume of the waste stream or the frequency of occurrence at the foundry

The matrix shown below illustrates the way in which a particular environmental effect can be scored under normal operating conditions.

The scores are multiplied by a weighting factor, which reflects the overall importance of the criteria at a particular site or within a particular company. You should adjust these as necessary to reflect your company's concerns. Adding the four multiplications together produces a total score for this environmental effect under normal

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operating conditions. This total score is then used to rank the particular environmental effect under normal operating conditions.

	Score			W	eigh	ing		
	3	2	1	0		Fact	0	
Legislation	Existing	Impending		None	х	2	=	a
Environmental damage	Known detriment	Possible detriment	Limited detriment	No detriment	X	3	=	b
Interested parties	Considerable interest	Moderate interest	Little interest	No interest	X	2	=	С
Quantity	High	Medium	Low	Nil	x	3	=	d

Normal operating conditions total score = (a + b + c + d).

Step B: Other operating conditions

The same environmental effect is also awarded a numerical score under other operating conditions to reflect the importance of four further criteria:

- 1. Abnormal operations, for example, factory start-up after a holiday shutdown period
- 2. Accident/emergency, for example, fire, accidental damage
- 3. Past activities, for example, activities of former site occupant, burial of foundry waste on site
- 4. Planned activities, for example, new product or production line, site development, implementing, and maintaining EMS

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The four scores are again added to produce a total score under other operating conditions as shown below. This total score is used to rank the environmental effects under other operating conditions. For working format, refer to Attachment no. 4.3.2 (2).

		Score			
-	12	6	3	0	
Abnormal operations		Increased environmental impact	No change	Reduced environmental impact	=
Accident/ Emergency		Increased environmental impact	No change	Reduced environmental impact	=
Past activities	Evident/requires action	Possible damage/ difficult to evaluate		No damage	=
Planned activities	High	Increased environmental impact	No change	Reduced environmental impact	=

Other operating conditions total score = (a + b + c + d).

- 11. After the scoring, prepare the final list with the total score. The top priority is assigned to the aspect of highest score, however, it is subject to the final approval of the general manager.
- 12. The business concerns are subdivided and assigned a number for low, medium, and high
 - Potential regulatory and legal exposure
 - Difficulty of changing the impact
 - Cost of changing the impact

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- Effect of change on other activities and processes
- Concerns of interested parties
- Effect on the public image of the organization

13. Legal and other requirements

The organization has established and maintained procedures to identify and have access to and understand all legal and other requirements to which is subscribes, directly attributable to the environmental aspects of its activities, products, or services.

To maintain regulatory compliance, an organization has identified and followed regulatory requirements applicable to its activities, products, or services. Regulations exist in several forms.

- Those specific to the activity (e.g., site-operating permits)
- Those specific to the organizations products or services
- Those specific to the organizations industry
- General environmental laws
- Authorizations, licenses, and permits

Following sources are used to identify environmental regulations and ongoing changes, including:

- · All levels of government
- Industry associations or groups
- Commercial databases
- Professional services

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To facilitate keeping track of legal requirements, an organization has established and maintained a list of all laws and regulations pertaining to its activities, products, or services.

- 14. Some issues considered in legal and other requirements
 - Traces and identification of relevant legal and other requirements
 - Tracking of legal and other requirements
 - Tracking of changes to legal and other requirements
 - Communication of relevant information on legal and other requirements to employees.

15. Internal performance criteria

Internal priorities and criteria's have been developed and implemented where external standards does not meet the needs of the organization or are nonexistent. Internal performance criteria, together with external standards, assist the organization in developing its own objectives and targets.

- 16. The areas where an organization has internal performance criteria include
 - Management systems
 - Employee responsibilities
 - Acquisition, property management, and divestiture
 - Suppliers
 - Contractors
 - Product stewardship

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- Environmental communication
- Regulatory relationships
- Environmental incident response and preparedness
- Environmental awareness and training
- Environmental measurement and improvement
- Process risk reduction
- Prevention of pollution and resource conservation
- Capital projects
- · Process change
- Hazardous material management
- Waste management
- Water management (e.g., waste, storm, ground)
- · Air quality management
- · Energy management
- Transportation

Documentation

- 1. Environmental significant evaluation matrix, refer to Attachment no. 4.3.2. (1)
- 2. Environmental aspects and impacts priority, refer to Attachment no. 4.3.2. (2)

SUBJECT: Legal and Other Require	SOP no.: EMS-4.3.2	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 3. Other example of significance aspect model, refer to Attachment no. 4.3.2. (3)
- 4. Example of an environmental flow chart for a construction site, refer to Attachment no. 4.3.2. (4)
- 5. Example of an environmental flow chart (transfer tank and cover manufacturing), refer to Attachment no. 4.3.2. (5)
- 6. Example of discharges from a manufacturing facility, refer to Attachment no. 4.3.2. (6)

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.3.2 Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.3.2 (1)

Environmental Aspect Significance Evaluation Matrix

Prepared by: Concerned Manager

SOURCE:	ACTIVITY:	PRODUCT:	SERVICES:
LOCATION	AREA		
ENVIRONMENTAL ASPECT		DETAILS OF II	MPACT
• Emission to air			
• Release to water			
Waste management (solid/liquent)	id)		
Contamination of land			
• Use of raw materials and natur	al resources		
Other local environmental and	community issues		
Any other aspect			

Matrix to rank env	ironmental effects	unde	er normal operatio	n con	ditions								
		Conditions/Score						Weighting factor					
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	То	tal	Remarks
Legislation	Existing		Impending				None		×	2		а	
Environmental damage	Known detriment		Possible detriment		Limited detriment		No detriment		×	3		b	
Interested parties	Considerable interest		Moderate interest		Little interest		No interest		×	2		С	
Quantity	High		Medium		Low		Nil		×	3		d	
Normal operating	conditions total =	(a + b	+c+d)							Total			
			Cone	lition	ıs / Score				Total				
Elements	Condition	12	Condition	6	Condition	3	Condition	0				Rema	rks
Abnormal operations			Increased environmental impact		No change		Reduced environmental impact			а			
Accident/ emergency			Increased environmental impact		No change		Reduced environmental impact			b			
Past activities	Evident/ requires action		Possible damage/ difficult to evaluate				No damage			с			
Planned activities			Increased environmental impact		No change		Reduced environmental impact			d			
Other operating co	nditions total scor	e = (a	+b+c+d				Total						

Remarks:			
Reviewed by:			
	FMS Coordinator	Signature	Date

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.3.2 (2)

Environmental Aspects and Impact Priority

Compiled by: EMS Coordinator

		Reference Attach	ment No: 4.3.2 (1)			
AREA	ACTIVITY, PRODUCT, OR SERVICES	Total under Normal Operating Conditions	Total under Other Operating Conditions	TOTALS	POLICY NO.	RISK REDUCTION PROGRESS TO DATE
Stores	Storage on site					
	Storage off site					
	Quarantine					
	Hazardous materials					
	Solvents					
	Inflammables					
	Released materials					
	Finished goods					
Production/ Assembly line	Slugs granulation					
	Cold extrusion					
	Lacquering					

		Reference Attach	ment No: 4.3.2 (1)			
AREA	ACTIVITY, PRODUCT, OR SERVICES	Total under Normal Operating Conditions	Total under Other Operating Conditions	TOTALS	POLICY NO.	RISK REDUCTION PROGRESS TO DATE
	Base coating					
	Drying					
	External coating					
	Drying					
Packaging	Boxing					
	Shrink wrapping					
Logistics	Shipping					
	Receiving					
	Transportation					
QC Laboratory	Chemical testing					

Reviewed by: EMS Review Committee	e (Remarks)		
Approved by: General Manager:			
	Signature	Date	

Attachment no. 4.3.2 (3)

Other Example of Significance Assessment Model Prepared by: Concerned Manager

Criteria	3 points	2 points	1 point
Regulation	Consistent regulatory noncompliance	Stricter regulatory requirements have been announced Temporary regulatory noncompliance	Used according to regulatory requirements No tightening of requirements is foreseen
Public opinion (internal and external)	The substance is subject to continual criticism by media and the public (despite regulatory compliance)	Independent experts call for stricter regulatory requirements	The substance is not subject to criticism
Economic criteria (material, waste, scrap)	Use of the substance generates significant losses of material	Use of the substance generates medium-size losses of material	Hardly any material losses
Quantity	Significant quantity or level	Medium quantity or level	Small or very small quantity or level
Ecological criteria	Use of the substance generates environmental impact throughout the production	Use of the substance generates environmental impact in some steps of the production process	No significant environmental impact during production

Remarks :		
Reviewed by: $_$		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.2 (4)

Example of an Environmental Flow Chart for a Construction Site

Demolition of fe			(to be i	ities/Levels Filled in by th	ie conce		_	
Inputs/Aspects	Manufacturing Process	Output/Aspects	Normal Operation	Abnormal operation	Costs	Require- ments	Moni- toring	Emergency risks
Fermenter	Demolition activities	Noise Scrap Waste Dust Visual impact						
Fermenter	Transport	Mud on road Noise Spills Increased traffic						

Remarks:		
Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.2 (5)

Example of an Environmental Flow Chart

Demolition of bu	iilding		Quar (to be	ntities/Level e filled in by	s the faci	lity)		
Inputs/Aspects	Manufacturing Process	Output / Aspects	Normal Operation	Abnormal operation	Costs	Require- ments	Moni- toring	Emergen risks
Sheet iron fittings acetylene gas Nitrogen gas water	Cutting	Water/sludge Emissions (smoke) Scrap Dust Noise						
Cutting oil	Machining - Grinding - Milling - Drilling	Water Scrap Lubricants Noise						
	-Bending							

Terrura.		
Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.2 (6)

Example of Discharges from a Manufacturing Facility

Α			Annual quantity	Monitoring weekly
		A Discharge to sewer	2000 m ³	
	D	B Cooling water to watercourse	160 kg	
F		C Oil from oil separator	-	
	С	D Emission to air (welding smoke)	100 kg	
В		E Emission to watercourse	-	
E		F Emission of VOC from paint booth	13 t	
		G Solid waste	2000 t	
		H Liquid hazardous waste	50 t	

Remarks:		
Reviewed by:		
(EMS Coordinator)	Signature	Date

300.30-6

Objectives and Targets

STANDARD OPERATING PROCEDURE

SUBJECT: Objectives and Targets	SOP no.: EMS-4.3.3	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe a procedure for identifying objectives and targets in accordance with clause 4.3.3 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

Note: The concerned responsible for product, activity, and services shall define objectives and targets in coordination with his manager, refer to Attachment no. 4.3.3 (1). Summary of the objectives and targets will be reviewed by EMS coordinator and approved by the general manager to define environmental policy.

SUBJECT: Objectives and Targets Based on: EN ISO 14001:2004 Written by: Checked by: Approved by: Date supersedes: mm/dd/yyyy Page: XXX

STANDARD OPERATING PROCEDURE

- 1. Objectives are established to meet the organization's environmental policy. These objectives are the overall goals for environmental performance identified in the environmental policy. When establishing objectives, an organization has taken into account the relevant findings from environmental reviews, and the identified environmental aspects and associated environmental impacts.
- 2. Environmental targets are then set to achieve these objectives within a specified time frame. The targets are specific and measurable.
- 3. The objectives and targets are based on measurable environmental performance indicators. These indicators are used as the basis for an environmental performance evaluation system and provide information on both the environmental management and the operational systems.
- 4. Objectives and targets are applied broadly across an organization and more narrowly to site-specific or individual activities. Appropriate levels of management have defined the objectives and targets. Objectives and targets are periodically reviewed and revised, and taken into consideration the views of interested parties.
- 5. The issues considered in environmental objectives and targets
 - Objectives and targets reflect both the environmental policy and significant environmental impacts associated with the organization's activities, products, or services.
 - The employees responsible for achieving the objectives and targets had input into their development.
 - The views of interested parties have been considered.
 - Specific measurable indicators have been established for objectives and targets.

STANDARD OPERATING PROCEDURE

SUBJECT: Objectives and Targets	SOP no.: EMS-4.3.3	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- Objectives and targets regularly reviewed and revised to reflect desired improvements in environmental performance.
- 6. Objectives include commitments to
 - Reduce waste and the depletion of resources
 - Reduce or eliminate the release of pollutants into the environment
 - Design products to minimize their environmental impact in production, use, and disposal
 - Control the environmental impact of sources of raw materials
 - Promote environmental awareness among employees and the community
- 7. Progress toward the objectives is generally be measured using environmental performance indicators such as
 - Quantity of raw materials or energy used
 - Quantity of emissions such as CO₂
 - Waste produced per quantity of finished product
 - Efficiency of materials and energy use
 - Number of environmental incidents (e.g., excursions above limits)
 - Number of environmental accidents (e.g., unplanned releases)
 - Percentage waste recycled
 - Percentage recycled material used in packaging
 - Number of vehicle kilometres per unit of production
 - Specific pollutant quantities, for example, NO_X, SO₂, CO, HC, Pb, CFCs

STANDARD OPERATING PROCEDURE

SUBJECT: Objectives and Targets	SOP no.: EMS-4.3.3	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- Investment in environmental protection
- Number of prosecutions
- Land area set aside for wildlife habitat
- 8. The objectives and targets should be consistent with commitment to continual improvement program.

Documentation

- 1. For objectives and targets, refer to Attachment no. 4.3.3 (1)
- 2. Summary of objectives and targets, refer to Attachment no. 4.3.3 (2)

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

Attachment no. 4.3.3 (1)

Objectives and Targets Significant Aspect Priority No. Prepared by: Concerned Responsible

Significant Environmental As	pect/Impact	
Objective:		Consistent to continual improvement
		YES □ NO □
Indicator:		
Target:		Consistent to continual improvement
		YES □ NO □
Policy Drafted:		
Action:		
Concerned Manager _		
(Coordinator)	Signature	Date
(2-0	2 4.0
Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (2)

Summary of Objectives and Targets

Copy to: Concerned Responsibility

Significant Aspect Identified	Significant Aspect Priority No.	Impact	Objective	Target	Indicator	Policy (Priority)	Prepared by Concerned Manager
Activities							
Product							
Services							

Reviewed by:		
(Coordinator)	Signature	Date
Approved by:		
(EMS Coordinator)	Signature	Date

300.30-7

Environmental Management Program(s)

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Environmental Manage	SOP no.: EMS-4.3.4	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe a procedure to establish environmental program(s) in accordance with clause 4.3.4 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure Clause

1. This is the responsibility of the concerned manager to develop the program in coordination with the EMS coordinator for each policy. The EMS coordinator shall review the program every month.

SUBJECT: Environmental Manage	SOP no.: EMS-4.3.4	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 2. Within the general planning of activities, an organization has established an environmental management program that addresses all of its environmental objectives. To be most effective, environmental management planning is integrated into the organizations strategic plan. Environmental management programs address schedules, resources, and responsibilities for achieving the organizations environmental objectives and targets.
- 3. Within the framework provided by the environmental management planning, an environmental management program identifies specific actions in order of their priority to the organization. These actions may deal with individual processes, projects, products, services, sites, or facilities within a site.
- 4. Environmental management programs help the organization to improve its environmental performance. They are dynamic and revised regularly to reflect changes in organizational objectives and targets.
- 5. The issues considered in environmental management program(s)
 - The organizations process for developing environmental management programs.
 - Instrument of all responsible parties in environmental management planning process.
 - Periodic review of the program.
 - Addressing the issues of resources, responsibility, timing, and priority in the program.
- 6. The following is an example of a process for developing an environmental management program.

SUBJECT: Environmental Management Program(s)		SOP no.: EMS-4.3.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Example No. 1

Policy : Conserve natural resources of water

Objective : Minimize water use wherever technically and commercially

practical.

Target : Reduce water consumption at selected sites by 15% of the

present levels with one year.

Program : Water reuse.

Action : Install equipment to recycle water used for rinsing in

process A for reuse in process B.

Example No. 2

Policy : Our company will seek to reduce electrical consumption

and improve an energy efficiency where possible.

Objective: Reduce electrical consumption by 30% of the present level

by year 2005, using 1999 standard.

Target : Reduce electrical consumption 10% in year 2000 (Production)

5% in year 2001 (Packaging) 5% in year 2002 (Maintenance) 4% in year 2003 (Turbines) 3% in year 2004 (Pumps)

2% in year 2005 (Air Conditioning)

Program : Resources optimization

Action : Install energy-saving devices at selected sites.

Increase staff awareness to save electricity.

Increase production batch sizes to save energy consumption.

SUBJECT: Environmental Management Program(s)		SOP no.: EMS-4.3.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Documentation

1. Refer to attachment EMS 4.3.4 (filled example).

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.3.4 Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.3.4 (1)

Environmental Management Program

Copy to: Concerned Responsible

Policy No.

1.	Policy statement, for example, Minimize water use whenever technically and commercially feasible							
2.	Description of objective, for example, Reduce water consumption at selected sites by 50,000 m³ from present level within one year							
3.	Description of target, for example, Carry out a program if investigations to measure the use of water at different parts of process. Install the necessary equipment to tackle the worst three users by October next year.							
4.	Summary: As ab	ove						
	Aspect Environmental Legal Internal standard Severity Priority Location Refer to site plan							
	Natural sweet water	Wastage of natural resources	None	None	Medium	Medium	Process assembly	Drawing No. 1

5.	Program, for example, install equipment to recycle rinse water for process "A" for reuse in process "B" by (Objective) October next year to be carried out by the production manager.				ю	
	Target March 2000	How (Means) Process Review	Responsibility Production	When February 2000	Achieved on	
6.	Monitoring:					
	Target April 2000	Indicator Water consumption	Frequency Weekly	Responsibility Production	Refer Record Production File	
7.	Cost and Investment					
	Target October 2000	Internal cost US\$50,000	External cost US\$200,000	Savings US\$50,000	Return 25%/year	
8.	Follow-up Objective achieved: Time frame respected: Corrective action: Comments: Satisf	YES NONE	Date : Date :	mm/dd/yy mm/dd/yy		
	ewed by: S Coordinator)	Signature	 Date			

300.30-8

Implementation and Operation

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Implementation and Operation		SOP no.: EMS-4.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe a procedure for implementing and operation of EMS in accordance with clause 4.4 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

Note: This is the responsibility of all concerned to participate in the implementation of EMS program as appropriate. EMS coordinator is responsible for the procedure compliance.

SUBJECT: Implementation and Operation		SOP no.: EMS-4.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 1. For effective implementation, an organization has developed the capabilities and support mechanisms necessary to achieve its environmental policy, objectives, and targets.
- 2. The capabilities and support required by the organization constantly evolve in response to the changing requirements of interested parties, a dynamic business environment, and the process of continual improvement. To achieve its environmental objectives and organization has focused and align its people, systems, strategy, resources, and structure.
- 3. The implementation of environmental management has been approached in stages and is based on the level of awareness of environmental requirements, aspects, expectations and benefits, and the availability of resources.
- 4. Resources—Human, physical, and financial
 - The appropriate human, physical (e.g., facilities, equipment), and financial resources essential to the implementation of an organization's environmental policies and the achievement of its objectives are defined and made available. In allocating resources, organizations have developed procedures to track the benefits as well as the costs of their environmentally or related activities. Insures such as the cost of pollution control, wastes, and disposal are included.
- 5. Issues considered in human, physical, and financial resources
 - Identify and allocate the human, technical, and financial resources necessary to meet its environmental objectives and targets, including those for new projects.
 - Tracking the costs and benefits of environmental activities.

SUBJECT: Implementation and Operation		SOP no.: EMS-4.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
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- 6. In order to manage these constraints the company, wherever possible, consider cooperative strategies with
 - Larger client organizations to share technology and know-how.
 - Other organizations on a supply chain or local basis to define and address common issues, to share know-how, to facilitate technical development, to use facilities jointly, to establish a way to study the EMS, to collectively engage a consultant.
 - Standardization organizations, associations, chambers of commerce, for training and awareness programs.
 - Universities and other research centers to support production and innovation.
- 7. To effectively manage environmental concerns, the EMS elements are designed or revised so that they are effectively aligned and integrated with the existing management system elements.

Management systems that have benefited from integration include:

- Organization policies
- Resource allocation
- Operational controls and documentation
- Information and support systems
- Training and development
- Organization and accountability structure
- Reward and appraisal system
- Measuring and monitoring systems
- · Communication and reporting

SUBJECT: Implementation and Operation		SOP no.: EMS-4.4
Distributed to:	Distributed to: Based on: EN ISO 14001:2004	
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 8. Issues considered in organizational alignment and integration.
 - Environmental management system integration into the overall business management process.
 - Balancing and resolving conflicts between environmental and other business objectives and priorities.
- 9. Responsibility for the overall effectiveness of the EMS is assigned to (a) senior person(s) or function(s) with sufficient authority, competence, and resources, i.e., EMS-Coordinator.
- 10. Operational managers have clearly defined the responsibilities of relevant personnel and are responsible and accountable for effective implementation of EMS and environmental performance. Employees at all levels are accountable, within the scope of their responsibilities, for environmental performance in support of the overall environmental management system.
- 11. Issues considered in accountability and responsibility.
 - a. The responsibilities and accountability of personnel who manage, perform, and verify work affecting the environment, and these are defined and documented.
 - b. Relationship between environmental responsibility and individual performance and this is periodically reviewed.
 - Responsible and accountable personnel
 - Obtain sufficient training, resources, and personnel for implementation
 - Initiate action to ensure compliance with environmental policy
 - Anticipate, identify, and record any environmental problems

SUBJECT: Implementation and Operation		SOP no.: EMS-4.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- Initiate, recommend, or provide solutions to those problems
- Verify the implementation of such solutions
- Control further activities until any environmental deficiency or unsatisfactory condition has been corrected
- Obtain appropriate training to act in emergency situations
- Gain an understanding of the consequences of non-compliance
- Gain an understanding of the accountability that applies to them
- Encourage voluntary action and initiatives
- 12. To ensure effective development and implementation of an EMS appropriate responsibilities are assigned. It should be recognized that companies and institutions have different organizational structures, and need to understand and define environmental responsibilities based upon their own work processes.

Documentation

- 1. Personnel and responsibilities, refer to Attachment no. 4.4 (1)
- 2. Structure and responsibility, refer to Attachment no. 4.4 (2)
- 3. Resources allocation, refer to Attachment no. 4.4 (3)
- 4. General implementation process, refer to Attachment no. 4.4 (4)
- 5. Example job description EMS coordinator, refer to Attachment no. 4.4 (5)

SUBJECT: Implementation and Operation		SOP no.: EMS-4.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4 (1)

Personnel and Responsibilities

Copy to: Concerned Responsible

Sample Environmental Responsibilities	Typical Person(s) Responsible
Establish overall direction	General manager, chief executive officer (CEO), board of directors
Develop environmental policy	President, chief environmental management system controller
Develop environmental objectives, targets, and programs	Relevant managers
Monitor overall EMS performance	Environmental system coordinator
Assure regulatory compliance	Senior operating manager
Ensure continual improvement	All managers
Identify customers expectations	Sales and marketing staff
Identify suppliers expectations	Purchasers, buyers
Develop and maintain accounting procedures	Finance/accounting managers
Comply with defined procedures	All staff

Note: In the case of SMEs, the person responsible can be the owner.

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4 (2)

Structure and Responsibility EXAMPLE

To: Person Concerned From: Concerned Manager

(EMS Coordinator)	Signature	Date
Reviewed by:		
Approved by:	Accepted by:	
Authorized to stop any activi environmental protection.	ty, product, or services not in co	ompliance with the
Authorization		
13. Prepare documents neede	d for the management review n	neetings.
12. Report on regulatory com	, 0	
	l statement if the facility is regis	
	al reports, for example, to autho	orities.
Report on environmental: Coordinate EMS audits.	management at the managemer	nt review meetings.
	n necessary for the managemer	
6. Maintain contacts with go	vernmental authorities.	
of environmental objective		
1 1 0	the process for regular identific	
1 1	for new environmental objectives. ward environmental objectives.	
2. Maintain a list of environr	O	tros.
environmental aspects.		
1. Maintain a list of environr	mental aspects, in particular the	significant
Responsibilities		
Summary (Job Title): Mainta	ain, monitor, and control the ele	ments of EMS
1 0 0		_
Department: Engineering	_ 1 0 -	B.Sc. Environmental Science
Job Title: <u>EMS Coordinator</u>	_ Reporting to: C	General Manager

Issue date: mm/dd/yyyy

From: Personnel Manager

Revision no.: New

Attachment no. 4.4 (3)

Resources Allocation

To: Concerned Manager

Policy No.:

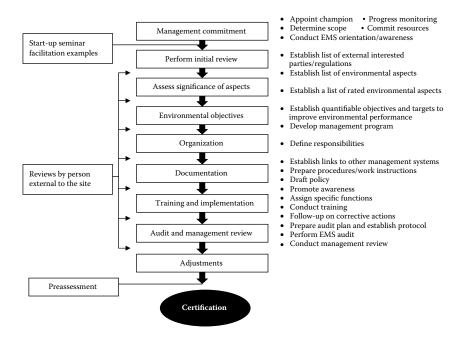
 Personnel Resources Job title Personnel qualification Practical experience Training received Computer awareness Personnel character 	
2. Financial resources (Provide details):Equipment costPersonnel cost	
3. Redirection of existing personnel	
4. Training requirements	
5. Benefits for the company	
6. Personnel motivation	
Reviewed by: (EMS Coordinator) Signature	 Date
Approved by: General Manager) Signature	Date

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4 (4)

General Implementation Process



Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4 (5)

Example Job Description of EMS Coordinator

The list contains examples of the ISO 14001 elements that usually the EMS coordinator (or any other person who has been given the responsibility to document the EMS) is responsible for.

Issue	Activity/Responsibility		
Policy	 Coordinate the establishment of a site-specific environmental policy that is relevant to the facility's size and activities. Ensure that the local environmental policy is in line with the company policy for environmental protection. Ensure that the local environmental policy fulfills the requirements of ISO14001, e.g., it shall contain commitments to continual improvement and compliance with relevant environmental legislation. Document the procedure for the environmental policy. 		
Environmental aspects	 Coordinate and document the initial review. This process can be more or less comprehensive depending on how well the processes are documented. Develop a site-specific model for how to assess the significance of the environmental aspects. Document the procedure for identifying environmental aspects. 		
Legal requirements	 Ensure that the organization has procedures for regular updating of relevant regulatory requirements. Establish a list of how the legal requirements are applied to the organization, that is, a list containing the laws and the environmental aspects, for example, emissions, where laws are applicable to the organization. 		
Environmental objectives	 Establish a list of environmental objectives and programs that have recently been completed. Establish procedures for how to identify environmental objectives and programs within all relevant functions of the organization. Establish a list of on-going environmental objectives and programs. Document the procedure for setting environmental objectives. 		

Issue	Activity/Responsibility		
Environmental programs	 Confirm that all environmental objectives have programs setting out how the objective and targets are to be achieved. Document the procedure for environmental programs. 		
Environmental organization	 Identify activities and functions that may have a significant impact on the organization's environmental performance. Delegate responsibilities. 		
Education and training	 Ensure that functions needing special education and training are identified. Identify training requirement for functions that may have a significant environmental impact. Coordinate EMS general training. Coordinate function specific training. Establish procedure for retaining of training records. 		
Communication	 Ensure that the environmental policy and the significant environmental objectives are communicated to the whole organization. Coordinate formal delegation of environmental responsibilities and authorities. Establish the procedure for external and internal communication. 		
EMS documentation	 Describe the elements of the EMS, for example, types of documents. Describe the organization and its environmental aspects. Maintain the EMS documentation, that is, regular updating. 		
Document control	 Establish a procedure for document control, for example, refer to the corresponding procedure within the quality system. Establish a list of environmental documents and the recipients of documents. 		
Processes	 Implement procedures for regular updating of environmental aspects, for example, environmental aspects of new or significantly modified manufacturing processes and new product lines. Identify and list all processes that need to have documented procedures in order to control their environmental impacts. Coordinate the documentation of procedures and instructions. 		
Emergency	 Coordinate an inventory of potential emergency situations. Establish procedures for how to train emergency situations. Document the procedure for emergency control. 		
Monitoring	 Identify those environmental aspects that are necessary to monitor in order to verify legal compliance. Establish procedures for how to monitor environmental aspects. Establish procedures for reporting regulatory compliance. 		
Nonconformance	Establish procedures for how to handle nonconformance. Verify that the nonconformance procedure is working.		

Issue	Activity/Responsibility	
Records	Establish procedures for how and where to retain environmental records.	
Internal EMS audits	 Establish a plan for when, and by whom, the internal system audits shall be conducted. Establish procedures for how to document EMS audits. Document the EMS audit procedure. 	
Management review	 Establish a list of issues to be addressed and documented at the management review meetings. Establish a schedule for when the management review meetings are to be conducted. Document the management review procedure. 	

300.30-9

Resources, Roles, Responsibility, and Authority

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Resources, Roles, Respo	SOP no.: EMS-4.4.1	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe a procedure for structure and responsibility in accordance with clause 4.4.1 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system representative) is responsible for SOP compliance.

Procedure

1. This is the management responsibility to provide resources for establishing, implementing, maintaining, and improving the EMS.

SUBJECT: Resources, Roles, Respo	SOP no.: EMS-4.4.1	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 2. This is the responsibility of concerned managers to maintain and follow the structural responsibilities. EMS coordinator shall review periodically (every three months) the compliance.
- 3. Top management has a key role to play in building awareness and motivating employees by explaining the organizations environmental values and communicating its commitment to the environmental policy. The environmental management system coordinator is hired to maintain the system.
- 4. It is the commitment of the individual people, in the context of shared environmental values, that transforms an environmental management system from paperwork into an effective process.
- 5. Motivation to continually improve is enhanced when employees are recognized for achieving environmental objectives and targets and encouraged to make suggestions that leads to improved environmental performance.
- 6. Key elements considered in environmental awareness and motivation
 - How has top management established, reinforced, and communicated organizational commitment to the environmental policy.
 - b. To what extent do employees understand, accept, and share the environmental values of the organization.
 - c. To what extent do shared environmental values serve to motive environmentally responsible action.
 - d. Method to recognize employees' environmental achievements.
- 7. The EMS coordinator will review the structure and responsibility every quarter to keep it updated.

SUBJECT: Resources, Roles, Respo	SOP no.: EMS-4.4.1	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Documentation

- 1. Structure and responsibility, refer to Attachment no. 4.4.1 (1)
- 2. Supplier questionnaire, refer to Attachment no. 4.4.1 (2)

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.4.1 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.1 (1)

Structure and Responsibility

Copy to: Concerned Responsible

Elements	Prepared by (Concerned Managers)	Frequency of Review	Remarks
1. Organization chart personnel			
qualification			
2. Resources identified and availed			
for establishing, implementing,			
maintaining and improving EMS			
3. Personnel qualifications			
4. Job description			
Training of staff to increase			
environmental awareness by			
 Internal means 			
 External means 			
6. Motivation schemes			
• Financial			
 Nonfinancial 			
7. Communication to employees by			
• Slogans			
 Sign boards 			
• Pictures			
• Memos			
8. Staff goals and objectives based			
on EMS objectives and targets			
 Management review 			
 New objectives and targets 			
 Corrective actions follow-up 			
 Audit findings follow-up 			
9. Interested parties			
• Supplier			
Questionnaire			

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.4.1 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.1 (2)

Supplier Questionnaire		
	Yes	No
Are you registered acc. to EMAS? If yes, please send us your environmental report		
2. Are you certified to ISO 14001 of BS 7750?		
If either of the above questions have been answered with "yes," you don't have to reply to the following questions.		
3. Are you planning to implement a certified environmental management system If so, which and when?		
Date:		
4. Do you have an environmental policy? If yes, please send us your policy.		
5. Have you undertaken an external or internal environmental audit? If yes, please send us a summary of your program.		
6. Do you have an up-to-date environmental impact assessment? If yes, please send us a summary of your program.		
7. Do you have an up-to-date environmental impact assessment? If yes, please send us a copy. If no, please describe briefly below what kind of environmental impacts your operations cause.		
8. Do you need consent, authorization environmental permit to operate?		
9. Have you an environmental contact person?		
Name, title	-	
10. Do you educate your staff in environmental issues?		
11. Do you have any sites for surface treatment, metal plating, pickling, etc.?		

	Yes	No
12. Do you have formal procedures for handling of hazardous waste from your sites?		
13. Did you receive instruction from our company to be in compliance with our EMS program during operations by your staff at our site.		
14. Other comments and responses to questions 1 to 13, if any		

300.30-10

Training Awareness and Competence

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Training Awareness and	SOP no.: EMS-4.4.2	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe a procedure for developing competence, training and awareness in accordance with clause 4.4.2 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

This is the responsibility of the concerned manager to identify the training needs, develop and implement comprehensive training program. EMS coordinator shall review the program every quarter.

SUBJECT: Training Awareness and	SOP no.: EMS-4.4.2	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 1. The knowledge and skills necessary to achieve environmental objectives are identified. These are considered in personnel selection, recruitment, training, development of skills, and ongoing education.
- 2. Appropriate training relevant to the achievement of environmental policies, objectives, and targets are provided to all personnel within an organization.
- 3. Employees (persons working for, or on behalf of the organization, could include contractors and temporary staff) have an appropriate knowledge base, which includes training in the methods and skills required to perform their tasks in an efficient and competent fashion and knowledge of the impact their activities can have on the environment if performed incorrectly.
- 4. The organization ensures that contractors working at the site provide evidence that they have the requisite knowledge and skills to perform the work in an "environmentally responsible manner."
- 5. Education and training provided to ensure that employees have appropriate and current knowledge of regulatory requirements, internal standards and the organizations policies and objectives. The level and details of training vary according to the tasks.
- 6. Training programs comprise the following elements:
 - Identification of employee training needs
 - Development of a training plan to address defined needs
 - Verification of conformance of training program to regulatory or organizational requirements
 - Training of target employee groups

SUBJECT: Training Awareness and	T: Training Awareness and Competence					
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New				
Written by:	Checked by:	Approved by:				
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX				

- Documentation of training received
- · Evaluation of training received
- 7. Key elements considered in knowledge, skills, and training
 - a. Identification of training needs by the organization
 - b. Analysis of specific job functions related to training needs
 - c. Development and review and modification of training needs as needed
 - d. Training documentation and track

Documentation

- 1. For training program development, refer to Attachment no. 4.4.2 (1).
- 2. For training program, refer to Attachment no. 4.4.2 (2).
- 3. Training program and record, refer to Attachment no. 4.4.2 (3).

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.4.2
Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4.2 (1)

Copy To: All Concerned

Examples of the types of environmental training which can be provided by the organization are as follows:								
Type of Training	Audience Purpose							
Raising awareness of the strategic importance of environmental management	Senior management	To gain commitment and alignment to the organizations environmental policy						
Raising general environmental awareness	All employees In-house Contractors Temporary Visitors Trainees, etc.	To gain commitment to the environmental policy, objectives and targets of the organization and instill a sense of individual responsibility						
Skills enhancement	Employees with environmental responsibilities	To improve performance in specific areas of the organization, e.g., operations, research, and development and engineering						
Compliance	Employees whose actions can affect compliance	To ensure regulatory and internal requirements for training are met						

SOP no.: EMS-4.4.2 Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4.2 (2)

Example List of Operations and Competence, Requirements

Environmental Aspect	Activity	Min. Training Level
Emission of dust	Maintenance of bag-filters	Filter training course provided by the filter manufacturer
Noise from fan test	Measurement of noise level	Training on noise detector provided to new employee

SOP no.: EMS-4.4.2 Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4.2 (3)

Cany Tax All Cancarnad

Name:	Responsibility:			Job title:												
		ation:]	Department:							
Programs	Training Procedure	Training Tools		Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Signature	Remark
Environmental awareness																
Aspects identification																
Impact analysis																
• ISO 14001 standard																
• Environmental regulatory requirements																
Specific skills and techniques																
Specific equipment operation																
Reorientation																
SOP reading																
Emergency handling																
Fire fighting																
• First aid																
Evacuation drill																
• Others																

300.30-11

Communication

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Communication	SOP no.: EMS-4.4.3	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe a procedure for developing EMS communication in accordance with clause 4.4.3 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

1. Communication includes establishing processes to report internally and, where desired, externally (pro-actively) on the environmental activities of the organization in order to

SUBJECT: Communication		SOP no.: EMS-4.4.3
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- Demonstrate management commitment to the environment
- Deal with concerns and questions about the environmental aspects of the organizations activities, products, or services
- Raise awareness of the organizations environmental policies, objectives, targets, and programs
- Inform internal or external interested parties about the organizations environmental management system and performance as appropriate
- Results from EMS monitoring, audit and management review are communicated to those within the organizations who are responsible for performance.
- 3. The provision of appropriate information to the organizations employees and other interested parties serves to motivate employees and encourage public understanding and acceptance of the organizations efforts to improve its environmental performance.
- 4. Key elements considered in communication and reporting
 - a. Process for receiving and responding to employee concerns
 - b. Process for receiving and considering the concerns of other interested parties
 - c. Communication of the organization's environmental policy and performance
 - d. Communication of results from EMS audits and reviews communicated to all appropriate people in the organization
 - e. Procedure for making the environmental policy available to the public

Communication 181

SUBJECT: Communication		SOP no.: EMS-4.4.3
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- f. Review of internal communication to ensure that it is adequate to support continual improvement around environmental issue
- 5. Items included in reports
 - Organizations profile
 - Environmental policy, objectives, and targets
 - Environmental management processes (including interested party involvement and employee recognition)
 - Environmental performance evaluation (including releases, resource conservation compliance, product stewardship, and risk)
 - · Opportunities for improvement
 - Supplementary information, such as glossaries
 - Independent verification of the contents
- 6. For both internal and external environmental communication and reporting
 - Two-way communication is encouraged.
 - Information is understandable and adequately explained.
 - Information is verifiable.
 - The organization presents an accurate picture of its performance.
 - Information is presented in a consistent form (e.g., similar units of measurement to allow for comparison between one period and another).

SUBJECT: Communication		SOP no.: EMS-4.4.3
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 7. The environmental information is communicated using the following:
 - Externally, through an annual report, regulatory submissions, public government records, industry association publications, the media, and paid advertising
 - The publication of telephone numbers where complaints and questions can be directed
 - Internally, though bulletin board postings, internal newspapers, meetings, and electronic mail messages

Documentation

1. Communication, refer to Attachment no.: 4.4.3.

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

Communication 183

SOP no.: EMS-4.4.3 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.3 (1)

Communication

Copy to: Concerned Responsible Communication: Internal/External

Communication Source	Reference to	Reasons	Concerned Manager Remarks
Customer Media Academic Science Government Contractors and suppliers Regulatory body Insurance company Banks Industrial federation	 Policy New or altered system request Significant aspect Objectives and targets Noncompliance report Suggestion for improvement Training request Audits 	Reasons	Remarks
 Competitors Employees Shareholders	Management reviews Others		

	Signature	Date
YES	NO	
	YES YES YES	YES NO YES NO

300.30-12

Environmental Management System Documentation

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Environmental Management System Documentation		SOP no.: EMS-4.4.4
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for the environmental management system documentation in accordance with clause 4.4.4 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

SUBJECT: Environmental Management System Documentation		SOP no.: EMS-4.4.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Procedure

Note: The departmental managers are responsible to prepare a list of critical EMS-related documents and the EMS coordinator shall review.

- 1. The company has established the summary of connected procedures to have an effective and meaningful Environmental Management System.
- 2. The ISO 14001:2004 specially requires specific reference documents in the following clauses:
 - a. 4.3.3 Objectives and targets
 - b. 4.4.1 Structure and responsibility
 - c. 4.4.4 EMS documentation including description of the scope of the EMS in the system documentation
 - d. 4.4.6 Operational control
 - e. 4.5.1 Monitoring measurement
 - f. 4.6 Management review
 - g. 4.3.1 Significant environmental aspects
- 3. The management has established and maintained information in paper and in electronic form as appropriate, to provide core elements of the management system and provide direction to related documentation.
- 4. The EMS auditor can document the procedure, work instruction as an objective evidence of adequate planning and control.

SUBJECT: Environmental Management System Documentation		SOP no.: EMS-4.4.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 5. The organization plans (these) activities, including maintenance, in order to ensure that they are carried out under specified conditions.
- 6. The company has established and maintained documented procedures to cover situations where their absence could lead to deviations from the environmental policy and the objectives and targets. The key documents are described in Step 2.
- 7. The following is the hierarchy of EMS documentation in the company.
 - Level 1—The "Signposting" document
 - Level 2—System procedures
 - Level 3—Operational procedures and technical "instructions"
 - Level 4—Data, records, etc.
- 8. The "signposting" document of the company is the top-level document and is, above all, a descriptive document for the company. It is the actual environmental policy and the following documents are described in the EMS manual.
 - Structure, responsibility, and authority descriptions.
 - Objectives and targets to define improvements goals.
 - A description of the company (as appropriate).
 - An outline of its operation.
 - Its relationship with other "linked" organizations.
 - A description of the core elements of the EMS and their interaction.
 - Reference to other supportive elements and documentation.

SUBJECT: Environmental Management System Documentation		SOP no.: EMS-4.4.4
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 9. The system procedures define the "day-to-day" activities relevant to an area, department, function, and so on that are required to ensure that the management system operates effectively. In general, they relate to "management" and/or "supervisory" issues, communications, and interfaces. (Documentation of detailed task-level actions for individuals is generally better served by operational procedures/technical instructions.)
 - e.g. Purchasing

Document control

Supplier evaluation and approval

Calibration

- 10. The operational procedures/technical instructions define the who, what/which, where, and when of an activity requiring control, but tend to be aimed toward discrete tasks and individual(s) performing them.
- 11. Legal and regulatory compliance procedures define methods of work/test/monitoring that require complying with mandated methods defined with external, regulatory documents.
- 12. Other interested parties' methods are also defined and maintained separately.
- 13. Document control is ensured through
 - The right information is available
 - In the right place
 - At the right time
 - In the right revision

SUBJECT: Environmental Management System Documentation		SOP no.: EMS-4.4.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 14. The control and handling of documentation is ensured through reviews and approvals by authorized personnel.
- 15. That the obsolete documents are
 - Removed from the possibility of use.
 - Retained if required at a suitable location.
 - · Identified as such.
- 16. All controlled documentation contain
 - A clear identifier as to
 - Subject
 - SOP no.
 - Distributed to
 - Based on
 - Revision no.
 - Written by
 - Checked by
 - Approved by
 - Date supersedes
 - Date issued
 - Page
 - Purpose
 - Responsibility
 - Procedure (details)
 - Reason(s) for revision

SUBJECT: Environmental Management System Documentation		SOP no.: EMS-4.4.4
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Documentation

1. Critical documentation index, refer to Attachment no. 4.4.4 (1).

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.4.4 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.4 (1)

Critical Documents Index

Key Procedures	Responsibility (Departmental Manager)
Environmental policy	
Identifying environmental aspects	
Setting environmental objectives	
Description of the scope of the EMS	
Environmental programs	
Retention of training records	
Internal and external communication	
Processing instructions	
Emergency control	
Regulatory compliance	
Monitoring	
Nonconform investigation	
Change control	
Corrective action and preventive measures	
Calibration	
Environmental monitoring records	
Auditing	
Management review	
Complaints	
Interested parties	

Reviewed by:			
(EMS Coordinator)	Signature	Date	

300.30-13

Document Control

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Document Control	SOP no.: EMS-4.4.5	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for document control in accordance with clause 4.4.5 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

Definition: Information and its supporting medium (paper, magnetic, electronic, or optical computer disc, photograph or master sample, or a combination thereof).

SUBJECT: Document Control	SOP no.: EMS-4.4.5	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 1. Operational processes and procedures are defined appropriately, documented and updated as necessary.
- 2. The organization has clearly defined the various types of documents that establish and specify effective operational procedures and control.
- The existence of EMS documentation supports employees awareness of what is required to achieve the organizations environmental objectives and enables the evaluation of the system and environmental performance.
- 4. The environmental documentation is integrated into existing documentation. For ease of use, the organization has considered organizing and maintaining a summary of the documentation to
 - Collate the environmental policy, objectives, and targets
 - Describe the means of achieving environmental objectives and targets
 - Document the key roles, responsibilities, and procedures
 - Provide direction to related documentation, and describe other elements of the organization are implemented
- 5. Key elements considered in EMS documentation
 - a. The environmental management procedures are identified, numbered, documented, communicated, and revised.
 - b. Process for developing and maintaining EMS documentation.
 - c. EMS documentation integration with existing documentation where appropriate.
 - d. Employees' access to EMS documentation needed to conduct their job activities.

SUBJECT: Document Control	SOP no.: EMS-4.4.5	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 6. All documentation is dated (with dates of revision), readily identifiable, organized, and retained for a specified period. The organization should ensure that
 - Documents are identified with the appropriate organization, division, function, acitivity, and/or contact person.
 - Documents are periodically reviewed, revised as necessary and approved by the authorized personnel prior to issue.
 - The current versions of relevant documents are available at all locations where operations essential to the effective functioning of the system are performed.
 - Obsolete documents are promptly removed from all points of issue and points of use.
- 7. The documents of external origin shall be determined by the management to be essential for the planning and operation of the EMS. The distribution of such documents shall be controlled.
- 8. The general documentation hierarchy is as follows:

Policy	
Manual	
Procedure	
Instructions	
Result Documents	

SUBJECT: Document Control	SOP no.: EMS-4.4.5	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Documentation

- 1. EMS documentation, refer to Attachment no. 4.4.5 (1)
- 2. Procedures index, refer to Attachment no. 4.4.5 (2)
- 3. SOP distribution record, refer to Attachment no. 4.4.5 (3)
- 4. Document retention time, refer to Attachment no. 4.4.5 (4)

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

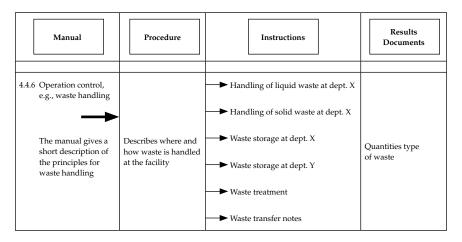
Document Control 197

> **SOP no.: EMS-4.4.5** Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4.5 (1)

Example of EMS Documentation



Procedure/Instructions

- * Objective
- * Sogmatire
- * Responsibility * Date
- * Authority
- Direction to the next level in the hierarchy

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.5 (2)

Procedures Index

Subject	Procedure no.	Issue Date

Document Control 199

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.5 (3)

SOP Distribution Record	
SOP no.:	
Subject:	

			SOP received		Supersed	ed SOP 1	eturned	
Copies to	Issued on	Supersedes	From	Ву	Date	Ву	То	Date

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.5 (4)

Document Retention Time

Document Description	Retention Time	Location	Responsibility

300.30-14

Operation Control

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Operation Control		SOP no.: EMS-4.4.6
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for operational control in accordance with Clause 4.4.6 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 system coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

1. Implementation has been accomplished through the establishment and maintenance of operational procedures and controls to

SUBJECT: Operation Control		SOP no.: EMS-4.4.6
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

ensure that the organizations environmental policy, objectives, and targets can be met.

- The organization has considered the different operations and activities contributing to its significant environmental impacts when developing or modifying operational controls and procedures. Such operations and activities include
 - Research and development design and engineering
 - Purchasing
 - Contracting
 - Handling and storage of raw materials
 - Production and maintenance processes
 - Laboratories
 - Storage of products
 - Transportation
 - Marketing and advertising
 - Customer service
 - Acquisition, construction, or modification of property and facilities
- 3. Activities are divided into three categories:
 - Activities to prevent pollution and conserve resources in new capital projects, process changes and resources management, property (acquisitions, divestitures, and property management), and new products and packaging

SUBJECT: Operation Control	SOP no.: EMS-4.4.6	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- Daily management activities to assure conformance to internal and external organizational requirements and to ensure their efficiency and effectiveness
- Strategic management activities to anticipate and respond to changing environmental requirements

Documentation

1. Operational control list, refer to Attachment no. EMS-4.4.7

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.4.6 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.6 (1)

Operational Control

From: Concerned Manager

	Procedure Available		Aspect		Impact	Remarks
Operation			S	IS		
Research and development	Yes	No				
Designing and engineering	Yes	No				
Purchasing	Yes	No				
Contracting	Yes	No				
Handling and storage of raw materials	Yes	No				
Production and material process	Yes	No				
Laboratories	Yes	No				
Storage of product	Yes	No				
Transportation	Yes	No				
Marketing and advertising	Yes	No				
Customer service	Yes	No				
Acquisition	Yes	No				
Construction	Yes	No				
Modification	Yes	No				
– Property						
– Facilities						
Contractors	Yes	No				

Note: S—Significant; IS—Insignificant

Reviewed by:
(EMS Coordinator) Signature Date

300.30-15

Emergency Preparedness and Response

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Emergency Preparedne	SOP no.: EMS-4.4.7	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for developing emergency preparedness and response in accordance with clause 4.4.7 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

SUBJECT: Emergency Preparedne	SOP no.: EMS-4.4.7	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Procedure

- Emergency plans and procedures have been established to ensure that there will be an appropriate response to unexpected or accidental incidents.
- 2. The organization has defined and maintained procedures for dealing with environmental incidents and potential emergency situations. The operating procedures and controls include, where appropriate, consideration of
 - Accidental emissions to the atmosphere
 - Accidental discharges to water and land
 - Specific environment and ecosystem effects from accidental release
- 3. The procedure have taken into account incidents arising, or likely to arise, as a consequence of
 - · Abnormal operating conditions
 - Accidents and potential emergency situations
- 4. Emergency plans include
 - Emergency organizations and responsibilities
 - A list of key personnel
 - Details of emergency services (e.g., fire department, spill cleanup services)
 - Internal and external communication plans
 - · Actions taken in the event of different types of emergencies

SUBJECT: Emergency Preparedness and Response		SOP no.: EMS-4.4.7
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- Information on hazardous materials, including each materials potential impact on the environment, and measures to be taken in the event of accidental release
- Training plans and testing for effectiveness

Documentation

- 1. Emergency preparedness and resources, refer to Attachment no. 4.4.7 (1)
- 2. Emergency plan, refer to Attachment no. 4.4.7 (2)

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.4.7 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.7 (1)

Emergency Preparedness and Resources

To: All Concerned Managers

Task no.:	Date:	Prepared by: Concerned Manager
1. Historical review of incidents	Ren	narks
Air pollution Water pollution Land pollution Noise pollution Nature of hazard Pollution time Transmissible May occur under extreme cone Lack of attention May occur under normal cond Nuisance potential People Business Historical Nature		
2. Key personnel responsible		
3. Emergency organization and re	sponsibilities	;
4. Emergency-handling procedure	2	
5. Material safety data sheet		
6. Training material and program		
7. Emergency drills (testing of effe	ectiveness)	
Reviewed by: (EMS Coordinator)	Signatur	e Date

SOP no.: EMS-4.4.7 Issue date: mm/dd/yyyy Revision no.: New

1 10... 1 VCVV

Attachment no. 4.4.7 (2)

Emergency Plan

To: All Concerned Managers

Emergency Type	Location	Responsibility	Reference Procedure	External Help	Key Telephone Number
ACTIVITY					
1)					
2)					
3)					
4)					
5)					
6)					
PRODUCT					
1)					
2)					
3)					
4)					
5)					
6)					
SERVICES					
1)					
2)					
3)					
4)					
5)					
6)					

Reviewed by:		
(EMS Coordinator)	Signature	Date

300.30-16

Checking and Corrective Action

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Checking and Corrective Action		SOP no.: EMS-4.5
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for checking and corrective action in accordance with clause 4.5 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

1. In the event of noncompliance, the effective, corrective, and preventative action are established and documented.

SUBJECT: Checking and Corrective Action		SOP no.: EMS-4.5
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 2. The noncompliance detected is extended for investigation and corrective action (as relevant)
 - Within the process
 - Within work operation/instructions
 - Via service reports
 - Via customer complaints
- 3. The major, minor, and critical defectives are identified and checked, which may adversely effect the environmental quality.
- 4. Measures are taken to prevent reoccurrence and documented.
- 5. All corrective action causes and resolutions are documented.
- 6. The corrective actions taken are recorded (as appropriate).
 - Documented evidence of individual occurrence
 - Minutes of management meetings
 - Changes to procedures (Reason for revision)
- 7. The records of product and system defects are analyzed to identify potential areas of non-conformance.
- 8. To eliminate potentate, nonconformance programs are developed and followed.
- 9. The changes to procedures and the results of preventive action are presented at management review meetings.

SUBJECT: Checking and Corrective Action		SOP no.: EMS-4.5
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Documentation

- 1. Checking and corrective action, refer to Attachment no. 4.5 (1)
- 2. Minutes of management reviews, refer to EMS procedure 4.6
- 3. Change control records, refer to Attachment no. 4.5 (2)

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.5

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.5 (1)

Checking and Corrective Action

To: Concerned Manager From: Responsible

1. Source	Details of Noncompliance
Activities	Major Minor Critical
Product	
Process	
Operational work	
Instructions	
Service report	
Customer complaint	
2. In-process control	
3. Preventive measure	
4. Corrective action program	
5. Change control approval	
11	
Concerned Manager	EMS Coordinator
6. Follow-up Audit	Ву:
Planned on:	Yes No
Close out:	10
Remarks:	
D : 11	
Reviewed by:	
(EMS Coordinator) Signatu	re Date

SOP no.: EMS-4.5

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.5 (2)

Change C	ontrol				
To: Conceri	ned Manager				
From:				Date:	
	Aspect		Pro	posed	
Element	Current Practice	Impact	Practice	Impact	Remarks
Activity					
Products					
Services					
	olicy revision:				
-	rget revision:				
Requires ch	Requires changes in program:				
Reviewed b (EMS Coor		Signatur	e	I	Date

300.30-17

Monitoring and Measurement

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Monitoring and Measurement		SOP no.: EMS-4.5.1
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by: Checked by:		Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for monitoring and measurement in accordance with clause 4.5.1 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

SUBJECT: Monitoring and Measurement		SOP no.: EMS-4.5.1
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Procedure

It is ensured to measure, monitor, and evaluate the environmental performance.

- 1. The organization has established, implemented, and maintained procedure(s) to monitor and measure key characteristics of operations of significant environmental impact (procedures shall include documentation of information to monitor performance; applicable operational controls and conformance to objectives and targets of the organization).
- 2. The system is in place for measuring and monitoring actual performance against the organizations environmental objectives and targets in the areas of management systems and operational processes. This includes evaluation of compliance with relevant environmental legislation and regulations. The results are analyzed and used to determine areas of success and to identify activities requiring corrective action and improvement.
- 3. The reliability of data is ensured by using calibrated instruments, test equipment, and software and hardware sampling and records are maintained.
- 4. Appropriate environmental performance indicators are identified for the organization as an ongoing process.
- 5. Such indicators are objective, verifiable, and reproducible.

SUBJECT: Monitoring and Measurement		SOP no.: EMS-4.5.1
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by: Checked by:		Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 6. They are relevant to the organizations activities, consistent with its environmental policy, practical, cost effective, and technologically feasible.
- 7. Key factors considered in measuring and monitoring are the following:
 - a. Regular monitoring of environmental performance
 - b. Establishment of specific environmental performance indicators to relate to the organizations objectives
 - c. Establish procedures to regularly calibrate the sample measuring and monitoring equipment and systems
 - d. Process to periodically evaluate compliance with relevant legal and other compliances

Documentation

1. Monitoring and measurement, refer to Attachment no. 4.5.1

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.5.1 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.1 (1)

Monitoring and Measurement

To: Concerned Manager From: Concerned Responsible

	Monitoring	Procedure				
Aspect	Frequency	no.	Indicator	Limit	Results	Remarks
Activity						
 Regulatory requests 						
Significant aspects						
Waste and scrap						
Use of energies						
Use of water						
Use of chemicals						
Emergency situation						
Emission to air						
Emission to water						
Noise level						
• Soil pollution						
Dust level						
Recycling						
Progress of program						
Product						
Regulatory requests						
Significant aspects						
Waste and scrap						
Use of energies						
Use of water						
Use of chemicals						
Emergency situation						
Emission to air						
Emission to water						
Noise level						
• Soil pollution						
Dust level						
Recycling						
Progress of program						
0 1 0						

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ılts Remarks

Reviewed by:		
(EMS Coordinator)	Signature	Date

300.30-18

Evaluation of Compliance

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Evaluation of Compliance		SOP no.: EMS-4.5.2
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for evaluation of compliance documentation in accordance with clause 4.5.2 of ISO 14001:2004 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system coordinator) is responsible for SOP compliance.

Procedure

Note: The departmental managers are responsible for the evaluation of compliance.

SUBJECT: Evaluation of Compliance		SOP no.: EMS-4.5.2
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 1. The company has established, maintained, and implemented procedures for monthly evaluation of compliance with applicable legal requirements.
- 2. The organization keeps records of the results of the periodic evaluations.
- 3. The organization evaluates compliance with other requirements to which it subscribes. The organization shall keep records of the results of the periodic evaluations.

Documentation

- 1. Critical documentation index, refer to Attachment no. 4.5.2 (1)
- 2. Evaluation records

Reasons for Revision

mm/dd/yyyy

(1) First time issued for (Your Company Name).

SOP no.: EMS-4.5.2 Issue date: mm/dd/yyyy Revision no.: New

nevision no.. i vew

Attachment no. 4.5.2 (1)

Critical Documents Index

Key Procedures	Responsibility (Departmental Manager)
Environmental policy Identifying environmental aspects Setting environmental objectives Description of the scope of the EMS Environmental programs Retention of training records Internal and external communication Processing instructions Emergency control Regulatory compliance Monitoring Nonconform investigation Change control Corrective action and preventive measures Calibration	
 Environmental monitoring records Auditing Management review Complaints Interested parties 	

Reviewed by:		
(EMS Coordinator)	Signature	Date

300.30-19

Nonconformity, Corrective Action, and Preventive Action

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Nonconformity, Correct Action	SOP no.: EMS-4.5.3	
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for nonconformity, corrective action, and preventive action in accordance with clause 4.5.2 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

SUBJECT: Nonconformity, Corrective Action, and Preventive Action		SOP no.: EMS-4.5.3
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Procedure

- The findings, conclusions, and recommendations reached as a result of measuring, monitoring, audits, and other reviews of the environmental management system are documented, and the necessary corrective and preventive actions are identified. The management ensures that these corrective and preventive actions have been implemented and that there is a systematic follow-up to ensure their effectiveness.
- 2. The organization has established, implemented, and maintained procedure(s) for dealing with actual and potential non-conformity(ies) and for taking corrective action and preventive action. The procedure(s) define requirements for
 - a. Identifying and correcting nonconformity(ies) and taking action(s) to mitigate their environmental impacts
 - b. Investigating nonconformity(ies), determining their cause(s), and taking actions in order to avoid their recurrence
 - Evaluating the need for action(s) to prevent nonconformity(ies) and implementing appropriate actions designed to avoid their occurrence
 - d. Recording the results of corrective action(s) and preventive action(s) taken
 - e. Reviewing the effectiveness of corrective action(s) and preventinve action(s) taken

Actions taken are appropriate to the magnitude of the problems and the environmental impacts encoutered.

SUBJECT: Nonconformity, Corrective Action, and Preventive Action		SOP no.: EMS-4.5.3
Distributed to: Based on: EN ISO 14001:2004		Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

The organization ensures that any necessary changes made to the environmental management system are documented.

Documentation

1. Nonconformance and corrective action report, refer to Attachment no. 4.5.3 (1)

Reasons for Revision

mm/dd/yyyy (1) First time issued for (Your Company Name).

SOP no.: EMS-4.5.3 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.3 (1)

To:	nd Corrective Action Rep	n:
Department:	Name:	
Deviation:		
Sent to:	Date:	
Corrective action:		
Date	: Name:	
Follow-up:		
Date	: Name:	
Reviewed by: (EMS Coordinator)		Date

300.30-20

Control of Records

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Control of Records		SOP no.: EMS-4.5.4
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for control of records in accordance with clause 4.5.4 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

SUBJECT: Control of Records	SOP no.: EMS-4.5.4	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Procedure

- Records are evidences of the ongoing operation of the EMS and cover, for example, the need for records is required only where to demonstrate conformity with requirements of EMS and of the standard.
 - · Legislative and regulatory requirements
 - Permits
 - Environmental aspects and their associated impacts
 - Environmental training activity
 - Inspection, calibration and maintenance activity
 - Monitoring data
 - Details of nonconformance: incidents, complaints, and followup action
 - Product identification composition and properly data
 - Supplier and contractor information
 - · Environmental audits and management reviews
- The management of documents includes means of identification, collection, indexing, filing, storage, protection, maintenance, retrieval, retention, and disposition of pertinent EMS documentation and records.
- 3. Following are the key elements of EMS records and information management:

SUBJECT: Control of Records	SOP no.: EMS-4.5.4	
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- a. What environmental information does the organization need to manage effectively
- b. What capability does the organization have to identify and track key indicators of performance and other data necessary to achieve its objectives
- c. How does the organizations record/information management system make information available to the employees who need it when they need it?
- 4. It is ensured that in the event of accident, the environmental records are retrievable. The copy of all records are kept by concerned responsible at a separate location.

Documentation

1. EMS record, refer to Attachment no. 4.5.4 (1)

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.5.4 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.4 (1)

EMS Record

Prepared by:

To: Concerned Responsible

Source	Records	Shelf-life	Responsibility	Location
Activity	Regulatory Legislation Permits Training Aspects/Impact Program Monitoring data Nonconformity(ies) Emergencies Manufacturing Customer Feedback EMS audit Management review			
Product	Regulatory Legislation Permits Training Aspects/Impact Program Monitoring data Nonconformity(ies) Emergencies Manufacturing Customer Feedback EMS audit Management review			

Source	Records	Shelf-life	Responsibility	Location
Services	Regulatory			
	Legislation			
	Permits			
	Training			
	Aspects/Impact			
	Program			
	Monitoring data			
	Nonconformity(ies)			
	Emergencies			
	Manufacturing			
	Customer			
	Feedback			
	EMS audit			
	Management review			

Reviewed by:		
(EMS Coordinator)	Signature	Date

300.30-21

Internal Audit

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Internal Audit	SOP no.: EMS-4.5.5	
Distributed to:	Distributed to: Based on: EN ISO 14001:2004	
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for internal audit in accordance with clause 4.5.5 of ISO 14001:2004 standard and local regulatory requirements.

Responsibility

The responsibility of all departmental managers or supervisors is to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

Procedure

- 1. Audits of the EMS are conducted on a periodic basis (every three months) to determine whether the system conforms to planned arrangements and has been properly implemented and maintained.
- 2. Audits of the EMS are carried out by organization personnel, and/ or by external parties selected by the organization. In any case, the person(s) conducting the audit is(are) in a position to do so objectively and impartially and should be properly trained.

SUBJECT: Internal Audit	SOP no.: EMS-4.5.5	
Distributed to:	Distributed to: Based on:	
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 3. The frequency of audits is guided by the nature of the operation in terms of its environmental aspects and potential impacts. Also, the results of previous audits are considered in determining frequency.
- 4. The EMS audit report is submitted in accordance with the audit plan.
- 5. The audits are conducted to determine
 - a) Conformance to planned arrangements for environmental management including the requirements of this International Standard.
 - b) EMS has been properly implemented and is maintained.
 - c) Provide information on the results of audits to management.

Documentation

- 1. General audit check list, refer to Attachment no. 4.5.5 (1)
- 2. Revision form (SOPs), refer to Attachment no. 4.5.5 (2)
- 3. Audit checklists prepared based on the SOPs (prepare the list based on your own documents)
- 4. EMS system audit program, refer to Attachments no. 4.5.5 (3)
- 5. General audit checklist based on 2nd edition ISO 14001:2004 requirement to perform gap analysis 4.5.5 (4)

Reasons for Revision

mm/dd/yyyy 1. First time issued for (Your Company Name).

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.5 (1)

Environmental Management System Audit Check List (General)

4.2 Policy	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there an environmental policy defining appropriateness; continual improvement, and public awareness on significant aspects affecting the environment.					
Is there a system for policy review based on Documentation Implementation Maintenance, and Communication					
3. Is the policy statement signed off by the management responsible.					
4.3.1 Aspects/Impacts/Effects	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Environmental objectives are set on the basis of aspects/impacts/effects analysis?					
Is there a procedure describing aspects/impacts/ effects analysis?					
3. The aspects/impacts/effects analysis carried out is documented.					
Procedures used to identify environmental aspects/ impacts are maintained updated.					

continued

4.3.2 Legal and Other Requirements	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure describing access to the legal and other requirements applicable to the environmental aspects of the company's Activities Products Services					
4.3.3 Objectives and Targets	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Are the objectives and targets consistent with environmental policy?					
Are the objectives and targets consistent with commitment to prevention of pollution?					
3. The communication (both internal and external) regarding environmental policy is • Maintained • Documented					
4.3.4 Environmental Management Program	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there an established documented environmental program?					
Is there a manual stating environmental policy, objectives, and targets?					
3. Is the control and distribution of the environmental management program satisfactory?					
Are resources, responsibilities and designations stated in the environmental management program?					
5. Is there a time frame described in the environmental management program to achieve objectives and targets?					

Internal Audit 241

4.4.2 Training Awareness, Competency, and Communication	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure identifying training needs applicable to the functions of significant impacts within the company?					
2. Are personnel adequately trained for the functions that they perform?					
3. Is there an in-house training program?					
4. Is there an external course attendance program?					
5. Are training needs effectively identified?					
6. Are records of training maintained for each employee?					
7. Are required levels of qualifications and experience defined for environmental activities?					
Are the internal and external communications regarding environmental policy maintained and documented?					
4.4.6 Operational Control	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure to identify and document the operations and procedures related to suppliers and contractors as they impact environmental policy?					
Is there a procedure to ensure that the contractors are aware of company's EMS requirement?					
Is there an established documented purchasing system?					
Are these procedures ensuring that purchased product conforms to the specified environmental standard?					
5. Is there a system for evaluation of suppliers and subcontractors?					continued

6. Is there a documented procedure for the audit of suppliers and subcontractors? 7. Is there an approved list of suppliers effecting the environmental policy? 8. Are purchased materials listed by some class or grade? 9. Is there a system to check					
purchased products against purchase order?					
10. Does order identify number and quality of material?					
Is there a procedure for verification of sub contractors products for environmental compliance?					
4.4.7 Emergency Preparedness and Response	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Do the work instructions/ procedure explain safety precautions during the specific activity?					
2. Are the employees trained to follow safety precautions at work?					
3. Are the emergency-handling procedures reviewed, revised, and updated? Output Description:					
3. Are the emergency-handling procedures reviewed, revised,					
Are the emergency-handling procedures reviewed, revised, and updated? 4. Are the emergency procedures tested (where					
3. Are the emergency-handling procedures reviewed, revised, and updated? 4. Are the emergency procedures tested (where practical) by simulation? 5. Is there an emergency/					
3. Are the emergency-handling procedures reviewed, revised, and updated? 4. Are the emergency procedures tested (where practical) by simulation? 5. Is there an emergency/accident reporting system? 6. Is there a procedure to identify aspects and impacts					

Internal Audit 243

4.5.1 Monitoring and Measurement	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Are there the procedures to identify the key operations impacting environment?					
Are the evaluation procedures described to ensure compliance with legislation and regulations?					
3. Are the evaluation records maintained?					
4.5.2 Nonconformance, Corrective, and Preventive Actions	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure to define responsibility to handle nonconformance followed by corrective action and preventive measures?					
Does the system make provision for the identification and segregation of non conforming items pending disposition?					
Is there a procedure of raising non conformance reports and notifying relevant personnel customers in a timely manner?					
4. Is there a procedure for promptly implementing the agreed remedial action?					
5. Is a provision made for review and approval of documents applicable to rework on non conforming products?					
6. Does the system ensure retainment of records of corrective actions taken?					
7. Does the system allow notifications to legislative authorities?					
8. Is there a procedure to describe corrective actions and preventive measures?					

continued

4.5.2 Nonconformance, Corrective, and Preventive Actions	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
9. Does the system allow investigation and correction of noncompliance detected • Within the process • Product • Services • Within work operations/ Instructions • Customer complaints					
10. Are CA Causes and resolutions recorded?					
11. Are findings on nonconformance prescribed for management review?					
4.5.4 EMS Audit	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure describing EMS audit Frequency Based on identified activities					
Does the procedure ensure determining conformity, implementation, and maintenance of the EMS.					
3. Does the procedure indicate to inform the results to the management?					
Does the procedure describe the appropriate experience and qualification of the external auditors?					
4.6 Management Review	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Does the procedure exist and describe periodical review of EMS?					
Does the procedure ensure to determine effectiveness and adequacy of the EMS.					
3. Does the procedure ensure changes in the existing EMS based on the changes?					

Internal Audit 245

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.5 (2)

Revision Form

DEPARTMENT:		PROCEDURE NO.:						
FROM:		TO:						
TITLE:		CC:						
DATE:								
Internal	External Audit	Customer complaint	Supplier					
(1) Statement of the problem:								
(2) Root cause of the problem:								
(3) Solution:								
(4) Solution implementation of the action plan:								
(5) Monitor dates/actions required by others:								
Date: Signature:								

Please attach additional pages if necessary

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.5 (3)

EMS System Audit Program

Copy to: Concerned Manager

Scope	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.	Departments	Auditor
General and policy	Х													
Aspects, legal, program		Х												
Structure, responsibility			Х											
Communication				х										
Documentation, document control					Х									
Operational control, emergencies						Х								
Monitoring							Х							
Corrective actions, records								Х						
Audit, review									Х					

Prepared by:		_
	Signature	Date
Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.5 (4)

Checklist ISO 14001:2004

(November 2004)

Overall Documentation Requirements	Reference SOPs	Reference Document	Reference Record	Remarks/ Observations	Completion Date
Perform documentation review and ensure that the following documents are available as required specifically by the standard: (a) Documented information on environmental aspects and impacts evaluation (b) Records of identified applicable environmental legal requirements and document(s) showing applicability to its environmental aspects (c) Documented policy, objectives, and targets and programs (d) Documented roles, responsibilities and authorities (e) Records on competence and performed training of own employees and of relevant personnel working on its behalf, for example contractors. Records of emergency preparedness training and tests (if applicable) (f) Documented communications from and with external interested parties, at least complaint records (g) Documented procedures for operations and activities that	SOPs	Document	Record	Observations	Date
may cause significant environmental impacts					

continued

(h) Documenting of information to monitor performance, applicable operational controls, and conformity with objectives and targets. Records to track calibration and maintenance of monitoring and measurement equipment (i) Documented changes resulting from corrective and preventive action (including incident reports) (j) Documenting evaluation of compliance with environmental legal requirements and other applicable environmental requirements to which your organization subscribes (k) Documented internal audit programs and records from audits					
(l) Records from management review					
Changes (referred to clause in stand	ard):		1	I	
Overall Documentation Requirements	Reference SOPs	Reference Document	Reference Record	Remarks/ Observations	Completion Date
3. Definitions Seven new terms are included, primarily for harmonization and compatibility with ISO 9001:2000 (these are audit, document, procedure, record, nonconformity corrective action, and preventive action).					
4.1 General Requirements More explicit on 1. The need to demonstrate continual improvement of the EMS. 2. The need for the organizations to clearly define the scope of the EMS.					
4.2 Environmental Policy More explicit regarding communication of policy to persons working on its behalf, not only to employees as in 1996 edition. (Communication to "external"					

Internal Audit 249

4.3.1 Environmental Aspects				
More explicit on				
Inclusion of planned or new				
developments and new or				
modified activities, products,				
and services within the aspects				
process (this was formerly under				
clause 4.3.4).				
2. Clear requirement for the				
information from the aspect				
process to be documented.				
3. Significant aspects shall be				
considered when establishing				
and maintaining/developing the				
EMS in general and as a basis to				
set the environmental objectives.				
,				
4.3.2 Legal and Other Requirements More explicit on				
Determining the applicability of				
legal/other requirements to an				
organization's environmental				
1 0				
aspects.				
2. Ensuring that environmental,				
legal, and other environmental				
requirements to which the				
organization subscribes are				
considered in developing,				
implementing, and maintaining				
the EMS.				
4.3.3 Objectives, Targets, and				
Program(s)				
Changes are				
1. More explicit to address that				
objectives and targets shall be				
consistent with commitment to				
continual improvement (also for				
environmental performance).				
2. Text under former clause 4.3.4				
on programs has been merged				
into this clause.				
4.4.2 Competence, Training, and				
Awareness				
The new version is more explicit,				
requiring procedure for awareness				
"training" also for relevant persons				
working on behalf of the				
organization, which could include				
contractors, temporary staff, etc.,				
and not only own employees or				
members as specified in the 1996				
version. (Communication of				
environmental policy (ref. 4.2) to			1	

"external" persons can, as stated in Annex A2 in the standard, be in alternative forms to the policy statement itself, such as rules, directives, and procedures covering pertinent sections of the policy)			
4.4.3 Communication The new version states that the organization shall establish (a) method(s) for external communication about its significant aspects if it is decided to communicate			
4.4.4 Documentation The new version is more detailed in defining the documentation needed to be included in an EMS. The scope of the EMS shall be described in the system documentation			
4.4.5 Control of Documents Changes are 1. Closer alignment to ISO 9001:2000 in terms of content and clausal structure 2. More explicit requirement to control documents of external origin 3. The term "document" is now clearly defined and is the same as for ISO 9001:2000			
4.5.1 Monitoring and Measurements The new version no longer requires a "documented procedure," but note that the clause requires procedure(s) that includes the documenting of information required to monitor performance, applicable operational controls, and conformity with objectives and targets.			
4.5.2 Evaluation of Compliance New clause partly covered by 4.5.1 in 1996-edition. Requires evaluation of compliance for both legal environmental requirements and other requirements to which an organization subscribes. There is no requirement for a documented procedure, but it is required to keep records of the evaluation(s)			

Internal Audit 251

The changes made imply that this issue has been given more emphasis			
4.5.3 Nonconformity, Corrective Action, and Preventive Action This clause has been reworded for clarity. A new version more clearly requires • Investigation and determination of causes related to actual non conformities to avoid their recurrence, • Procedure for evaluating need for action(s) to prevent occurrence of potential nonconformities, • Records of the results of corrective and/or preventive actions taken, and • Review of the effectiveness of the actions taken.			
4.5.4 Control of Records The new version also makes a more general requirement for the establishment and maintenance of any records required "to demonstrate conformity to the requirements of its EMS and of this International Standard".			
4.5.5 Internal Audit This clause has been reworded for clarity, but also note that Annex A refers to the standard ISO 19011:2002 for guidance.			
4.6 Management Review The new version has been harmonized with ISO 9001:2000, with a more detailed list of agenda/content for management review. The input to the management review shall include a) Results of internal audits and evaluations of compliance with legal requirements and with other requirements to which the organization subscribes; b) Communication(s) from external interested parties, including complaints; c) The environmental performance of the organization;			

d)	The extent to which objectives and targets have been met;			
e)	Status of corrective and			
	preventive actions;			
f)	Follow-up actions from			
	previous management reviews;			
g)	Changing circumstances			
	including developments in			
	legal and other requirements			
	related to its environmental			
	aspects; and			
h)	Recommendations for			
	improvement.			

300.30-22

Management Review

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Management Review		SOP no.: EMS-4.6
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Purpose

To describe the procedure for management review in accordance with clause 4.6 of ISO 14001 standard.

Responsibility

This is the responsibility of all departmental managers or supervisors to understand and implement general requirements described in the procedure. The ISO 14001:2004 systems coordinator (environmental management system controller) is responsible for SOP compliance.

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Management Review		SOP no.: EMS-4.6
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

Procedure

- 1. A continual improvement process is applied to an environmental management system to achieve overall improvement in environmental performance.
- 2. The organizations management at appropriate intervals (6 months) conducts a review of the EMS to ensure its continuing suitability and effectiveness.
- 3. The review of the EMS is broad enough in scope to address the environmental dimensions of all activities, products, or services of the organization, including their impact on financial performance and possibly competitive position.
- 4. The review of the EMS includes, but not limited to,
 - Results of internal audits and evaluations of compliance legal requirements and with other requirements to which the organization subscribes
 - b) Communication(s) from external interested parties, including complaints
 - c) The environmental performance of the organization
 - d) The extent to which objectives and targets have been met
 - e) Status of corrective and preventive actions
 - f) Follow-up actions from previous management reviews
 - g) Changing circumstances, including developments in legal and other requirements related to its environmental aspects
 - h) Recommendations for improvement

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Management Review		SOP no.: EMS-4.6
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 5. The outputs from management review includes any decisions and actions related to possible changes to environmental policy, objectives, targets, and other elements of the environmental management system, consistent with the commitment to continual improvement.
- 6. Key documents considered in the review of EMS
 - a. Periodical review of EMS
 - b. Appropriate involvement of employees in the review of the EMS and follow-up
 - c. Incorporation of interested parties views into the EMS review
- 7. The concept of continual improvement is embodied in the EMS. It is achieved by continually evaluating the environmental performance of the EMS against its environmental policies, objectives and targets for the purpose of identifying opportunities for improvement.
- 8. The continual improvement process is extended to
 - Identify areas of opportunity for improvement of the environmental management system, which lead to improved environmental performance
 - Determine the root cause or causes of nonconformances or deficiencies
 - Develop and implement (a) plan(s) of corrective and preventive action to address root cause(s)
 - Verify the effectiveness of the corrective and preventive actions
 - Document any changes in procedures resulting from process improvement
 - Make comparisons with objectives and targets

STANDARD OPERATING PROCEDURE YOUR COMPANY NAME HERE

SUBJECT: Management Review		SOP no.: EMS-4.6
Distributed to:	Based on: EN ISO 14001:2004	Revision no.: New
Written by:	Checked by:	Approved by:
Date supersedes: mm/dd/yyyy	Date issued: mm/dd/yyyy	Page: XXX

- 9. Key elements considered in corrective and preventive action and continual improvement are the following:
 - a. Identification of the process for corrective and preventive action and improvement
 - b. Verification by the organization that corrective and preventive actions and improvements are effective and timely

Documentation

1. Management review minutes, refer to Attachment no. 4.6 (1)

Reasons for Revision

mm/dd/yyyy (1) First time issued for (Your Company Name)

SOP no.: EMS-4.6

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.6 (1)

Management Review l	Form	
PARTICIPANTS:		DATE:
A. Inputs to the review of Audit summaries Changes in viewp Results of any personal Monitoring summ Summary of comm Summary of report Proposals for new B. The review should ai Is the EMS satisfact Is it meeting comp Dis we meet our of Did we achieve regord What changes do we Do our objectives tious? Less ambition	could include the fol- coints and opinions of formance improvementaries showing compliants to regulators or changed objective im to answer these quotory? If not, what never the construction of the country of the country of the country? If not answer these quotory? If not, why gulatory compliance we need to be broader? ous?	lowing: If interested parties ent projects liance results ng performance es uestions: eds to be done? If not, why not? Narrower? More ambi-
Remarks by:		
Reviewed by: (EMS Coordinator)	Signature	 Date

Signature

300.40-1

Examples of Environmental Policy Statements

This section is exclusively written to provide examples of EMS programs which can be directly applied by any process-related industry or by an organization for the successful implementation and development of environmental management systems and programs. The examples include policy statement, objective, targets, and the actions required. The examples quoted can be modified according to the individual company's requirements.

The management has defined the organization environmental policy and has ensured that it includes a commitment to continuous improvement and prevention of pollution is appropriate to the nature, scale, and environmental impacts of its activities, products, or services. Includes a commitment to comply with relevant environmental legislation and regulations, and with other requirements to which the organization is associated, which provides the framework for setting and reviewing environmental objectives and targets.

The Environmental Management System (EMS) is documented, implemented, maintained, and communicated to all employees and is available to the public for information.

The environmental policy recognizes all activities, products, or services causing impacts on the environment. The (Your Company Name) is committed to:

Environmental Policy

The Environmental Management System (EMS) is documented, implemented, maintained, and communicated to all employees and is available to the public for information.

The environmental policy recognizes all activities, products, or services causing impacts on the environment.

1. Minimize any significant adverse environmental impact of new developments through the use of the integrated environmental management procedures and planning.

- Development of environmental performance evaluation procedures and associated indicators.
- 3. Embody life cycle thinking.
- 4. Design products in such a way to minimize their environmental impacts in production, use, and disposal.
- 5. Sharing environmental experience.
- 6. Work toward sustainable development.
- 7. Encourage the use of EMS by suppliers and contractors.
- 8. Comply with and follow up on the requirements of relevant laws and standards for environmental protection.
- Choose raw materials, materials and processes with small negative environmental impact, to economize with resources and to decrease emissions and waste amounts.
- 10. Perform environmental assessments when a process is changed.
- 11. Have an open dialogue on environmental issues with our staff, customers, suppliers, and other stakeholders.
- 12. Follow up on and set new targets for our environmental work on a regular basis to ensure a continuous decrease in environmental impacts.
- 13. Will develop manufacturing processes with minimum environmental impact, particularly the production.
- 14. Will educate, train, and motivate our employees to carry out their tasks in an environmentally responsible manner.
- 15. Will periodically conduct environmental audits in order to continually improve our environmental performance.
- 16. Will establish environmental management system to keep us informed about the impact of all our operations, allowing us to achieve the most effective and cost-efficient improvements in performance.
- 17. We are committed to publishing targets for continual improvement in performance, and will work toward these with annual action plans.
- 18. Will reduce the impact of our transport operations by maximizing the efficiency of our routes and vehicles, reviewing our selection of fuels and vehicles, and thinking flexible about delivery methods.
- 19. Will consider the environmental impacts of our suppliers, alongside quality and cost. We will set environmental standards for our suppliers, and work with them to achieve these standards.

- 20. Will reduce the amount of waste resulted from our operations. We will minimize use of materials, design, and modify operations to minimize waste production, use materials longer where practicable.
- 21. Conserve natural resources of water where technically and practically possible.
- 22. Will reduce the amount of waste and will always investigate recycling opportunities for used materials.
- 23. Will seek to reduce the consumption of ozone-depleting substances (ODSs) where possible.
- 24. Will adopt means and ways to manage the disposal of hazardous substances and minimize their consumption where possible.
- 25. Will seek to reduce electrical consumption and improve energy efficiency where possible.

The legal responsibility for the environmental impact of the operations lies with the managing director, directors, each departmental manager, and staff are responsible with his/her scope of operation for the implementation of the environmental system.

Approved by:	
	Managing Director

300.50*-*1

Examples of Objectives, Targets, and EMS Programs

Policy no. 1A

Environmental Management System Program

POLICY No. 1A : Minimize any significant adverse environmental impact of new

developments through the use of integrated environmental

management procedures and planning

OBJECTIVE : Review, develop, and implement ISO 14001:2004 Environmental

Management System

TARGET : Achieve certification by December 2000

PROGRAM : Pollution prevention and continuous improvement

Actions

Recommendation

- Seek approval from the Managing Director to initiate the work on ISO 14001:2004 EMS.
- Identify key persons.
- Identify Environmental Management System (EMS) coordinator.
- Resource workshop on ISO 14001:2004.
- Conduct staff training on elements of ISO 14001:2004 standard and implementation.
- Follow Management Review/Review Local Legislation.
- Identify aspects of significant impacts on environment.
- Refer enclosed schedule.
- Achieve Certification.

Responsibility:	
1 5	
Signature/Date:	

Policy no. 2A

Environmental Management System Program

POLICY No. 2A Development of environmental performance evaluation

procedures and associated indicators

OBJECTIVE Establish the aspects of immediate and significant environmental

concern and establish procedures for monitoring

TARGET Write system procedures and implement them by July 2000 PROGRAM

The Environmental Management System Documentation

Development

- Write Environmental Management System (EMS) manual.
- Write procedures based on ISO 14001 standard.
- Identify environmental performance indicator to monitor the progress.

Responsibility:		
-		
Signature/Date:		

Policy no. 3A

Environmental Management System Program

POLICY No. 3A : Embody life cycle thinking

OBJECTIVE : Achieve recycling approach 100% of the present level by year 2004

TARGET : Optimize use of recycle products

25% in year 2001 25% in year 2002 25% in year 2003 25% in year 2004

PROGRAM : Recycling

Action

 Rubbish collected for recycling can be taken to a municipality recycling center. Cardboard, paper, plastic bags/bottles/cups, glass, and aluminum cans can be recycled.

Responsibility:	
1 3	
Signature/Date:	

Policy no. 4A

Environmental Management System Program

POLICY No. 4A : Design products in such a way to minimize their environmental

impacts in production, use, and disposal

OBJECTIVE : Pollution prevention where possible

TARGET : Continuous basis effective July 2000 and onwards **PROGRAM** : New Product Development and Associated Activities

- Ensure materials segregation.
- · Provide instruction for materials and equipment handling.
- Use closed equipment for processing.
- Provide adequate extraction (ventilation) system in rooms.
- Provide staff adequate protective clothing.
- Develop cleaning procedure.
- Maintain calibration program.
- Introduce cleaning in place system in production.
- Maintain pressure inside the rooms as per procedures.
- Regulate waste disposal as per company's procedures.
- Resource material safety data sheets.
- Training staff on environmental awareness.
- Conduct emergency handling workshops.

Responsibility:	
Signature/Date:	

Policy no. 5A

Environmental Management System Program

POLICY No. 5A : Sharing environmental experience

OBJECTIVE : To induce pollution prevention, learn best technology available,

practical commercially feasible

TARGET : Effective July 2000 on continuous basis. Embody life cycle thinking

in new projects. Share experience at least once in a year from the

year 2001

PROGRAM : Continuing Education

- Attend IRCA or EARA registered courses.
- Join professional organizations.
- Subscribe to journals or obtain information through Internet.
- Publish articles in journals.
- Communicate to interested parties.
- Give presentations in conferences and forums.

Responsibility:	
Signature/Date:	

Policy no. 6A

Environmental Management System Program

POLICY No. 6A : Work toward sustainable development

OBJECTIVE : Pollution Prevention and Counts Improvement

TARGET : Effective July 2000 **PROGRAM** : Life Cycle Thinking

- Educate and train employees.
- Communicate with interested parties.
- Adopt best technology available to prevent pollution where possible.
- Review product life cycle.

Responsibility:	
•	
Signature/Date:	

Policy no. 7A

Environmental Management System Program

POLICY No. 7A : Encourage the use of EMS by suppliers and contractors

OBJECTIVE : To induce and optimize environmental compliance and pollution

prevention globally among our suppliers

TARGET : Prevent Environmental pollution

10% in year 2000 (vendors) 20% in year 2001 (vendors) 30% in year 2002 (vendors) 40% in year 2003 (vendors)

PROGRAM : Suppliers Awareness Program

Actions

Recommendations

- Create a company environmental policy and request suppliers/ contractors and others to comply with the requirements of this policy.
- Create a questionnaire for the supplier to motivate environmental compliance thinking.

Responsibility:	
Signature/Date:	

Policy no. 7B

Environmental Management System Program

POLICY No. 7B : Encourage the use of EMS by suppliers and contractors

OBJECTIVE : To induce and optimize environmental compliance and pollution

prevention globally among our suppliers

TARGET : Prevent Environmental pollution

10% in year 2000 (vendors) 20% in year 2001 (vendors) 30% in year 2002 (vendors) 40% in year 2003 (vendors)

PROGRAM : Suppliers Awareness Program

Action

Follow-up with suppliers to provide material safety data sheet for each material considered to be significant environmental impact.

Responsibility:		
F J ·		
Signatura/Data:		

Policy no. 8A

Environmental Management System Program

POLICY No. 8A : Comply with and follow-up on the requirements of relevant laws

and standards for environmental protection

OBJECTIVE : To be in compliance with local environmental legislation

TARGET : Develop and implement the program effective July 2000 and work

on continuous basis. Achieve compliance to local legislation by

year 2005

PROGRAM : Legislation Compliance

- Obtain local legislation applicable, if any.
- Obtain legislation applicable in other states.
- Develop standard for the company.

Responsibility:	
Signature/Date:	

Policy no. 9A

Environmental Management System Program

POLICY No. 9A : Choose raw materials, materials and processes with small negative environmental impact, to economize with resources and to decrease emissions and waste amount

OBJECTIVE : To prevent the environmental pollution by managing our processes associated activities and services

: Evaluate the process, activities, and services associated risk by

year 2001 and initiate corrective action by year 2003

PROGRAM : Products/Activities and Services Optimization

Actions

TARGET

- Review process flow for each dosage form and evaluate the risks involved.
- Initiate corrective actions both short term and long term wherever necessary.

Responsibility:	
Signature/Date:	

Policy no. 9B

Environmental Management System Program

POLICY No. 9B : Choose raw materials, materials and processes with small negative

environmental impact, to economize with resources and to

decrease emissions and waste amounts

OBJECTIVE : Pollution Prevention

TARGET : Effective July 2000 and on continuous basis

PROGRAM : Induce Life Cycle Thinking

Action

• Resource materials from the environmental-friendly sources where possible.

Responsibility: $__$		
1 3		
Signature/Date:		

Policy no. 10A

Environmental Management System Program

POLICY No. 10A : Perform environmental assessments when a process is

changed

OBJECTIVE : Pollution Prevention

TARGET: Effective July 2000, the projects commencing from year 2001

shall be reviewed for environmental compliance

PROGRAM : Continuous Improvement

- Review if the process changes are made with a particulate reference to the environment.
- Review processes introduced for the first time.
- Make necessary change in process change SOP.

Responsibility:	
Signature/Date:	
Digitalate Date.	

Policy no. 11A

Environmental Management System Program

POLICY No. 11A : Have an open dialogue on environmental issues with our

staff, customers, suppliers, and other stockholders

OBJECTIVE : Encourage use of EMS

TARGET : Publish at least one report per year, effective year 2001

PROGRAM : Pollution Prevention

Action

	•	
Responsibility:		
Signature/Date:		

• Publish environmental trend reports for information.

Policy no. 12A

Environmental Management System Program

POLICY No. 12A : Follow-up on and set new targets for our environmental

work on a regular basis to ensure a continuous decrease

in environmental impacts

OBJECTIVE : To continuously reduce the amount of waste resulted from

our operations

TARGET : Reduce waste generation

25% in year 2001 (Maintenance) 25% in year 2003 (Maintenance) 50% in year 2003 (Wash Rooms)

PROGRAM : Miscellaneous Waste Management

Action

Recommendation

 Environmental-friendly batteries that do not contain heavy metals such as mercury, cadmium, or lead (which cause air pollution when burned in a refuse incinerator) are widely available.

Responsibility:	
-	
Signature/Date:	

Policy no. 12B

Environmental Management System Program

POLICY No. 12B : Follow-up on and set new targets for our environmental

work on a regular basis to ensure a continuous decrease

in environmental impacts

OBJECTIVE : Work toward sustainable development
TARGET : Conduct four Management Reviews per year

PROGRAM : Life Cycle Thinking

 Conduct management review on a quarterly basis. 	
Responsibility:	
Signature/Date:	

Policy no. 13A

Environmental Management System Program

POLICY No. 13A : Will develop manufacturing processes with minimum

environmental impact, particularly the production

 $\begin{tabular}{ll} \textbf{OBJECTIVE} & : & Prevent environmental pollution through process optimization \\ \end{tabular}$

TARGET : All processes review for environmental compliance

10%—2001 20%—2002 30%—2003 50%—2004 75%—2005 100%—2006

All new processes to be reviewed effective from October 2000

PROGRAM : Process Review

- Prepare a checklist to avoid or minimize the environmental pollution through manufacturing processes.
- Review all processes.
- Review new processes before implementation.

Responsibility:	
Signature/Date:	
Digital arci Date	

Policy no. 14A

Environmental Management System Program

POLICY No. 14A : Company will educate, train, and motivate its employees to carry

out their tasks in an environmentally responsible manner

 $\begin{tabular}{lll} \textbf{OBJECTIVE} & : & \textbf{To economize with resource and to decrease emissions and waste} \\ \end{tabular}$

amounts

TARGET : Do not purchase new files, but relabel old files

25% in year 2001 50% in year 2002 100% in year 2003

PROGRAM : Stationery and Office Supplies Optimization

Actions

Environmental issues for paper are numerous and include:

- Loss of natural habitats to environmentally damaging intensive tree farming
- Pollution during manufacture (e.g., bleaching agents, effluent, optical brightening agents (OBA), etc.)
- Energy usage
- Waste disposal: landfill and incineration

Recommendations

Most stationery retailers stock a range of products labeled "environmentally friendly." However, it is important to establish the criteria for this label, as some supplier's labeling systems are misleading. If purchasing "environmentally friendly" items, company should obtain accurate, detailed information.

Responsibility:	
Signature/Date:	

Policy no. 14B

Environmental Management System Program

POLICY No. 14B : Company will educate, train, and motivate its employees to

carry out their tasks in an environmentally responsible manner

OBJECTIVE : To economize with resource and to decrease emissions and

waste amounts

TARGET : Do not purchase new files, made from nonrecycled materials

100% in year 2002

PROGRAM : Stationery and Office Supplies Optimization

Action

• Most stationery companies will source specific products on your behalf if they do not already stock them.

Responsibility:	
Signature/Date:	

Policy no. 14C

Environmental Management System Program

POLICY No. 14C	:	Company will educate, train, and	id motivate its employees to o	carry
		out their tasks in an environmen	entally responsible manner	

OBJECTIVE : To economize with resource and to decrease emissions and

wasta amounts

waste amounts

TARGET : Purchase stationery from environmental-friendly source

50% in year 2001 50% in year 2002

PROGRAM : Stationery and Office Supplies Optimization

 Use specialist suppliers where possible. 	

Responsibility:	
1	
Signature/Date:	

Policy no. 14D

Environmental Management System Program

POLICY No. 14D : Company will educate, train, and motivate its employees to

carry out their tasks in an environmentally responsible manner

OBJECTIVE : To economize with resource and to decrease emissions and waste

amounts

TARGET : Induce computer-based communication technical and

nontechnical

50% in year 2002 (Technical) 50% in year 2003 (Nontechnical)

PROGRAM : Stationery and Office Supplies Optimization

Action

 An IT-based requisition procedure could be used to save time and paperwork. Links with stationery suppliers are becoming increasingly sophisticated with technological developments and there are a number of systems used [electronic data interchange (EDI), for example]. Organizations could have a direct computer link with the supplier. Suppliers can also give you detailed printouts for improved control.

Responsibility:		
1 5		
Signature/Date:		

Policy no. 14E

Environmental Management System Program

POLICY No. 14E	 Company will educate, train, and motivate its employees to carry out their tasks in an environmentally responsible manner
OBJECTIVE	: To economize with resource and to decrease emissions and waste amounts
TARGET	: Purchase recycled secondary packaging materials 100% in year 2004
PROGRAM	: Secondary packaging material optimization
	10% in year 2001
	20% in year 2002
	20% in year 2003
	20% in year 2004
	30% in year 2004

Action

• Filing products made from recycled products and board include: ring binders, dividers, lever arch files, suspension files, box files, record cards, folders, memo pads, post-its, and shorthand pads.

Responsibility: _		
Signature/Date: _		

Policy no. 14F

Environmental Management System Program

POLICY No. 14F : Company will educate, train, and motivate our employees to

carry out their tasks in an environmentally responsible manner

OBJECTIVE : To maintain a beautiful environment within the company premises and the surrounding without detrimental effects

on the environment

TARGET: Introduce housekeeping inspection effective July 2000.

Two audits per year

PROGRAM : Housekeeping Program

Action

 A beautiful environment is not an essential part of organizational activities. Water (and chemical) use should be monitored, and ultimately reduced without any detrimental effects on the attractiveness of the company's environment.

Recommendations

- If not already doing so, consider the use of recycled waste water for watering trees and plants around the grounds (see the above section on the reuse of waste water for further details).
- The use of chemical fertilizers should be monitored. Leaching of nitrates and phosphates into ground water systems or even directly into surface water bodies should be avoided as pollutants are liable to spread gradually through it.
- Protection of the groundwater is of critical importance for three reasons:
 - If it becomes polluted, it is very difficult to rehabilitate.
 - Aquifers (unconfined, confined, or perched) act as natural low-cost storage systems for large volumes of potable water which require relatively little treatment before use.
 - Groundwater provides the base flow of many surface water systems that may be of amenity value.

- The use of chemicals over an extended period of time will gradually reduce the fertility of the ground and therefore its ability to survive without external interference. Less/nonharmful (nonchemical) fertilizers could be used as a substitute that would not impact on the integrity of the ground, the water systems, or the diversity of flora and fauna.
- Consider producing your own compost from vegetable wastes/ grass clipping, and so on. To be used on plants and flower beds instead of buying fertilizers.
- Avoid wherever possible the use of pesticides (especially the act of "insurance spraying"). A small number of fat-soluble persistent pesticides (e.g., DDT, and aldrin and dieldrin) are broken down so slowly that they have time to spread and affect populations of nontarget species outside the areas of application and can cause immense damage along the animal/bird food chain.
- It is often better to choose native plants and flowers that are able to withstand hot conditions and possible drought.

Responsibility:	
Signature/Date:	

Policy no. 14G

Environmental Management System Program

POLICY No. 14G : Company will educate, train, and motivate our employees to

carry out their tasks in an environmentally responsible manner

OBJECTIVE : Pollution Prevention

TARGET : Effective July 2001, at least one training session per year

PROGRAM : Environmental Awareness

- Arrange workshop.
- Distribute articles for reading.
- · Conduct lectures.
- Distribute reading material.
- Use sign boards.
- Display slogans on the notice boards.
- Introduce motivational award.

Responsibility: _	
Signature/Date: _	

Policy no. 15A

Environmental Management System Program

POLICY No. 15A : Company will periodically conduct environmental audits in

order to continually improve our environmental performance

OBJECTIVE : Pollution prevention and initiate corrective actions where

applicable

TARGET : Conduct at least one audit per year effective 2001

PROGRAM : Continuous Improvement

- Write auditing procedure.
- Define frequency.
- · Conduct audit.
- Initiate corrective program.

Responsibility:	
Signature/Date:	

Policy no. 16A

Environmental Management System Program

POLICY No. 16A : We will establish environmental management system to keep us

informed about the impact of all our operations, allowing us to achieve the most effective and cost-efficient improvements in

performance

OBJECTIVE : Efficient improvements in performance

TARGET : Effective July 2001, at least two reports per year

PROGRAM : Cost efficiency

- Establish environmental indicators based on cost.
- Monitor the impact as cost.
- Report to the higher management the benefits.

Responsibility:	
Signature/Date:	

Policy no. 17A

Environmental Management System Program

POLICY No. 17A : Company is committed to publishing targets for continuous

improvement in performance, and will work toward these

with annual action plans

OBJECTIVE : Pollution Prevention

TARGET : Effective year 2001, publish at least two reports indicating targets

to be achieved

PROGRAM : Continuous Improvement

- Refer to management review.
- Refer to agreement and impacts.
- · Define targets.
- Establish program.
- Assign responsibility.
- Publish reports on targets twice a year.

Responsibility:	
-	
Signature/Date:	

Policy no. 18A

Environmental Management System Program

POLICY No. 18A : Company will reduce the impact of its transport operations by

maximizing the efficiency of routes and vehicles, selection of fuels and vehicles, and thinking flexible about delivery methods

OBJECTIVE : Reduce consumption of fuel due to transportation by 50%

by year 2002, using 1999 standard

TARGET : Reduce consumption of fuel

25% in year 2001 (Staff transportation) 25% in year 2002 (Heavy duty trailer)

PROGRAM : Transport (if appropriate) management

Actions

What needs to be considered when selecting vehicles for the company fleet?

- Fuel efficiency of the vehicle
- Purchase cost of the vehicle
- Cost and type of fuel
- Maintenance requirements
- Range between tank refills
- Likely distances of trips to be travelled by the vehicle
- Overall performance
- Environmental/public health considerations
- Automatic transmission vs. manual transmission (a vehicle with automatic transmission uses up to 10% more fuel than a similar model with manual transmission)

Responsibility:	
Signature/Date:	
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Policy no. 18B

Environmental Management System Program

POLICY No. 18B	:	Company will reduce the impact of its transport operations by maximizing the efficiency of routes and vehicles, selection of fuels and vehicles, and thinking flexible about delivery methods
OBJECTIVE	:	Reduce emission of lead due to transportation by 50% of the present level by year 2003, using 1999 standard
TARGET	:	Reduce emission of lead 25% in year 2002 (Staff transportation) 25% in year 2003 (Heavy duty trailer)

Transport (if appropriate) management

Action

PROGRAM

 The use of lead-free petrol is encouraging as it is significantly less harmful to our health and also the health of the environment. Virtually all vehicles produced over the past ten years are designed specifically to use unleaded fuel, without the need of a catalytic converter.

Responsibility:	
Signature/Date:	
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Policy no. 18C

Environmental Management System Program

POLICY No. 18C : Company will reduce the impact of its transport operations by maximizing the efficiency of routes and vehicles, selection of fuels and vehicles, and thinking flexible about delivery methods

OBJECTIVE : Reduce emission of particulates due to transportation by 5% of the present level by year 2003, using 1999 standard

TARGET : Reduce emission of particulates
2% in year 2002 (Staff transportation)
3% in year 2003 (Heavy duty trailer)

PROGRAM : Transport (if appropriate) management

Action

 Vehicles using diesel emit more particulate (smoke) emissions and nitrogen oxides than petrol-run cars that have catalytic converters, but ultra-low sulfur diesel that reduces smoke emission is available.

Responsibility: $__$		
1		
Signature/Date:		

Policy no. 18D

Environmental Management System Program

POLICY No. 18D : Company will reduce the impact of its transport operations by

maximizing the efficiency of routes and vehicles, selection of fuels and vehicles, and thinking flexible about delivery methods

OBJECTIVE : Reduce emission and nitrogen oxides due to transportation by

100% of the present level by year 2002, using 1999 standard

TARGET : Reduce emission of lead

100% in year 2001 (Staff transportation) 100% in year 2002 (Heavy duty trailer) Transport (if appropriate) Management

Actions

PROGRAM

- · Servicing.
- Making sure company vehicles are regularly tuned and serviced (90% of inefficient vehicles can be re-tuned in just 15 min) can save money and reduce exhaust emissions.
- Daily service: quick visual check of body, tyres (a 2 psi drop in tyre pressure increases fuel consumption by 3%, and tyres underinflated by 7 psi waste half a gallon of fuel per tank), lights, windscreens, and mirrors.
- Weekly service: check brakes, screen-wash levels, oil and water under the bonnet.
- Monthly service: physical check of tyre pressure (over-inflated tyres have a shorter life and can be dangerous), full check of all under-bonnet levels, check for exhaust leaks, check that steering is "true" (i.e., not pulling to one side), check for service requirement against time and/or mileage.
- Keeping company vehicles serviced can account for up to 18% of total fuel saving, and will reduce the possibility of unexpected breakdowns.

Responsibility:	
Signature/Date:	

Policy no. 18E

Environmental Management System Program

POLICY No. 18E : Company will reduce the impact of its transport operations by

maximizing the efficiency of routes and vehicles, selection of fuels and vehicles, and flexible thinking of delivery methods

OBJECTIVE : Reduce consumption of fuel due to transportation by 15% of the

present level by year 2002, using 1999 standard

TARGET : Reduce consumption of fuel

5% in year 2001 (Staff transportation) 10% in year 2002 (Heavy duty trailer)

PROGRAM : Transport (if appropriate) management

- Training and driving style.
- Driving training can account for up to 11% of total fuel saving. Train all drivers in economical driving techniques, including:
 - Drive smoothly, avoiding harsh acceleration and heavy braking.
 - Use the gearbox efficiently to maintain revolutions in the midrange (1500–2500 r.p.m.).
 - Research in The Netherlands by Novem (Netherlands Agency for Energy and the Environment 1996) has found that correct use of gears can reduce nitrogen oxide emissions by over 20% while reducing fuel consumption by an average of 15%.
 - Avoid "pumping" the accelerator or reviving the engine unnecessarily—this wastes fuel.
 - Plan all trips in advance.
 - Use of air-conditioning can increase fuel consumption by around 15%—do you use it unnecessarily?
 - Use of roof racks, open windows/ sunroofs, and others increases aerodynamic drag and so contributes to increased fuel use. Remove unnecessary roof racks.

Responsibility:	
Signature/Date:	
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Policy no. 18F

Environmental Management System Program

POLICY No. 18F : Company will reduce the impact of our transport operations by

maximizing the efficiency of routes and vehicles, selection of fuels and vehicles, and thinking flexible about delivery methods

OBJECTIVE : Optimize emission of lead and nitrogen oxides due to

transportation by 50%

TARGET : Reduce emission of lead and nitrogen oxides

25% in year 2001 (Staff transportation) 25% in year 2002 (Heavy duty trailer)

PROGRAM : Transport (if appropriate) management

- · Vehicle use.
- Reduce the need to travel (telesales, telecommunications, etc.).
- Plan and schedule journeys appropriately.
- Maintain the vehicle in good condition.

Responsibility:	
Signature/Date:	

Policy no. 19A

Environmental Management System Program

POLICY No. 19A : Will consider the environmental impacts of our suppliers,

alongside quality and cost. We will set environmental standards for our suppliers, and work with them to achieve these standards.

OBJECTIVE : Pollution Prevention

TARGET : Develop questionnaire for suppliers by 2001 and send

information to the supplier in phases

25% in year 2001 50% in year 2002 75% in year 2003 100% in year 2004

Send copies of environmental policy to all the suppliers

25% in year 2001 50% in year 2002 75% in year 2003 100% in year 2004

PROGRAM : Continuous Education and Training

- Prepare questionnaire for suppliers to inculcate importance of the environment.
- Share our programs with the supplier to optimize pollution prevention.

Responsibility:	
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Signature/Date:	

Policy no. 20A

Environmental Management System Program

POLICY No. 20A : Company will reduce the amount of waste we create: We will

minimize our use of materials, design, and modify our operations to minimize waste production, use materials longer where practicable, and always investigate recycling

opportunities for used materials.

OBJECTIVE : Prevent pollution by reducing waste generation by 7% of the

present level by year 2007, using 1999 standard

TARGET : Reduce waste generation

1% in year 2001 (Quality Control) 1% in year 2002 (Quality Control) 1% in year 2003 (Production) 1% in year 2004 (Packaging) 1% in year 2005 (Stores) 1% in year 2006 (Maintenance)

1% in year 2007 (Administration)

PROGRAM : Waste Management

Actions

"Clean Up the World Campaign" aims at making individuals, companies, and communities more aware of local environment issues, particularly the importance of reducing waste, recycling, and waste management.

Waste reduction initiatives

- Find out what waste is produced at your site.
- Ask if any of this waste can be reduced, and by whom.
- Make someone responsible for reducing waste.
- Establish waste collection points for recyclable items.
- Provide separate collection bins for each category of waste.
- Join a local waste minimization club or start one with companies on neighboring sites.
- Encourage employees to reduce waste, for example, by donating a percentage of any savings raised to a local charity.
- Use the minimum packaging needed.

- Return product packaging to suppliers—agree reduced packaging with customers/suppliers.
- Minimize or reuse your own product packaging (if appropriate).
- Reuse cardboard cartons and plastic bags.
- Compact nonrecyclable by-products to make disposal more manageable.

Responsibility: $_{ extstyle -}$		
Signature/Date:		

Policy no. 20B

Environmental Management System Program

POLICY No. 20B : Company will reduce the amount of waste resulted from our

operations. We will minimize our use of materials, design, and modify our operations to minimize waste production, use materials longer where practicable, and always investigate

recycling opportunities for used materials.

OBJECTIVE : Prevent pollution by reducing waste of water by 5% of the present

level by year 2002, using 1999 standard where possible

TARGET : Reduce waste generation

2% in year 2001 3% in year 2002

PROGRAM : Waste Management

- The basis of an effective waste minimization plan is a detailed waste water audit study. Such a plan will dramatically reduce water costs as well as the costs of treatment and disposal.
- Find out water is wasted at site and can be saved.
- A waste water minimization plan should consider:
 - Means of avoiding excessive water use/waste water generation
 - Means of reducing the strength of contaminant entering the waste stream
 - Means of water reuse/recycling
 - Unexplained water use outside "production" hours

Responsibility:	
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Signature/Date:	

Policy no. 20C

Environmental Management System Program

POLICY No. 20C : Company will reduce the amount of waste resulted from our

operations. We will minimize our use of materials, design, and modify our operations to minimize waste production, use materials longer where practicable, and always investigate

recycling opportunities for used materials.

OBJECTIVE : Prevent pollution by 100% safe disposal of chemical waste

by 2007

TARGET : Induce safe disposal of waste

5% in year 2001 5% in year 2002 10% in year 2003 10% in year 2004 20% in year 2005 25% in year 2006 25% in year 2007

PROGRAM : Waste Management

Actions

Recommendations/Guidelines

Permits

- Where appropriate, ensure that a permit is held for the discharge
 of all waste, to the sewer, land or the marine environment, are
 obtained from the local bodies. It would be useful to keep these
 on file for at least two years. Check that all waste contractors are
 licensed to take the waste (if appropriate).
- A condition of this permit is the periodic monitoring and reporting of the quantity and quality of this waste. If the quality of the waste exceeds prescribed standards, it may need to be disposed of as hazardous waste.

Responsibility:	
Signature/Date:	

Policy no. 21A

Environmental Management System Program

POLICY No. 21A : Conserve natural resources of water where technically and

practically possible

OBJECTIVE : Minimize water use wherever technically and commercially practical

 ${\bf TARGET} \hspace{1.5cm} : \hspace{.2cm} {\bf Reduce \ water \ consumption \ at \ selected \ sites \ by \ 15\% \ of \ the \ present}$

levels within one year 5% in year 2001 (Gardening)

10% in year 2002 (Water Fall)

PROGRAM : Water Recycling

Actions

Install equipment to recycle water used for rinsing in process A for reuse in process B.

If the following policies are properly implemented, and expenditure over a similar time span is monitored, then the savings made can be calculated. Research shows that the average company could save 15% of its water and effluent bill by minimizing water use.

Recommendations/Guidelines

Measure and monitor consumption (cheap meters can be bought if need be), concentrating on the main areas of use.

Inside Buildings

- Encourage male staff to use the urinals provided for urinating and not the toilet cubicles, as is often the case. It is unnecessarily wasteful of water to flush away one person's urine. If, as is likely, many people are following this practice, an enormous amount of water is wasted over a period of one year. Cleaning time would also be reduced.
- The use of the Biomat system in the men's urinal toilets is a very useful and cost-effective system. The Biomat is an antiseptic,

- scented mat that is placed in the urinal. It kills odors, maintains hygiene levels, and does not require the use of water for flushing. The urinal is cleaned and washed out at appropriate intervals.
- Passive infra-red (PIR) sensors are also a cost-effective way to save water for urinals. Research shows that companies using the older raised cistern (flush tank) for urinals can reduce water use by up to 70%. The PIR sensors typically use long-life batteries lasting three through four years (PIR sensors can be extended to control lighting and fans as well as water supplies).
- Fit "Hippos" (or even a plastic water bottle filled with water or sand) in toilet cisterns to reduce flush volumes. If flushing is subsequently ineffective then the levels of water/sand can be adjusted. Toilets plumbed after 1993 will probably have a 7.5 liter cistern. Through fitting "Hippos" in toilet cisterns, approximately 30% of the water will be saved with each flush regardless of the size of the cistern. 190,080 gallons (864,000 L) of water a year can be saved from 40 flush toilets (not including urinals).
- Test for leaking toilets by adding food coloring to the tank. If any color appears in the bowl after 30 min, then the toilet is leaking. A leaking toilet can waste up to 200 gallons of water per day.
- To reduce water wastage from sink taps (and shower heads), consider fitting spring-loaded return valves, in-line flow restrictors or spray taps, or timer/sensor controlled taps that work just as effectively as normal taps and only dispense water when required by operatives. (Low flow, high velocity showers use water efficiently. Typical water use for a shower is 35 liters, with power showers using substantially more.) Research shows the companies can reduce water use by up to 50% using flow restrictors from sink taps alone.
- Water wastage in food service areas is notoriously large—do not wash hands or kitchen equipment under running water.
- Ensure that dripping or leaking taps are quickly repaired—
 (a tap that drips twice per second wastes 1200 gallons over a year).

 Leaks and burst pipes can be extremely costly, as the following data show:
 - A 1/2 inch water pipe loses 50 gallons per minute (gpm)
 - A 3/4 inch pipe loses 110 gpm
 - A 1 inch pipe loses 210 gpm
 - A 2 inch pipe loses 850 gpm

- A 3 inch pipe loses 1900 gpm
- A 4 inch pipe loses 3400 gpm
- If possible, check the water meter while no water is being used. If the dials are moving then there is a leak in the system.
- Report faults immediately.
- Where possible, collect the water from the air-conditioners in a rain barrel to use for outside watering (if appropriate).
- Ensure that hot water is stored at 60°C (approx. 145°F). Storing water below this temperature increases the risk of *Legionella*. Storing water above this temperature is unnecessary and wastes energy—reset the immersion heater thermostat if necessary.
- Pipe-work should be lagged as this ensures that hot water pipes provide hot water and cold water pipes provide cold water (especially important in summer).

Outside Buildings—Guidelines for the Reuse of Waste Water for Horticultural Purposes

The conservation of water is of such importance that recycling techniques have to be developed for every type of usage of water. Treating waste water for reuse is a specialist task and an explanation of the full range of possible separation technologies is beyond the scope of this report. A brief set of guidelines are included.

The use of treated waste water for irrigation, while bringing many benefits, has associated public health risks. Recycled water and sludge may spread diseases due to bacteria, worm eggs, and virus particulates present in the treated water or sludge, or due to bacteria that grow in the irrigation system. Warm, nutrient rich water is an ideal media for promoting the growth of organisms such as *Legionella*, and the correct treatment is therefore essential.

- For unrestricted irrigation (Class A waters): all sewage effluents must be treated to secondary standard, sand filtered and chlorinated. The maximum *E. coli* level in the final effluent shall be less than 1/100 mL.
- For restricted irrigation (Class B waters): the effluent shall be treated to secondary standard and *E. coli* level must be reduced to 1000/100 mL.

Irrigation Method	Permissible Water Class
Drip irrigation on to trees and bushes	A or B
Low mist hand spray	A or B
Spray irrigation in parks and green spaces that are closed to the public or after the hours of use, subject to a 2-h break before public use begins	A or B
Unlimited spray irrigation of public areas with precautions to reduce mist formation	A only

- Ensure that company meets the above standard or the treatment system must be upgraded within 6 months.
- Waste water irrigation points shall be regularly tested for bacteria including *Legionella*, especially where spray irrigation is practiced. Any branch of the network where *Legionella* is detected or where bacterial levels are elevated must be isolated and treated.
- Chlorine dioxide (or any other material of equivalent effectiveness) must be used to disinfect for *Legionella* and slime-borne organisms. Chlorination is not adequate for this purpose.
- The irrigation of recycled water shall be timed to avoid periods of public use.
- Drip irrigation applies water slowly to exactly the areas where it is needed with minimal wastage.
- If possible, irrigation of the grounds should take place at the coolest part of the day to minimize water lost to evaporation. Water administered during hot parts of the day (as has been observed) will either not be able to infiltrate far enough into the ground to reach plant roots (which will slowly turn toward the surface and eventually die) or required much larger volumes of water to do the same job. Furthermore, the likelihood of the plants being scorched is increased.
- All areas where recycled water is used shall be sign-posted to alert staff not to drink the water.
- Staff involved in the application of recycled water shall be subject to regular health evaluation.
- Irrigation waters shall be monitored at the point of application by taking the first water flushed from the line and collecting this in a 1 L sterile bottle. The point(s) chosen should provide statistical coverage of the irrigation area.

- Staff collecting irrigation waters should avoid all contact with the water and wear a high efficiency particle and mist face shield. Staff should wash their hands thoroughly after sampling.
- Water used in the decorative fountains at the entrance must also undergo the above safety checks to negate potential dangers to human health.

Responsibility:		
Signature/Date:		

Policy no. 22A

Environmental Management System Program

POLICY No. 22A : Company will reduce the amount of waste and will always

investigate recycling opportunities for used materials.

Embody life cycle thinking.

OBJECTIVE : Achieve recycling approach 50% of the present level by

year 2005

TARGET : Optimize use of recycle products

25% in year 2003 (Stationery) 25% in year 2005 (Stationery)

PROGRAM : Recycling of office waste paper

Actions

Close the Recycling Loop—Collecting materials for recycling is only the beginning of the chain. *If you are not buying recycled, you are not recycling.*

Recommendations

Before considering recycling, there are other issues that need to be addressed. Ask yourself, "can I reduce my use of this item?" and "can I reuse this item before throwing it away?" First REDUCE, then REUSE, and only then RECYCLE.

- Paper is a natural resource that is reusable and can be recycled up to five times. Large amounts of the office waste paper could be collected in a separate container and taken away for recycling instead of thrown away with the general rubbish.
- Recycled stationery paper can be more expensive unless a lower grade of whiteness is accepted, though most general stationery items are used in-house and there is little justification to use products made from virgin materials where recycled alternatives exist.
- Paper could also be reused as most paper sent to waste has only been used on one side. Faxes and internal memos, for example,

could be sent on paper that has only been used on one side. Paper
documents that require circulation could be enclosed in reusable
envelopes, and so on.

Responsibility:	
Signature/Date:	

Policy no. 22B

Environmental Management System Program

POLICY No. 22B : Company will reduce the amount of waste and will always

investigate recycling opportunities for used materials.

Embody life cycle thinking.

OBJECTIVE : Achieve recycling approach 50% of the present level by

year 2005

TARGET : Optimize use of recycle products

25% in year 2001 (Stationery) 25% in year 2002 (Stationery)

PROGRAM : Recycling of laser printer cartridges

Action

• Laser printer toner cartridges can be refilled or remanufactured (although not all cartridge types are recyclable). Also, check that the printer warranty is not affected and the supplier will guarantee to cover the cost of repair due to cartridge failure. The cost of recycling and using remanufactured toner cartridges can be very cost-effective, saving around 20% against new cartridges.

Responsibility:	
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Signature/Date:	

Policy no. 22C

Environmental Management System Program

POLICY No. 22C : Company will reduce the amount of waste and will always

investigate recycling opportunities for used materials.

Embody life cycle thinking.

OBJECTIVE : Achieve recycling approach 50% of the present level by year 2005

TARGET : Optimize use of recycle products

25% in year 2003 (Stationery) 25% in year 2005 (Stationery)

PROGRAM : Recycling of desk-jet cartridges

Action

Desk-jet cartridges can be refilled, which reduces waste and represents a considerable saving compared to buying a new product—an average of 50%. Ensure that the supplier handles these refills.

Responsibility:	
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Signature/Date:	

Policy no. 22D

Environmental Management System Program

POLICY No. 22D : Company will reduce the amount of waste and will always

investigate recycling opportunities for used materials.

Embody life cycle thinking.

 ${\bf OBJECTIVE} \hspace{1.5cm} : \hspace{1.5cm} {\bf Achieve \ recycling \ approach \ 50\% \ of \ the \ present \ level \ by \ year}$

2005

TARGET : Optimize use of recycle products

25% in year 2003 (Stationery) 25% in year 2005 (Stationery)

PROGRAM : Procurement recyclable cartridges for laser and desk-jet

printers

Action

 Consider the recyclability of cartridges when purchasing new printers.

Responsibility:	
Signature/Date:	

Policy no. 22E

Environmental Management System Program

POLICY No. 22E : Company will reduce the amount of waste and will always

investigate recycling opportunities for used materials.

Embody life cycle thinking.

OBJECTIVE : Achieve recycling approach 50% of the present level by year 2005

TARGET : Optimize use of recycle products

25% in year 2003 25% in year 2005

PROGRAM : Recycling of plastic waste from the company

Action

Plastic vending cups used for drinking water could be kept, reused
a second or third time by staff instead of them being thrown away
after the first use. Permanent pottery mugs/cups or recyclable
paper cups could be better alternatives. 250,000 plastic cups used
over a period of a year equates to one tonne of waste! Reusing and
recycling cups will reduce the amount spent on purchasing them
and also reduce the amount of waste sent to landfill.

Responsibility:	
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Signature/Date:	

Policy no. 22F

Environmental Management System Program

POLICY No. 22F : Company will reduce the amount of waste and will always

investigate recycling opportunities for used materials. Embody

life cycle thinking.

OBJECTIVE : Achieve recycling approach 50% of the present level by year 2005

TARGET : Optimize use of recycle products

25% in year 2003 25% in year 2005

PROGRAM : Procurement of recycled toilet paper

Action

• Recycled toilet paper is available at little or no extra cost with an acceptable level of quality.

Responsibility:	
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Signature/Date:	

Policy no. 22G

Environmental Management System Program

POLICY No. 22G : Company will reduce the amount of waste and will always

investigate recycling opportunities for used materials.

Embody life cycle thinking.

OBJECTIVE : Achieve recycling approach 50% of the present level by year 2005

TARGET : Optimize use of recycle products

25% in year 2003

25% in year 2005

PROGRAM : Recycling

•	Rubbish could be collected in recycled refuse sacks.

Responsibility:	
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Signature/Date:	

Policy no. 23A

Environmental Management System Program

POLICY No. 23A : Company will seek to reduce the consumption ozone-

depleting substances (ODSs) where possible

OBJECTIVE : Reduce ozone-depleting substances consumption by 100%

of the present level by year 2006, using 1999 standard

TARGET : Reduce ozone-depleting substances consumption

5% in year 2001 5% in year 2002 10% in year 2003 10% in year 2004 20% in year 2005 50% in year 2006

PROGRAM : Ozone-Depleting Substances Identifying in the Company

Operation

Actions

Guidelines/Recommendations

The "controlled substances" (that must cease to be produced in, or imported by 2006, according to international legislation of the Montreal Protocol) shall include:

CFC-11—Trichlorofluoromethane

CFC-12—Dichlodifluoromethane

CFC-111—Trichloroethane (a.k.a. Methyl Chloroform)

CFC-113—Trichlorotrifluoromethane

CFC-114—Dichlorotetrafluoromethane

CFC-115—Chloropentafluoromethane

R-500—Dichlorodifluoro/Difluoromethane

R-502—Chlorodifluoro/Chloropentafluoromethane

Halon 1211—Bromochlorodifluoromethane

Halon 1301—Bromotrifluoromethane

Halon 2402—Dibromotetrafluoromethane

CCI4—Carbon tetrachloride	
CH3CCl3—Methyl chloroform	
CH3Br—Methyl bromide	
HBFC—Hydrobromofluorocarbons	
Responsibility:	
Signatura/Data:	

Policy no. 23B

Environmental Management System Program

POLICY No. 23B : Company will seek to reduce the consumption of ozone-

depleting substances (ODSs) where possible

OBJECTIVE : Reduce ozone-depleting substances consumption by 100%

of the present level by year 2006, using 1999 standard

TARGET : Reduce ozone-depleting substances consumption

5% in year 2001 5% in year 2002 10% in year 2003 10% in year 2004 20% in year 2005 50% in year 2006

PROGRAM : Ozone-Depleting Substances reduction in Refrigeration

and Air Conditioning System

- Refrigeration and air conditioning.
- Ensure that old fridges are properly disposed of so that CFCs are removed (refrigerant gases, of course, only affect the environment when released).
- New equipment should be specified to contain R134a (HFC) or, ideally, a hydrocarbon gas (Calor). R134a is generally the preferred substitute but, although it does not affect the ozone layer, this does have a severe global warming effect, raising some concerns. Other preferable substitutes include R125, R143a, and R22 that have low ozone depletion potential and are available on the market. R22, however, is a class II ozone-depleting substance and its use will eventually be phased out under the Montreal Protocol. Ammonia is sometimes used in primary circuits but can cause safety problems. It is recommended that future options are monitored and all measures taken to ensure minimal leakage of gases through regular maintenance. Losses (i.e., amounts needed to top-up systems during servicing) should be tracked.

- New equipment must not contain CFC's 11, 12, 113, 114, 115 (see above), and other halogenated CFCs.
- All existing air conditioning and refrigeration equipment utilizing the aforementioned controlled substances must be:
 - 1. Maintained leak-free
 - 2. Supplied with gases from existing supplies or recycled sources
 - 3. Converted to use approved alternative refrigerants
- The venting of controlled refrigerants during equipment maintenance is not permitted.
- Recovery, recycle, and reuse of refrigerants shall be practiced during repair and maintenance.

Signature/Date:	

Policy no. 23C

Environmental Management System Program

POLICY No. 23C : Company will seek to reduce the consumption of ozone-

depleting substances (ODSs) where possible

 $\begin{tabular}{lll} \textbf{OBJECTIVE} & : & Reduce ozone-depleting substances consumption by 100% \\ \end{tabular}$

of the present level by year 2006, using 1999 standard

TARGET : Reduce ozone-depleting substances consumption

5% in year 2001 5% in year 2002 10% in year 2003 10% in year 2004 20% in year 2005 50% in year 2006

PROGRAM : Ozone-Depleting Substances reduction using cleaning

products without CFCs

- Dry cleaning (if appropriate).
- All products containing CFC-113 and 111-Trichloroethane (also known as methyl chloroform) which are ozone-depleting substances shall not be used in new equipment.
- Owners of existing equipment shall investigate alternatives and shall inform the EPA within two years of the selected alternative and the deadline for decommissioning all equipment utilizing controlled substances.
- Alternative substances that have low ozone-depleting potential including, but not limited to, trichloroethane, perchloroethylene, and methylene chloride shall be used in dry cleaning activities.
- Company could examine whether there is a need to clean items at all and whether water-based caustic systems can be used before considering vapor and solvent degreasing systems.

Responsibility:	
Signature/Date:	

Policy no. 23D

Environmental Management System Program

POLICY No. 23D : Company will seek to reduce the consumption ozone-

depleting substances (ODSs) where possible

OBJECTIVE : Reduce ozone-depleting substances consumption by 100%

of the present level by year 2006, using 1999 standard

TARGET : Reduce ozone-depleting substances consumption

5% in year 2001 5% in year 2002 10% in year 2003 10% in year 2004 20% in year 2005 50% in year 2006

PROGRAM : Ozone-Depleting Substances reduction through selection

of Fire Protection Materials free from ODSs

- Fire protection systems
 - Halons 1211, 1301, and 2402 shall not be used in any new fire protection system from January 1, 1996. Alternative fire suppressant substances already available shall be used in newly built fire protection systems.
 - The venting of Halons during repair and maintenance of existing fire protection systems is not allowed. Existing large premises shall install equipment to recover, recycle, and reuse Halon.
 - All Halon-filled cartridges or cylinders for fire extinguishers shall be regularly maintained and periodically serviced only to qualified premises with Halon recovery equipment to minimize leakages.
 - Keep a regular maintenance schedule for fire protection systems.

Responsibility:	
Signature/Date:	

Policy no. 23E

Environmental Management System Program

POLICY No. 23E : Company will seek to reduce the consumption of ozone-

depleting substances (ODSs) where possible

 $\begin{tabular}{ll} \textbf{OBJECTIVE} & : & \textbf{Reduce ODS consumption by } 100\% \ \textbf{of the present level by year} \\ \end{tabular}$

2003, using 1999 standard

TARGET : Reduce CFCs consumption

10% in year 2001 (Carpentry Shop)

40% in year 2002 50% in year 2003

PROGRAM : Reduction of ODS through selection of organism solvent-free

adhesive used for the repairs of Office Equipment—Fixtures

and Fittings procurement

Action

• Avoid solvent-based wood preservatives (often organic volatile chemicals) and lacquers (which contain approx. 15% solvents).

Responsibility:	
Signature/Date:	

Policy no. 23F

Environmental Management System Program

POLICY No. 23F : Company will seek to reduce the consumption of ozone-

depleting substances (ODSs) where possible

 $\begin{tabular}{lll} \textbf{OBJECTIVE} & : & \textbf{Reduce ODS consumption by } 100\% \ \textbf{of the present level by year} \\ \end{tabular}$

2003, using 1999 standard

TARGET : Reduce CFCs consumption

10% in year 2001 (Carpentry Shop)

40% in year 2002 50% in year 2003

PROGRAM : Reduction of ODS through selection of organism solvent-free

adhesive used for the repairs of Office Equipment—Fixtures

and Fittings procurement

•	Avoid solvent-based wood preservatives (often organic volatile
	chemicals) and lacquers (which contain approx. 15% solvents).

Responsibility:	
Signature/Date:	

Policy no. 23G

POLICY No. 23G : Company will seek to reduce the consumption of ozone-depleting

Environmental Management System Program

		substances (ODSs) where possible					
OBJECTI	VE :	1) 1))					
		2003, using 1999 standard					
TARGET	:	Reduce CFCs consumption					
		10% in year 2001 (Carpentry Shop)					
		40% in year 2002					
		50% in year 2003					
PROGRA	MME :	Recycling based Office Equipment—Fixtures and Fittings					
		procurement					
Action							
• In	vestigate	packaging—recyclable content, recyclability, and					
	trieval.	paragrag recyclinate content, recyclination, until					

Responsibility:

Signature/Date:

Policy no. 23H

Environmental Management System Program

POLICY No. 23H : Company will reduce the amount of waste and will always

investigate recycling opportunities for used materials

 $\textbf{OBJECTIVE} \hspace{1.5cm} : \hspace{0.5cm} \textbf{Reduce tropical hardwood consumption by 100\% of the} \\$

present level by year 2004, using 1999 standard

TARGET : Reduce tropical hardwood consumption

25% in year 2001 (Carpentry Shop)

25% in year 2002 25% in year 2003 25% in year 2004

PROGRAM : Procurement of nontropical wood for office Equipment—

Fixtures and Fittings manufacturing in house

Action

Recommendation

 Avoid tropical hardwoods and check the sources of raw materials—furniture and other fittings may contain timber from unmanaged forests. Sustainably managed and grown temperate hard and softwoods from North America, Europe, and Russia are preferable. Consider wood substitutes.

Responsibility:		
Signature/Date:		

Policy no. 23I

Environmental Management System Program

POLICY No. 23I : Company will seek to reduce the consumption of ozone-depleting substances (ODSs) where possible

OBJECTIVE : Reduce ODS consumption by 100% of the present level by year 2003, using 1999 standard

TARGET : Reduce CFCs consumption
10% in year 2001 (Carpentry Shop)
40% in year 2002
50% in year 2003

PROGRAM : Environmental-friendly Office Equipment—Fixtures and Fittings procurement

Action

•	Avoid	products	where	CFCs	(ODS)	are	used	as a	blow	ing	agei	nt.
---	-------	----------	-------	------	-------	-----	------	------	------	-----	------	-----

Responsibility:	
Signature/Date:	

300.60-1

Practical Help

Virtual Pharmaceutical Industries

The intention of Chapter 300.60.1 is to provide the end users with the practical help, how to walk through ISO 14001:2004 Environmental Management System development using the ready use attachments provided at the end of the standard operating procedures. The attachments are filled based on the following assumption; however, the individual user should identify and build requirements specific to their operations, that is, products and services.

The similarity in the contents of the hypothetically filled attached forms may be incidental and does not provide any guarantee to the end users concerning the specific needs and the legislations applicable from one country to another.

Assumption

Virtual Pharmaceutical Industries is located in (Address) the United States. It is involved in finished pharmaceuticals manufacturing of the following dosage forms and supporting operations.

- Tablets processing
- Capsule processing
- Powder processing
- Semisolid processing
- Liquid processing
- Sterile processing
- Sterile powder filling

- Plastic dosing cups manufacturing plant
- Aluminum caps manufacturing plant

Following is the list of sources of aspects identified jointly by the key departmental manager in coordination with the EMS coordinator.

- 1. Waste treatment plant
- 2. Steam generation/boilers (light diesel oil)
- 3. Burning diesel (electricity generator)
- 4. HVAC system CFCs
- 5. Plastic dosing cups manufacturing plant
- 6. Aluminum caps manufacturing plant
- 7. Transportation
- 8. Laundry
- 9. Kitchen
- 10. Civil work and maintenance
- 11. Tablets processing
- 12. Capsule processing
- 13. Powder processing
- 14. Semisolid processing
- 15. Liquid processing
- 16. Sterile processing
- 17. Sterile powder filling
- 18. QC & PDL laboratory
- 19. Stores
- 20. Administration
- 21. Civil work and construction

On the basis of the above-mentioned information, the company decided to establish the ISO 1400:2004 Environmental Management System. The attachments provided in the Practical Help section are provided as a guideline or are filled as an example for the end users. The contents filled in the examples do not guarantee the end users to follow the same concerning their operational environment (see Table 1).

Table 2 provides Virtual Pharmaceutical Industries Environmental Aspects Significance Evaluation Matrix.

In Table 3, the local municipality environmental protection and safety technical guidelines are listed. Table 4 provides information about the action programs and the concerned department. The operational control procedures of the Virtual Pharmaceutical Industries are listed in Table 5. The environmental policy of the Virtual Pharmaceutical Industries is described in Table 6. The attachments are listed under Section 300.60.1. However, the specific attached number is identified by its number within parentheses at the end of the section, such as 300.60.1.4.1(1).

List of Referenced SOPs with Filled Attachments

TABLE 1

Section	Subject	SOP no.	Template	Comments
1	General requirements	EMS-4.1	EMS-4.1(1)	Example
			EMS-4.1(2)	Example
			EMS-4.1(3)	Example
			EMS-4.1(4)	Example
			EMS-4.1(5)	Example
			EMS-4.1(6)	Guide
			EMS-4.1(7)	Guide
			EMS-4.1(8)	Guide
			EMS-4.1(9)	Guide
			EMS-4.1(10)	Guide
			EMS-4.1(11)	Example
			EMS-4.1(12)	Example
			EMS-4.1(13)	Example
			EMS-4.1(14)	Example
2	Environmental	EMS-4.2	EMS-4.2(1)	Guide
	policy		EMS-4.2(2)	Example
			EMS-4.2(3)	Example
3	Planning	EMS-4.3	EMS-4.3(1)	Example
			EMS-4.3(2)	Guide
			EMS-4.3(3)	Guide
3.1	Environmental aspects	EMS-4.3.1	EMS-4.3.1(1) A to U	Example
			EMS-4.3.1(2) A to I	Example
			EMS-4.3.1(3) A to K	Example
			EMS-4.3.1(4) A to B	Example
			EMS-4.3.1(5) A to C	Example
3.2	Legal and other requirements	EMS-4.3.2	EMS-4.3.2(1)	Example
			EMS-4.3.2(2)	Guide
			EMS-4.3.2(3)	Guide
			EMS-4.3.2(4)	Guide
			EMS-4.3.2(5)	Guide
			EMS-4.3.2(6)	Guide
3.3	Objectives and targets	EMS-4.3.3	EMS-4.3.3(1) A to M	Example
			EMS-4.3.3(2)	Example
			EMS-4.3.3(3)	Example
3.4	Environmental management program(s)	EMS-4.3.4	EMS-4.3.4(1)	Guide

TABLE 1 (continued)

Section	Subject	SOP no.	Template	Comments
4	Implementation and operation	EMS-4.4	EMS-4.4(1)	Guide
			EMS-4.4(2)	Guide
			EMS-4.4(3)	Example
			EMS-4.4(4)	Guide
			EMS-4.4(5)	Guide
4.1	Resources, roles, responsibility, and authority	EMS-4.4.1	EMS-4.4.1(1)	Example
			EMS-4.4.1(2)	Guide
4.2	Competence, awareness, and training	EMS-4.4.2	EMS-4.4.2(1)	Guide
			EMS-4.4.2(2)	Guide
			EMS-4.4.2(3)	Example
4.3	Communication	EMS-4.4.3	EMS-4.4.3(1)	Guide
4.4	Documentation	EMS-4.4.4	EMS-4.4.4(1)	Guide
4.5	Control of document	EMS-4.4.5	EMS-4.4.5(1)	Guide
			EMS-4.4.5(2)	Example
			EMS-4.4.5(3)	Example
			EMS-4.4.5(4)	Example
4.6	Operational control	EMS-4.4.6	EMS-4.4.6(1)	Example
4.7	Emergency preparedness and response	EMS-4.4.7	EMS-4.4.7(1)	Example
			EMS-4.4.7(2)	Example
5	Checking and corrective action	EMS-4.5	EMS-4.5(1)	Guide
			EMS-4.5(2)	Guide
5.1	Monitoring and measurement	EMS-4.5.1	EMS-4.5.1(1)	Guide
5.2	Evaluation of compliance	EMS-4.5.2	EMS-4.5.2(1)	Example
5.3	Nonconformity, corrective action, and preventive action	EMS-4.5.3	EMS-4.5.3(1)	Guide
5.4	Control of records	EMS-4.5.4	EMS-4.5.4(1)	Guide
5.5	Internal audit	EMS-4.5.5	EMS-4.5.5(1)	Guide
			EMS-4.5.5(2)	Guide
			EMS-4.5.5(3)	Guide
6	Management review	EMS-4.6	EMS-4.6(1)	Guide

Note: NR = Not required.

TABLE 2Environmental Aspect Significance Evaluation Matrix

No.	Source	Activity	Date	Product	Services	Location	Area
A.1	Waste water treatment	Recycling	mm/dd/yyyy	N/A	N/A	Waste water treatment	Utilities
A.2	Steam generation/ Boilers (light diesel oil)	Steam generation	mm/dd/yyyy	N/A	Steam generation	Boiler plant	Boiler room
A.3	Burning of diesel (electricity generation)	Power generation	mm/dd/yyyy	N/A	Electricity generation	Generator plant	Plant I, II, III, & administration, housing
A.4	HVAC systems CFCs	Cooling	mm/dd/yyyy	N/A	Air conditioning	Technical floor plant I, II, III, & administration	Plant I, II, III, & administration offices
A.5	Plastics	Manufacturing	mm/dd/yyyy	Plastic dosing cups	Plastic dosing cups manufacturing	Near admin. block	Plastic dosing cups Mfg. plant
A.6	Aluminum	Manufacturing	mm/dd/yyyy	Aluminum caps	Aluminum caps manufacturing	Near admin.	Aluminium caps Mfg. plant
A.7	Transportation	Shipping	mm/dd/yyyy	All products	N/A	Ras-Al-Khaimah	Inside & outside UAE
A.8	Laundry	Washing	mm/dd/yyyy	Washing of Lab. coats and uniforms	Steam generation	Washing room	Laundry
A.9	Kitchen	Cooking	mm/dd/yyyy	N/A	Catering	Administration	Administration
A.10	Civil works and maintenance	_	mm/dd/yyyy	N/A	Carpentry/ Fabrication/ Construction/ Cement manufacturing	Maintenance	Workshop & cement mixing plant

A.11	Tablets processing	Tabletting	mm/dd/yyyy	All tablet products	N/A	Plant I	Mfg. & Pkg. solids
A.12	Capsules processing	Capsulation	mm/dd/yyyy	All capsules	N/A	Plant II	Mfg. & Pkg.
A.13	Powders processing	PPS manufacturing	mm/dd/yyyy	PPS	N/A	Plant II	Mfg. & Pkg.
A.14	Semisolids processing	Semisolid manufacturing	mm/dd/yyyy	All creams, ointments, and suppositories	N/A	Plant III	Mfg. & Pkg.
A.15	Liquids processing	Liquid products manufacturing	mm/dd/yyyy	All syrups, suspensions, and drops	N/A	Plant III	Mfg. & Pkg.
A.16	Sterile processing	Sterile manufacturing	mm/dd/yyyy	All terminally and aseptically sterilized products, ready-to-use syringes, and lyophilized products	N/A	Plant III	_
A.17	QC lab and PDL lab	Testing formulation	mm/dd/yyyy	N/A	N/A	Plant I, II, & III	Admin. Bldg.
A.18	Stores	Storage	mm/dd/yyyy	N/A	N/A	Plant I, II, & III	Inside & outside the factory
A.19	Administration	Routine operations	mm/dd/yyyy	N/A	N/A	Offices	Plant I, II, III Admin. Bldgs.
A.20	Civil works and maintenance	_	mm/dd/yyyy	N/A	Carpentry/ Fabrication/ Construction/ Cement manufacturing	Maintenance	Workshop & cement mixing plant

TABLE 3

Local Mun	icipality Environmental Protection & Safety Technical Guidelines
Number 1	Application for Waste Discharge Permits to Sewer, Land, and Marine Environment
Number 2	Guidelines for Waste Audit Reports
Number 3	Guidelines for Safety Audit Reports
Number 4	Guidelines for Preparation of Environmental Impact Statements for New Industrial Premises
Number 5	Oil Spill Response and Preparedness
Number 6	Industrial Compressed Gas Cylinders
Number 7	Heat Stress at Work
Number 8	Entry into Confined Spaces
Number 9	Electrical Safety at Work
Number 10	Guarding of Dangerous Machinery
Number 11	Approval of Swimming Pool Plans
Number 12	Requirement for Waste Water Separators
Number 13	Industrial Waste Water Disposal
Number 14	Personal Protective Equipment—Head Protection
Number 15	Personal Protective Equipment—Eye and Face Protection
Number 16	Personal Protective Equipment—Hearing Protection
Number 17	Personal Protective Equipment—Protective Clothing
Number 18	Personal Protective Equipment—Hand Protection
Number 19	Personal Protective Equipment—Foot Protection
Number 20	Personal Protective Equipment—Fall Protection/Safety Lines
Number 21	Personal Protective Equipment—Respiratory Protection
Number 22	Safe Use of Industrial Organic Solvents
Number 23	Procedures for Testing the Leaching Characteristics of Hazardous Wastes
Number 24	Sampling of Hazardous Wastes
Number 25	First-Aid Requirements
Number 26	Application for Approval to Dispose of Hazardous Wastes
Number 27	Annual Approvals for Hazardous Waste Disposal
Number 28	Minimization of Industrial Waste Water
Number 29	Requirements for the Discharge of Waste Gases, Fumes, and Dusts to the Atmosphere
Number 30	Paint Spray Booths
Number 31	Safety in Vehicle Repair and Servicing Shops
Number 32	Acetylene Generators
Number 33	Disposal of Outdated Pharmaceuticals and Medicines
Number 34	Requirements for the Use of Waste Oil in Boilers and Furnaces
Number 35	Guidelines of Sampling, Preservation, and Analysis of Water and Waste Water Samples

TABLE 3 (continued)

Local Municipality Environmental Protection & Safety Technical Guidelines

	* *
Number 36	Guidelines for Service Station Waste Disposal
Number 37	Transport of Nonhazardous Liquid Wastes by Tank Vehicles
Number 38	Health & Safety in Kitchens & Food Preparation Areas
Number 39	Septic Tank/Soak Away Design
Number 40	Examination and Certification of Boilers and Pressure Vessels
Number 41	Examination and Certification of Cranes, Hoists, Lifts, and Other Lifting Appliances
Number 42	Requirements for Concrete Batching Plants
Number 43	Placarding of Vehicles Carrying Dangerous Goods
Number 44	Requirements for the Reduction of Construction/ Demolition Noise
Number 45	Requirements for the Control of Entertainment Noise
Number 46	Clearance of Dangerous Goods
Number 47	Guidelines for the Disposal of Used Chemical Containers
Number 48	Safety in Handling Asbestos
Number 49	Hazardous Waste Exemption Policy
Number 50	Requirements for the Transport of Hazardous Waste
Number 51	Sampling and Preservation of Water Borne Oils
Number 52	Metal Finishing Industries
Number 53	Environmental Impact Assessment Procedures
Number 54	Clean-up of Contaminated Land
Number 55	Replacement of CFCs in Degreasing and Cleaning
Number 56	Establishment of Environmental Management Systems—Implementation of ISO-14001
Number 57	Bunding of Storage Tanks and Transfer Facilities
Number 58	Policy on the Control of Ozone-Depleting Substances
Number 59	Management of Medical Wastes from Clinics and Laboratories
Number 60	Approval of Environmental Auditors
Number 61	Development of Emergency Response Procedures for Accidents Involving Dangerous Goods
Number 62	The Reuse and Irrigation of Waste Water and Sludge
Number 63	Environmental Guidelines for Tourists and Leisure Travel within the Country
Number 64	Safety, Health & Environment Requirements for Laundry Operations
Number 65	Liquefied Petroleum Gas Cylinders

TABLE 4

December and	Action Plan/ Program
Department Utilities (Meinten and)	AP1
Utilities (Maintenance)	API
Waste Water Treatment Plant	
Action Plan/Program Review Update up to mm/dd/yyyy	4 D4
Utilities (Maintenance)	AP1
Utilities (Maintenance)	AP2
Steam Generation (Boilers)	
Action Plan/Program Review Update up to mm/dd/yyyy	
Electrical & Electronics	AP3
Action Plan/ Program Review Update up to mm/dd/yyyy	
HVAC (Maintenance)	AP4
Action Plan/Program Review Update up to mm/dd/yyyy	
Plastic Dosing Cup Plant	AP5
Action Plan/Program Review Update up to mm/dd/yyyy	
P.P. Cap Plant	AP6
Action Plan/Program Review Update up to mm/dd/yyyy	
Administration	AP7
Action Plan/Program Review Update up to mm/dd/yyyy	
Utilities/ Laundry	AP8
Action Plan/Program Review Update up to mm/dd/yyyy	
Cafeteria	AP9
Action Plan/Program Review Update up to mm/dd/yyyy	
Maintenance	AP10
Action Plan/Program Review Update up to mm/dd/yyyy	
All Departments	AP11
Action Plan/Program Review Update up to mm/dd/yyyy	
QC & PDL	AP12
Action Plan/Program Review Update up to mm/dd/yyyy	
Stores	AP13
Action Plan/Program Review Update up to mm/dd/yyyy	
Administration	AP14
Action Plan/Program Review Update up to mm/dd/yyyy	

TABLE 5

Operational Controls/Procedures & Record Required

EMS-008	Waste Water
EMS-009	Waste
EMS-010	Measurement & Monitoring
	Recycled Water Produced and Used for Irrigation Utilities (Maintenance)
EMS-011	Measurement & Monitoring
	Waste Water Treatment Plant
	Waste Sludge Produced and Safely Disposed
	Utilities (Maintenance)
EMS-012	Measurement & Monitoring
	Waste Treatment Plant
	Utilities (Maintenance)
EMS-113	Boilers
EMS-114	Measurement & Monitoring
	Fuel Consumption
	Electrical Department (Generator)
EMS-115	Measurement & Monitoring
	Oil Consumption
	Electrical Department (Generator)
EMS-116	HVAC System Optimization & Energy
EMS-117	Stand-Alone Fridges and Freezers
EMS-118	Ozone-Depleting Substances
EMS-119	Measurement & Monitoring
	HVAC System Consumption of CFC's
EMS-120	Measurement & Monitoring
	HVAC System Consumption of R22
EMS-121	Measurement & Monitoring
	HVAC System Consumption of R11
EMS-122	Measurement & Monitoring
	Plastic Pallets Consumptions Plastic Dosing Cups Manufacturing Plant
EMS-123	Measurement & Monitoring
	Aluminum Sheet Consumption
	Aluminum Caps Manufacturing Plant
EMS-124	Transport
EMS-125	Dry Cleaning
EMS-126	Laundry
EMS-127	Kitchen
EMS-128	Dishwashers
EMS-129	Catering

continued

TABLE 5 (continued)

Operational Controls/Procedures & Record Required

EMS-130	Hazardous Substances
EMS-131	Electrical Equipment and Machinery
EMS-132	Waste Reduction/Minimization Initiatives
EMS-133	Fire Protection Systems
EMS-134	Stationary & Office Supplies
EMS-135	Photocopy Machines
EMS-136	Office Equipment & Fixtures & Fittings
EMS-137	Recycling
EMS-138	Measurement & Monitoring
	Volatile Organic Solvents (VOSs)
	Quality Control Dept. and Product Development Lab
EMS-139	Measurement & Monitoring
	Chlorinated Solvents (ODS)
	Quality Control Dept. and Product Development Lab
-	

TABLE 6

Environmental Policy

Virtual Pharmaceutical Industries (VPI) commit itself to conduct our operations in compliance with relevant local environmental legislation and regulations applicable, with other requirements to which the organization is associated, which provides the framework for setting and reviewing environmental objectives and targets. In the absence of governmental regulation, we operate in an environmental responsible manner.

The VPI are committed to the following:

AP1: VPI will conserve the natural resources of water through recycling and optimization of consumption where technically and practically possible.

AP2: To comply with the legislation of local environmental requirements for the discharge of controlled and uncontrolled emission to atmosphere due to company's operations, activities, and services.

AP3: VPI recognizes the interrelation between energy and the environment, and will promote the efficient use of energy throughout our system.

AP4: VPI will seek measures to reduce the consumption of ozone-depleting substances (ODSs) through effective maintenance of its HVAC system.

AP5: VPI will encourage the recycling of plastic waste through continuous awareness programs for the staff and the customers.

AP6: VPI will reduce and encourage the safe disposal and recycling of aluminum waste through continuous customer awareness programs.

AP7: VPI will reduce the impact of its transport operations by maximizing the efficiency of routes and optimization of vehicles maintenance and awareness programs for the drivers.

AP8: VPI will adopt means and ways to manage the disposal of hazardous substances and minimize their consumption where possible.

AP9: VPI will educate, train, and motivate employees to carry out their tasks in an environmental responsible manner.

AP10: VPI will reduce the amount of waste resulted from its operations. We will minimize use of materials, design, and modify operations to minimize waste generation where possible.

AP11: VPI will periodically conduct environmental system audits based on ISO 14001 to continually improve our environmental performance.

AP12: Work toward sustainable development of the Environmental Management System (EMS) for its pharmaceutical manufacturing, packaging process, and associated support functions.

AP13: Encourage the use of EMS by bulk pharmaceutical manufacturers and packaging materials suppliers.

Directors, each departmental manager, and staff are responsible with his/her scope of operation for the implementation of the environmental system under the guidance of the EMS coordinator.

General Manager Virtual Pharmaceutical Industries

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (1)

Activities/Products and Services

Aspect	Prepared by (Concerned Manager)	Aspect	Impact	Annual Quantities	Annual Value
Activities					
Steam generation Boilers operation	Utilities manager	Light diesel oil	 Pollution Global warming CO₂ and CO emission Air pollution 	XYZ	XYZ
Products Tablets processing Services	Production manager	Dust generation	Air pollution	300 kg	600 US\$
Shipping	Transportation	Light diesel oil	Ozone depletion	50,000 L	10,000 US\$

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.1

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (2)

Significant Aspects (List)

Aspects	Prepared by (Concerned Manager)	Technique Used	Significant, Impact on Environment
Activities 1) Steam generator 2) 3) 4) 5) 6) 7) 8)	Utilities manager	 Questioner ✓ Interview Checklist Direct inspections measurements Record review Benchmarking 	Emission of CO and CO ₂
Products 1) Tablet processing 2) 3) 4) 5) 6) 7)	Production manager	 • Questioner ✓ • Interview • Checklist • Direct inspections measurements • Record review • Benchmarking 	Air pollution
Services 1) Transportation 2) 3) 4) 5) 6) 7)	Shipping manager	 • Questioner ✓ • Interview • Checklist • Direct inspections measurements • Record review • Benchmarking 	Ozone depletion

Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (3)

Internal and External Legal Requirements Review

Aspects	Reviewed by (Concerned Manager)	Current Practice	Internal Requirement	External Legal Requirements	Remarks
Activities 1) 2) 3) 4) 5) 6) 7) 8)	Utilities	Refer to Attachment 4.3.1 (B)	Yes	Local regulations	Review required
Products 1) 2) 3) 4) 5) 6) 7) 8)	Production manager	Refer to Attachment 4.3.1 (K)	Yes	Local regulations	Review required
Services 1) 2) 3) 4) 5) 6) 7) 8)	Transportation	Refer to Attachment 4.3.1 (G)	Yes	Local regulations	Review required

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.1

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (4)

Historical Review

Incidents Effecting Environment	Prepared by (Concerned Manager)	Year	Impact	Remarks
Activities 1) Steam generation 2) 3) 4) 5) 6) 7) 8)	Utilities manager	mm/dd/yyyy	None	Satisfactory
Products 1) Tablets 2) 3) 4) 5) 6) 7) 8)	Production manager	mm/dd/yyyy	None	Satisfactory
Services 1) Transportation 2) 3) 4) 5) 6) 7) 8)	Shipping manager	mm/dd/yyyy	None	Satisfactory

Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (5)

Customers Feedback

Aspects	Customer Concerned	Remarks (Concerned Manager)
Activities 1) Steam generator 2) 3) 4) 5)	Local regulation	Monitoring required
Products 1) Tablets 2) 3) 4) 5)	Employees	Dust to be controlled and monitored
Services 1) Transportation 2) 3) 4) 5)	Local population Health	Monitoring and control required

Reviewed by:		
(EMS Coordinator)	Signature	Date

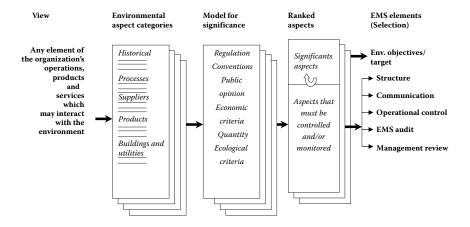
SOP no.: EMS-4.1

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (6)

General Overview of the Aspects Identification Process



Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (7)

Examples of Legal Requirements List

Regulation	Application	Procedure			
Air		xxx			
Environmental Protection Act 1990	Solvents to atmosphere	xxx			
Environmental Protection Regulation 1991	Solvents to atmosphere				
Environmental Protection Regulation 1993	Solvents to atmosphere				
Water					
Surface Waters Regulations	Discharge to water course	xyz			
Water Resource Act	Discharge to cooling water to sewer	ууу			
Control of Pollution Act	Discharge to cooling water to sewer				
Waste					
Environmental Protection Act	Waste management	zzz, xy, yz			

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (8)

Examples of Product Aspects

Product	Aspect	Amount	Comment
Motors	Energy loss Recyclability Maintenance materials Noise	Moderate High Solvents needed High	Small improvement in energy efficiency gives large change in lifetime impact
Gas turbines	Energy loss Recyclability Maintenance chemical	Low High Solvents needed	Small improvement in energy efficiency gives large change in lifetime impact
Filters for yyy duty	Resource content Recyclability Eco-toxicity	High Nil High	Filter is special waste at end of life due to contamination
Rail vehicles, aluminum bodyshell	Resource content Energy content Energy consumption Recyclability Noise production Cd contamination from conductor wire	High High High 85% Moderate Low	Many other aspects known. Full LCA to be integrated into design process
Rail vehicles, composite bodyshell	Resource content Energy content Energy consumption Recyclability Noise production Cd contamination from conductor wire	Moderate Low Low Nil Moderate Low	Many other aspects known. Full LCA to be integrated into design process

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (9)

Example of a Supplier Aspects List

Supplier	Materials	Aspects	Notes
A company	Molded plastic components	Discharge of VOCs to atmosphere. Consumption of nonrenewable resource	Emissions likely to have significant odour
B company	Plastic-insulated power cables	Discharge of VOCs to atmosphere	Low emissions
C company	Steel forgings	Consumption of large quantities of water for steel manufacture	Looking at recycle
D company	Chromium-plated metal parts	Discharge of chromium waste to watercourse	Prosecuted twice May go out of business We need alternative
E company	Solvent-based paints	Discharge of large quantities of VOCs to atmosphere	Looking to reduce emissions
F company	Hardwood flooring	Consumption of tropical hardwoods from nonmanaged forests	Supplies from managed sources now available. We will switch at end of contract
G company	Oils and lubricants	Consumption of nonrenewable resource. Sulphur dioxide emissions	Recently prosecuted for environmental damage to protected estuary
H company	Steel castings	Dust emissions to atmosphere, energy consumption, carbon dioxide emissions	Local pressure due to dust emissions
I company	Painted bodyshells	VOC emissions to atmosphere	Largest single source of VOCs in region. Abatement plan to be considered

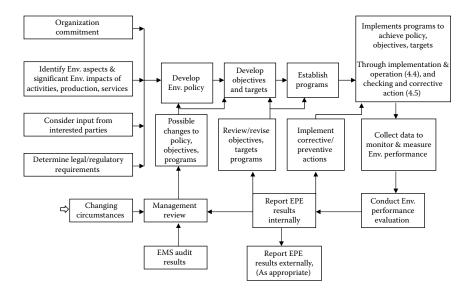
Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.1 (10)

Inter-Relation of ISO 14001 Clauses

The flow chart below shows the elements of an EMS and how they relate to each other.



SOP no.: EMS-4.1 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (11)

Initial Internal Review

Prepared by: Concerned Manager

ENVIRONMENTAL ASPECT	re	efe- ence	:	En No	nit ise	Mo tor		Leg Require		Respons for Monito		Object		Target	Set	Procedur Monitori and Cont	ng	Staff Trains		Audit Conduc		Qualificat	ion	EM Progr		Manage Revie		
	Y	N	1 .	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Remarks
NOISE POLLUTION																												
AIR POLLUTION • Emissions	~		•			~		Local legis- lation		Mr. David		OT2A OT2B OT2C		OT2A	1	EMS-111 EMS-112 EMS-113	ı	Mr. David	ı	EMS coordi- nator		Certified boiler operator		AP2		EMS coordi- nator & team		To be reviewed
SOIL AND GROUND WATER PROTECTION Hazardous materials Storage areas Tanks Ground water Spills Integrity testing (Tanks) Contractors																												

Signature

Attachment no. 4.1 (12)

Initial Internal Review

Prepared by: Concerned Manager

ENVIRONMENTAL		rence an		nit oise	Mon	itored		gal rements	Respon Moni	sible for toring		ective et		rget et	Moni	edure toring control		aff ined		dits lucted	Qualit	fication		MS grams		gement iews	
ASPECT	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Remarks
Major accidents		1		1		1		1		1		1		1		1		1		1		✓		1		1	Not Applicable
Hazards regulations		1		✓		✓		✓		✓		✓		1		✓		1		1		✓		✓		✓	Not Applicable
Ozone-depleting substances		1		✓		√		1		√		√		1		1		1		1		1		1		1	Not Applicable
Poly-chlorinated biphenyls		1		1		√		√		√		1		1		1		1		1		1		✓		1	Not Applicable
Special process requirements		1		1		√		1		1		√		1		1		1		1		1		1		1	Not Applicable
Products controlling growth of natural		1		1		~		√		√		1		1		1		1		1		1		1		1	Not Applicable
– Flora		1		✓		1		1		1		1		1		1		1		1		1		1		1	Not Applicable
– Fauna		1		1		1		✓		√		✓		1		✓	Ì	1		1		✓		1		✓	Not Applicable
- Promote wildlife		1		✓		✓		✓		✓		✓		1		✓		✓		1		✓		✓		✓	Not Applicable
 Recreational facilities 		1		1		√		1		1		√		1		1		~		1		1		1		1	Not Applicable
- Parks		1		1		1		1		1		1		1		✓		1		1		✓		1		✓	Not Applicable

1		16	
NT	_	NI	_

N = No

Reviewed by: (EMS Coordinator)

Signature

Date

SOP no.: EMS-4.1 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (13)

Initial Internal Review

Prepared by: Concerned Manager

RESOURCE MANAGEMENT		rence an		nit oise	Mon	itored		gal ements		sible for toring		ective et	Tar S	get et		edure toring ontrol		aff ined		dits ucted	Qualif	fication		AS rams		gement iews	
ASPECT	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Remarks
Water consumption	✓			1	√		✓	✓	✓		✓		1		✓		✓		√		1		1		✓		Satisfactory
• Fuel	✓			1	✓				1		√		1		✓		✓		✓		✓		✓		✓		Satisfactory
Electricity	✓			✓	✓			✓	✓		✓		✓		✓		✓		✓		1		1		✓		Satisfactory
Recycling activities	1																										
- Products		✓		✓		✓		~		√		1		✓		✓		✓		1		✓		1		√	Satisfactory
- Materials	✓	✓		✓		✓		✓		✓		1		✓		✓		✓		1		✓		1		1	Satisfactory
- Process		1		√		1		✓		*		1		✓		1		1		√		1		√		1	Refer plan required
Use of land				1		√		✓		√		1		✓		✓		✓		1		✓		1		✓	Satisfactory
Activities leading to	✓				✓			✓		✓		1		✓		✓	✓		✓		✓			1		✓	
- Odor		1		1		✓		✓		√		1		✓		✓		✓		1		√		1		1	Satisfactory
- Dust		✓		✓		✓		✓				1		✓		✓		✓		1		✓		1		✓	Satisfactory
- Vibrations		1		✓		✓		✓		✓		1		✓		✓		✓		✓		✓		✓		✓	Satisfactory
- Visual impact		1		1		1		✓		✓		1		✓		✓		✓		/		✓		1		✓	Satisfactory

Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.1 (14)

Final Management System Assesment Review (Internal) Prepared by: Concerned Manager

Management System	Yes	No	Date	Remarks
Environmental aspects identified of activities, products, or services	✓		mm/dd/yyyy	Satisfactory (or if any)
 Aspects of significance impact on environment determined 	✓		mm/dd/yyyy	Satisfactory (or if any)
 The top 5 impacts determined 	✓		mm/dd/yyyy	Satisfactory (or if any)
Objectives and targets made	✓		mm/dd/yyyy	Satisfactory (or if any)
 Policy documented authorized 	✓		mm/dd/yyyy	Satisfactory (or if any)
Policy made available to public	✓		mm/dd/yyyy	Satisfactory (or if any)
EMS integrated with			3333	
- Quality system	✓.		mm/dd/yyyy	Satisfactory (or if any)
 Health and safety 	✓		mm/dd/yyyy	Satisfactory (or if any)
- None	✓		mm/dd/yyyy	Satisfactory (or if any)
 Regulatory requirements listed 	✓		mm/dd/yyyy	Satisfactory (or if any)
 Program made for EMS 	✓		mm/dd/yyyy	Satisfactory (or if any)
 EMS responsibilities defined 	✓		mm/dd/yyyy	Satisfactory (or if any)
EMS coordinator appropriated	✓		mm/dd/yyyy	Satisfactory (or if any)
Training provide on				
- Communication	✓		mm/dd/yyyy	Satisfactory (or if any)
 Documentation 	✓		mm/dd/yyyy	Satisfactory (or if any)
 Document control 	✓		mm/dd/yyyy	Satisfactory (or if any)
 Conditions considered 				
- Normal	✓		mm/dd/yyyy	Satisfactory (or if any)
- Abnormal	✓		mm/dd/yyyy	Satisfactory (or if any)
- Accidents/emergencies	✓		mm/dd/yyyy	Satisfactory (or if any)

Reviewed by:		
(EMS Coordinator)	Signature	Date
Approved by:		
(General Manager)	Signature	Date

SOP no.: EMS-4.2

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.2 (1)

Responsibilities

Copy To: All Concerned

Environmental Responsibilities	Typical Person(s) Responsible
Establish overall direction	General manager, chief executive officer (CEO), board of directors
Develop environmental policy	President, Environmental Management System (EMS) coordinator
Develop environmental objectives, targets, and programs	d Relevant managers
Monitor overall EMS performance	Chief environmental manager
Assure regulatory compliance	Senior operating manager
Ensure continual improvement	All managers
Identify customers expectations	Sales and marketing staff
Identify suppliers expectations	Purchasers and buyers
Develop and maintain accounting procedures	Finance/accounting managers
Comply with defined procedures	All staff
Note: In the case of small industrial units the	person responsible can be the owner.
Reviewed by:	
(EMS Coordinator) Signatu	re Date

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.2 (2)

Policy Audit Checklist

To: Concerned Manager Policy No.: _____

1. Policy Statement	YES	NO	Remarks				
COMMENTS							
1. Policy statement was made prior to identification of							
environmental aspects	YES	NO	NO				
2. No modification to the policy statement were made	YES	NO	YES				
3. Policy statement links to aspects	YES	NO	YES				
4. The policy statement is supported with objectives and targets	d YES	NO	YES				
5. The employees at all levels of the organization are aw the policy statement (understand and implemented)	vare of YES	NO	YES				
6. The policy was made aware by report/display	YES	NO	Display/ Report				
7. The policy statement ensures that as a minimum, regrand legislation compliance will be achieved (if there i as part of objectives and targets	•	NO	YES				
8. The interested parties' requirements are respected	YES	NO	YES				
The compliance to the policy has resulted in the conti improvement in overall performance and is measural		NO	YES				
10. The policy has resulted in the prevention of pollution use of processes/practices/materials or products/red control pollution, which may include recycling, treatr process changes control mechanisms, efficient use of resources, and materials substitution	luce or	NO	YES				
11. The policy compliance refers to best available technol where economically viable, cost effective, and judged appropriately		NO	YES				
12. Management systems	YES	NO	YES				
 Improved definition of responsibilities, management structure, and interfaces 	nt YES	NO	YES				
 Better control and dissemination of documentation information 	/ YES	NO	YES				

1. Policy Statement	YES	NO	Remarks
Process parameters better defined and formalized	YES	NO	YES
 Defined management and operational practices 	YES	NO	YES
Efficiency of corrective/preventive action systems	YES	NO	YES
Quality of monitoring and measurement information	YES	NO	YES
Effectiveness of audit and review cycle	YES	NO	YES
13. Training/Communication	YES	NO	YES
 Staff, suppliers, contractors/subcontractors, and customer and public environmental awareness programs 	YES	NO	YES
14. Products	YES	NO	YES
Reduction of material input	YES	NO	YES
 Selection of alternative materials with less significant environmental impacts 	YES	NO	YES
 Improved recyclability of products 	YES	NO	YES
 The use of less/alternative packaging 	YES	NO	YES
 Increased efficiency in distribution/transport 	YES	NO	YES
 The design of products to minimize their environmental impacts during production, use, and disposal 	YES	NO	YES
15. Processes	YES	NO	YES
 The use of cleaner technologies that are more efficient in resource and material consumption 	YES	NO	YES
The recovery and reuse of materials	YES	NO	YES
Recyclability waste products	YES	NO	YES
 Reduction of wastes 	YES	NO	YES
 Reduction and elimination of polluting releases to the environment 	YES	NO	YES
 Prevention of environmental accidents, mitigation of their environmental impacts, and contingency planning 	YES	NO	YES
16. Natural resources	YES	NO	YES
Minimization of resource usage	YES	NO	YES
Use of renewable energy sources	YES	NO	YES
Minimization of energy consumption	YES	NO	YES
Recovery and reuse of energy	YES	NO	YES
17. Raw materials and bought-in goods	YES	NO	YES
Use renewable materials	YES	NO	YES
Use recyclable materials	YES	NO	YES
 Pressure suppliers improvement in the manufacture of raw materials 	YES	NO	YES
 Preventative measures in transport, storage, and handling 	YES	NO	YES

Remarks (if an	y):	Satisfactory							
Reviewed by:	(EMS Coordinator)		Date						

cc: General Manager

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.2 (3)

Policy Comm	dd/yyyy	the staff war ancible for the avagua	ion		
The policy was	s explained to	the staff responsible for the execut	1011.		
Code No. Name	Department	Designation	Signature		
XYZ	QA	Quality affairs director EMS coordinator			
XYZ	Administration	Administration director			
XYZ	Production	Production director			
XYZ	Packaging	Pack. & materials-handling director			
XYZ	Maintenance	Maintenance director			
XYZ	PDL	PDL director			
XYZ	QC	QC director	irector		
XYZ	QC	QC manager			
XYZ	Project	Project director			
Reviewed by:					
	(EMS Coord	linator) Signature Da	ate		

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.3 (1)

Environmental Management System Plan Copy to: Concerned Responsible

			MONTH												
S. No.	TASKS	RESPONSIBILITY	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	REMARKS
1	Review of Aspects														Completed
	 Activities 		\times												Completed
	 Product 		\times												Completed
	 Services 			\times											Completed
2	Identification of significant aspects				X										Completed
3	Development of objectives and targets					X									Completed
4	Propose policy							\times							Completed
5	Approval of policy								\times						Completed
6	EMS Program									\times					Completed
7	Evaluation of performance										\times				Completed
8	Internal Audit											\times			Completed
9	Management Review												\times		Completed
10	Preinspection													$>\!\!<$	Completed
11	Certification													$>\!\!<$	Completed
12	Surveillance Visit													> <	Completed

Reviewed by: XYZ mm/dd/yyyy
(EMS Coordinator) Signature Date

SOP no.: EMS-4.3

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.3 (2)

EMS Certification Plan

				R	esult	Path	าร			Codes:X = Executes work	Te	am I	Resp	on	sib	ilit	ies	
Goal No.	Target date	Planning	Aspects	Documentation	Metrics	Training	Auditing, checking	Start up	Certification	D = Takes decision solely d = Take decision jointly R = Responsible for progress C = Must be consulted I = Must be informed A = Available to advise Goal Definitions	Team leader	Team member 1	Team member 2	Team member 3				All employees
1		P								When management support has been obtained, and resources and	X	I	Ι	Ι	Ι	Ι	Ι	Ι
2		L								deliverables agreed When an initial review of the business has been completed					Ι	Α	I	
3		Į								When a milestone plan for the EMS project has been agreed by the project team	d	d	d	d	Ι	A		
4			•							When the company's environmental aspects have been agreed	d	d	d	d		A		
5			•							When the legal requirements and other constraints have been identified	R							
6										When site policy, objectives and targets have been agreed	X	Χ	Х	X	D		Ι	Ι
7				1						When system procedures, work instructions, and controls have been designed and issued	X	X	X	X		С	Ι	
8					Á					When metrics/feedbacks on environmental performance are in place	X	X	X	X	Ι			
9						Y				When the key staff have been trained and all staff are aware of thecompany's program	R						Ι	
10							/			When audit program is running	R	I	Ι	I		I		
11							Ì	\		When first management review has taken place	R	I	Ι	Ι	Χ	Χ	Ι	
12							•	\		When the EMS has been checked against the standard	R	I	Ι	Ι				
13							1			When the EMS has been checked against the significant aspects	R	I	Ι	Ι				
14									\	When the EMS has been checked for loop closure	R	I	I	Ι				
15									1	When the initial visit by the certifier has taken place	R	I	I	Ι	Ι	Ι		
16									•	When the audit visit has taken place	R	I	Ι	Ι	Ι	Ι	I	Ι
17									Ţ	When certification has been obtained	R	I	Ι	Ι	Ι	Ι	I	Ι

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.3
Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.3 (3)

Example of Approach to Achieving a Certified EMS Note: Modify the approach for your company

- When management support has been obtained and resources agreed
- 2. When the **Legal Requirements** have been identified
- When an Initial Review of the business has been completed and when the company's Environmental Aspects have been identified
- 4. When a milestone plan for the EMS project has been agreed
- 5. When **Policy**, **Objectives**, and **Targets** have been agreed
- 6. When the **Environmental Program** has been agreed
- When System Procedures, Work Instructions, and controls have been designed and issued
- 8. When metrics/feedbacks on **Environmental Performance** are in place
- When the key staff have been Trained and all staff are Aware of the company's program
- 10. When the **Audit** program is running
- 11. When the first **Management Review** has taken place

- Top management agreement and active support. Resources needed include money, time, and people
- Constrains, including regulatory, insurance, contractual, business requirements, public perceptions, views of other interested parties, etc.
- Rate and rank environmental aspects to identify the most significant. Include potential liabilities from the initial review
- Plan project and agree project responsibilities. Identify and obtain support of the project team
- Agree policy, objectives, and targets. Must be relevant to the significant aspects
- Design and agree program. Agree responsibilities. Needs to be simple and easily understood
- Design, draft, agree, implement. Documentation should be so clear, easily understood, and as short as possible. Involve employees in writing work instructions. Try to use flow diagrams, not text
- Design, implement. Relating metrics to turnover or output will allow benchmarking against other companies
- Train key staff. Incorporate into existing staff a training program, if appropriate. Implement program of staff briefings to ensure awareness of company staff
- Design audit protocols and program. Implement. Auditors and audit program must be credible.
- Implement. Needs to be at least one management review to obtain certification

12. When the EMS has been checked against the standard	Fill in the clause trace table. Fill any missing or incomplete areas
13. When the EMS has been checked against significant aspects	Confirm all significant effects managed
14. When the EMS has been checked for loop closure	Check whether all loops closed, e.g., corrective actions, nonconformances, and communications
15. When the Initial Visit by the certifier has taken place	Incorporate any changes required
16. When the Audit Visit has taken place	Close out any nonconformances
17. When Certification has been obtained	Success

SOP no.: EMS-4.3.1

Issue date: mm/dd/yyyy
Revision no.: New

Attachment no: 4.3.1 (1) A

Register of Environmental Impacts

Environmental Aspect Significance Evaluation Matrix

SOURCE: A1. Waste Water Treatment Recy			PRODUCT: N/A	SERVICES: N/A						
LOCATION: Waste Water Treatment Plant		A	REA Utilities							
ENVIRONMENTAL ASPI	ECT	IN	OTHER FORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE				
B1. Controlled and uncontrolled emissions to atmosphere		 degradation, natural No controlled and un Total amount of wast 92037 M² 	t design is based on biological principle controlled emission are emitted e water treated in year 2000 = can still accommodate 25% more	-	Pollution prevention	PI-001				

SOURCE: A1. Waste Water Treatment	ACTIV Recyc		DATE: mm/dd/yyyy	PRODUCT: N/A		SERVICES: N/A	
LOCATION: Waste Water Treatment Pla	ant		А	REA Utilities			
ENVIRONMENTAL ASP	ECT		IN	OTHER FORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
C1. Controlled and uncont discharges to water	rolled	us • Th • Ca • A	sed only for irrigati ne water quality is apacity 500 m³/day	suitable for irrigation s working at 70% of its capacity and	_	Marine water conservation Marine flora and fauna conservation	PI-002 PI-003
D1. Contamination of land			ne waste water trea intamination	tment process does not involve land	_	Marine water preservation Natural flora and fauna conservation Preservation of land	PI-002 PI-004 PI-005
E1. Solid Waste		• Ca	arton boxes, insigni	er to local municipality for safe	_	Health & safety Pollution prevention	PI-006 PI-001
F1. Use of raw materials an natural resources	nd other		atalyst is used for b antities are insigni	iological degradation and the ficant	_	No impact	PI-007
G1. Use of energy		• El	ectrical energy con	rom RAK electricity department sumption is insignificant and the nly if sufficient effluent is to be treated	Natural resource utilization	No impact	PI-007
H1. Use of water		• Tl	ne waste water is 90	% recycled for irrigation water	_	Good housekeeping, irrigation around the plant	PI-008
I1. Noise, odour, dusts, vibration and visual impact			ne process is contro o significant odour is an open space op	is produced	_	No impact Pollution prevention	PI-007 PI-001
J1. Effects on ecosystems			satisfactory (under control) and does or impact on ecosystem	_	Preservation of natural flora and fauna	PI-110	

K1. Upstream effects—energy, water, and raw materials	The plantation helps in maintaining the ecosystem	_	Promotes flora and fauna Good housekeeping Helps promote wildlife preservations and birds	PI-110 PI-008 PI-111
L1. Downstream effects	Irrigation	_	_	_
M1. Past effects	Discharge of waste water to municipality drainage system	Marine water contamination	_	NI-001
N1. Future effects	Maintain ecosystem	_	Marine water conservation Pollution prevention	PI-002 PI-001
O1. Selection test	• N/A	_	_	_
P1. Environmental impact evaluation	• N/A	• N/A	_	_
Q1. Identification of level of significance	As follows	As follows	_	_

Key: 0 = Insignificant, 1–20 = Slightly significant, 21–35 = Significant, 36–Max. = Highly significant, PI = Positive impact code, NI = Negative impact.

		Coı	nditions / Scor	e					Weigl	nting Fac	ing Factor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	Tot	al	
Legislation	Existing	3	Impending			3	None	3	3×	2	6	а	
	Local legislation No. 16												
	Personal protection equipment												
	Local information bulletin,												
	Appendix 1,												
	1.1 Regulation on the re-use and land												
	disposal of water and sludge.												
	1.2 Regulation on the disposal of												
	waste water into marine environment.												
	Local official information Appendix 1												
	1.3 Regulation on air pollution												
	control from stationary sources												
	1.4 Occupational health & safety												
	regulation												
	1.5 Protected areas regulations												
Environmental	Known detrimental		Possible		Limited		No	0	0×	3	0	b	
damage			detrimental		detrimental		detrimental						
							None						
Interested	Considerable interest	3	Moderate		Little interest		No interest	0	3×	2	6	С	
parties	Local legislation		interest										
Quantity	High		Medium	+	Low		Nil	0	0×	3	0	d	
						1	None						

			B: Ranking of	Envir	onmental E	Effect	Under	Otl	her Opera	ating	g Conditi	on	s				
					Condit	ions/	Score								To	tal	
Elements	Condition	12	Condi	tion		6	С	ond	lition	3		(Condition	0			Remarks
Abnormal operations	_		Increased environ	menta	nl impact		No C		nge known	3	Reduced impact		nvironmental		3	а	
Accident / emergency			Increased environ: • Accidental over holding tank			6	No cl	nan	ge		Reduced impact		nvironmental		6	b	
Past activities	Evident/requires action —		Possible damage/ evaluate • Drained in sev • Marine polluti	vage s		6		-	_		No dam	nag	e	0	6	С	
Planned activities			Increased environ	menta	ll impact		No cl	han	ge		impact • Mair	t nte	nvironmental nance of waste reatment plant.	0	0	d	
Other Operati	ng Conditions Total S	core	= (a+b+c+d)	Tota	al B	•									15		
			C: 0	Cost F	actor Rank	cing o	f Envii	oni	mental Ef	ffect	s						
Elements	Very high	4	High	3	Med	lium		2	L	ow		1	None	0	To	otal	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$				<10,000 US\$							0	
Estimated	N/A		N/A		N/A				N/A				N/A			0	
Cost Factor	Total C															0	
FINAL SCOR	$E: = A + B + C \qquad I$	denti	fication Level of Sig	nifica	nce											27	
Reviewed by: (EMS Coordina	ator)		Sign	ature		_			-		Da	ate					

EMS no.: 4.3.1

Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) B

Environmental Aspect Significance Evaluation Matrix

SOURCE: A2. Steam Generation/ Boilers (Light Diesel Oil)	ACTIVITY: Steam Generation	DATE: mm/dd/yyyy	PRODUCT: N/A	SERVICES: Steam Generation						
LOCATION: Boiler Plant										
ENVIRONMENTAL ASPE	СТ	ОТІ	HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE				
B2. Controlled and uncontrolled emissions to atmosphere	Two and to Two experience Light The 6	boilers are used hey meet the EL old boilers purch ses in fuel bills one of EU environties oil boiler	s are in operation; load is 5 ts/h for plant I steam generations operations J standard for environmental compliance hased in 1982 are old and have high. These two boilers will be replaced by a commental compliance to reduce emissions are used; capacity is 5 t steam/h throlled, and monitoring of CO ₂ , CO, urried out	 Global warming CO₂ and CO emissions Air pollution/soot 	_	• NI-002 • NI-003 • NI-004				

	 Light diesel oil is used, which is of good quality Approximate consumption is 10,000 gallons/month The boilers are of compact type CO₂ and CO are produced in insignificant quantities The process does not involve compression so nitrogenous compounds are not emitted. 			
C2. Controlled and uncontrolled discharges to water	_	_	Marine water preservation	PI-002
D2. Contamination of land	Light diesel storage tanks are bunded	_	Preservation of land	PI-005
E2. Solid waste	Solid waste is oil used in pumps, handed over to service stations for safe disposal	_	Pollution prevention	PI-001
F2. Use of raw materials and other natural resources	Light diesel oil	Global warming Consumption of natural resources	_	NI-002 NI-005
G2. Use of energy	Electrical consumption is insignificant	Natural resource utilization	No impact	PI-007
H2. Use of water	90% of water used is recovered through condensation, only 10% is the loss, which is insignificant.	_	No impact	PI-007
I2. Noise, odor, dusts, vibration, and visual impact	The overall process is self-contained. No dust is produced. The noise due to boilers operations is slightly high; staff is provided with ear protection Boiler operation generates smoke (dust) that is monitored and controlled by boiler tuning and maintenance, insignificant impact	_	No impact	PI-007
J2. Effects on ecosystems	The overall system is satisfactory (under control) and does not lead direct threat to the ecosystem	Global warming	_	NI-002
K2. Upstream effects—energy, water, and raw materials	 Reduced emission of CO₂ and CO level, through adequate monitoring 	_	Pollution prevention	PI-001
L2. Downstream effects	Reduced emission of CO ₂ and CO	_	Reduced global warming	PI-111

SOURCE: A2. Steam Generation/ Boilers (Light Diesel Oil)	2. Steam Generation/ Steam			PRODUCT: N/A	Ste	SERVICES: eam Generation				
LOCATION: Boiler Plant			AREA: Boiler Room							
ENVIRONMENTAL ASPE	СТ		ОТН	HER INFORMATION	IMPACT IMPACT +VE					
M2. Past effects		• Increa	sed emission of	CO ₂ and CO	Air pollution	_	NI-004			
N2. Future effects		• Reduc	ed emission of	CO ₂ and CO	_	Pollution prevention	PI-001			
O2. Selection test		• N/A			• N/A	_	_			
P2. Environmental impact evaluation	As abo	ove		As above	_	_				
Q2. Identification of level of significance		As foll	lows		As follows	_	_			

Key: 0 = Insignificant, 1–20 = Slightly significant, 21–35 = Significant, 36–Max. = Highly significant, PI = Positive impact code, NI = Negative impact.

	A: R	ank	ing of Environmental l	Effe	cts Under Norm	al O	peration Condit	ions					
			Conditions/Sco	ore					Weig	hting Fact	tor		
Elements	Condition	3	Condition 2 Condition 1 Condition		0	Multiply	Factor	То	tal	Remarks			
Legislation	Existing Local official legislation No. 16: Personal protection equipment No. 40: Examination and certification of boilers and pressure vessels. No. 57: Bunding of storage tanks and transfer facilities Local official information bulletin, Appendix 1, 1.2 Regulation on air pollution control from stationary sources 1.2 Occupational health & safety regulation		Impending				None	3	3	2	6	a	
Environmental damage	Known detrimental		Possible detrimental • Temporary increase of CO ₂ and CO level	2	Limited detrimental		No detrimental	0	2×	3	6	b	
Interested parties	Considerable interest local municipality	3	Moderate interest		Little interest		No interest None	0	3×	2	6	С	
Quantity	High 10,000 gallons/month	3	Medium		Low	1 1	Nil		3×	3	9	d	
Normal Operating	g Conditions Total = $(a + b + c)$	+d	Total A								27		

			B: Ranking of Environm	enta	l Effect Under Other Operating	g Co	onditions				
			(Conc	litions/Score				To	tal	
Elements	Condition	12	2 Condition 6 Condition 3 Condition 0								Remarks
Abnormal operations	_		Increased environmental impact • No monitoring and control of CO ₂ and CO	6	No change		Reduced environmental impact	3	6	а	
Accident / emergency			Increased environmental impact		No change • Only possible if storage vessel leaks due to natural disaster, e.g., earthquake	3	Reduced environmental impact	3	3	b	
Past activities	Evident/ requires action —		Possible damage/difficult to evaluate —	6	_		No damage	0	6	с	
Planned activities			Increased environmental impact		No change	3	Reduced environmental impact Planned activity reduces environmental impact	3	3	d	
Other Operati	ng Conditions Tot	al Sc	core = (a + b + c + d) Total B						18		

	C: Cost Factor Ranking of Environmental Effects											
Elements	Very High	4	High	3	Medium	2	Low	1	None	0	Total	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0	
Estimated	N/A 1.5 million US\$		N/A		N/A		N/A		N/A		0	
Cost Factor	Cost Factor Total C										0	
FINAL SCORE: = A + B + C Identification Level of Significance											45	

Remarks: Action program required fo	Remarks: Action program required for the replacement of old boilers to control emissions									
Reviewed by:										
(EMS Coordinator)	Signature	Date								

EMS no.: 4.3.1

Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) C

Environmental Aspect Significance Evaluation Matrix

SOURCE: A3. Burning of Diesel (Electricity Generation)	ACTIV Pow Gener	ver	DATE: nm/dd/yyyy	PRODUCT: N/A	_	SERVICES: icity Generation			
LOCATION: Generator Plant									
ENVIRONMENTAL ASPECT OTHER INFORMATION					IMPACT -VE	IMPACT +VE	IMPACT CODE		
B3. Controlled and uncont emissions to atmosphere	 3. Controlled and uncontrolled emissions to atmosphere There are six standby generators Only used when power fails Industrial quality diesel is used Operational hours variable The emission are controlled by efficient maintenance, which is insignificant Annual competition of diesel ≅ 600 gallons Uncontrolled emissions are CO₂, CO, and nitrogen compounds Not monitored 				Health & safety Global warming Smog	_	• NI-006 • NI-002 • NI-006		

C3. Controlled and uncontrolled discharges to water	Mobile oil discarded is handed over to the local municipality for safe disposal	_	Marine water conservation	PI-002
D3. Contamination of land	1800 L mobile oil is drained and transferred to local municipality for disposal at the time of maintenance every year	_	Preservation of land	PI-005
E3. Solid waste	Air filters, insignificant quantity sold to contractors	_	No impact	PI-007
F3. Use of raw materials and other natural resources	Diesel is stored in closed tanks bunded	_	Pollution prevention	PI-001
G3. Use of energy	Diesel is used to product energy	Global warning Smog	_	NI-002 NI-006
H3. Use of water	Water is used in radiators, insignificant quantities	_	No impact	PI-007
I3. Noise, odor, dusts, vibration, and visual impact	Creates noise; staff use ear protection, since it is away from the administration block, noise is insignificant Vibration is localized; does not effect environment, insignificant Smoke dust, insignificant	_	No impact No impact No impact	PI-007 PI-007 PI-007
J3. Effects on ecosystems	• Generates CO ₂ , CO, and nitrogen compounds	Health & safety Global warning	_	NI-006 NI-002
K3. Upstream effects—energy, water, and raw materials	Variable	Global warming Health & safety	_	NI-002 NI-006
L3. Downstream effects	Variable	Global warming Health & safety	_	NI-002 NI-006
M3. Past effects	Uncontrolled emissions	Global warmingAir pollutionHealth & safety	_	NI-002 NI-004 NI-006
N3. Future effects	Insignificant	_	Pollution prevention Health & safety	PI-001 PI-113

SOURCE: A3. Burning of Diesel (Electricity Generation)	ng of Diesel Power		PRODUCT: N/A	SERVICES: Electricity Generation						
LOCATION: Generator Plant		Plant I, II, III	AREA: , & Administration, Housing							
ENVIRONMENTAL ASPI	ЕСТ	ОТН	ER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE				
O3. Selection test	• N/	A		• N/A	_	_				
P3. Environmental impact evaluation	• As	above		As above	_	_				
Q3. Identification of level of significance	of • As	follows		As follows	_					

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ranking of	Env	ironmental Effe	cts	Under Normal	Ope	ration Condition	ns					
		Co	nditions/Score						Weig	hting Fact	or		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	To	tal	Remarks
Legislation	Existing Local official legislation No. 16 Personal protection equipment Local official information bulletin, Appendix 1 1.1 Regulation on air pollution control from stationary sources 1.2 Occupational health & safety regulation 1.3 Noise control regulation Local official legislation No. 5: Oil spill response No. 10: Guarding of dangerous machinery No. 29: Request for the discharge of waste gases, fumes, & dust to atmosphere		Impending				None		3x	2	6	a	
Environmental damage	Known detrimental Global warming Air pollution Health & safety	3	Possible detrimental		Limited detrimental		No detrimental		3×	3	9	b	
Interested parties	Considerable interest Local municipality	3	Moderate interest		Little interest		No interest		3×	2	6	с	
Quantity	High		Medium		Low	1	Nil	0	1×	3	3	d	
Normal Operat	ing Conditions Total = $(a + b + c + d)$	Tot	al A				•		•		24		

	B: Ranking of Environmental Effect Under Other Operating Conditions												
			(Conc	ditions/Score				Total				
Elements	Condition	12	Condition	6	Condition	3	Condition	0			Remarks		
Abnormal operations			Increased environmental impact No control over the emission	6	No change		Reduced environmental impact		6	а			
Accident/ emergency			Increased environmental impact • Accidental fire in reserve diesel	6	No change		Reduced environmental impact		6	b			
Past activities	Evident/ requires action		Possible damage/difficult to evaluate	6	Emission of toxic gases	3	No damage • No diverse events reports		3	с			
Planned activities			Increased environmental impact		No change	3	Reduced environmental impact Reduced level of emission due to planned maintenance	0	0	d			
Other Operati	ng Conditions Tot	al So	core = (a + b + c + d) Total B						15				

	C: Cost Factor Ranking of Environmental Effects											
Elements	Very High	4	High	3	Medium	2	Low	1	None	0	Total	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0	
Estimated	N/A		Applicable <1,00.000 US\$	3	N/A		N/A		N/A		3	
Cost Factor	Cost Factor Total C										3	
FINAL SCORE: = A + B + C Identification Level of Significance											42	

Remarks: Action program required to procure equipment for the monitoring of emission due burning of diesel (monitoring of CO, CO₂, and nitrogen compounds injurious to health)

Reviewed by:
(EMS Coordinator)

Signature

Date

EMS no.: 4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) D

Environmental Aspect Significance Evaluation Matrix

SOURCE: A4. HVAC System CFCs	ACTIVITY: Cooling	DATE: mm/dd/yyyy	PRODUCT: N/A		SERVICES ES: ir Conditioning	
LOCATION: Technical Floor Plant I, II, III, & Administration Plant I			AREA: III, & Administration Offices			
ENVIRONMENTAL ASP	ECT	го	THER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
B4. Controlled and uncont emissions to atmosphere	air co • As ponew legis none • Only	onditioning equip er company polic purchases are in c ation. As new im nvironmental-frie few old refrigera	comprised of old and new refrigeration and ment y and local official legislation—after 1996 all compliance with the provisions of local ports after 1996 do not permit endly gases in the cooling systems tors are filled with CFCs ensures that they are not leaked	Health & safety Ozone depletion	_	NI-006 NI-007

	New equipments purchased; it is ensured they do not contain CFCs 11, 12, 113, 114, 115, and halogenated CFCs New equipments are free from R13a and mostly contain R11&R22 which is a better choice New equipments are free from ammonia Gas is refilled in-house through recycling procedure where possible The venting of controlled refrigerant is not permitted during maintenance The yearly purchase of gases is insignificant and amounts only to approximately in kilograms			
C4. Controlled and uncontrolled discharges to water	At the time of HVAC system maintenance, the water is drained from the chillers but recycled through waste treatment plant The maintenance is once in a year	_	Irrigation	PI-008
D4. Contamination of land	 Oil changed from the chillers at the time of maintenance is insignificant ≈ 50 gallons Disposal of oil is managed by handing over to service stations for disposal through local municipality 	_	Land preservation Marine water preservation	PI-005 PI-002
E4. Solid waste	 Old AC metal ductings are reused for small projects AC filters are reused where possible or sold to recyclers Oil from the chillers is handed over to service stations for disposal by local municipality 	_	Pollution prevention	PI-001
F4. Use of raw materials and other natural resources	Gases R13a and R11 are used for refilling Purchased quantities of gases are insignificant for the HVAC system	_	Reduction in ozone depletion	PI-010
G4. Use of energy	 High energy consumption An energy management system is installed to monitor energy consumption Energy consumption is optimized by schedule maintenance and temperature control Energy saving models to be installed to reduce energy consumption 	High energy consumption	_	NI-008

SOURCE: A4. HVAC System CFCs		TIVITY:	DATE: mm/dd/yyyy	PRODUCT: N/A	1	SERVICES ES:	
LOCATION: Technical Floor Plant I, II, & Administration			3333	AREA: III, & Administration Offices			
ENVIRONMENTAL ASP	ЕСТ			HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
H4. Use of water			s—28,000 gallon	water is used in a closed-loop system in s; however, at the time of maintenance it is	_	Water recycling Irrigation	PI-009 PI-008
I4. Noise, odor, dusts, vibra and visual impact	ation,		on and noise ins te area, called te	significant. The equipment is installed in a chnical area	_	No impact	PI-007
J4. Effects on ecosystems		The ov	erall effect will l	pe ozone reduction	Ozone depletion Health & safety	_	NI-007 NI-006
K4. Upstream effects—ene water, and raw materials	rgy,	• Reduc	tion in use of CF	Cs	_	Health & safety Ozone restoration	PI-006 PI-112
L4. Downstream effects		Opera	tion control on C	CFCs	_	Ozone restoration	PI-112
M4. Past effects		• Excess	ive use of CFCs		Ozone depletion	_	NI-007
N4. Future effects		• Replac	ement of CFCs l	by using ozone-friendly gases	_	Ozone conservation Health & safety	PI-112 PI-113
O4. Selection test		N/A			• N/A	_	_
P4 Environmental impact evaluation		As above			• N/A	_	_
Q4. Identification of level of significance	of	As follows			As follows	_	_

Key: 0 = Insignificant, 1–20 = Slightly significant, 21–35 = Significant, 36–Max. = Highly significant, PI = Positive impact code, NI = Negative impact.

	A: Ranking of Environmental Effects Under Normal Operation Conditions Conditions/Score Weighting Fact													
Elements	Condition	3	Condition	2	Condition	1	Condition	0				tal	Remarks	
Legislation	Existing Local legislation No. 16 Personal Protection Equipment Local information on Appendix 1 1.1 Regulation on air pollution control from stationary sources 1.2 Occupational health & safety regulation Environmental protection & safety Guidelines. No. 29: Requirements for the discharge of waste gases fumes and dust to the atmosphere. No. 20: Personal protective equipment No. 58: Policy on the control of ozone deleting substances.	3					None		3×	2	6			
Environmental damage	Known detrimental	1	Possible detrimental		Limited detrimental Continous use of CFCs may cause limited reduction of ozone layer	1	No detrimental		1×	3	3	b		
Interested parties	Considerable interest Local legislation	3	Moderate interest		Little interest		No interest		3×	2	6	С		
Quantity	High										3	d		

	B: Ranking of Environmental Effect Under Other Operating Conditions													
			Condition	ns/Sc	ore				То	tal				
Elements	Condition	12	Condition	6	Condition	3	Condition	0			Remarks			
Abnormal operations	_		Increased environmental impact • Venting of CFCs at the time of maintenance	6	No change	3	Reduced environmental impact	0	6	а				
Accident / emergency			Increased environmental impact Only possible if there is a natural disaster, e.g., earthquake and gas kit leakage	6	No change	3	Reduced environmental impact	0	6	b				
Past activities	Evident/ requires action —		Possible damage/difficult to evaluate • Before 1996, the old systems were based on CFCs • Ozone depletion	6	_		No damage	0	6	С				
Planned activities			Increased environmental impact		No change	3	Reduced environmental impact Planned maintenance and programs will reduce the impact	3	3	d				
Other Operati	ng Conditions Tot	al So	core = (a + b + c + d) Total B		•		,		21					

	C: Cost Factor Ranking of Environmental Effects														
Elements	Very high	4	High	3	Medium	2	Low	1	None	0	Total	Remarks			
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0				
Estimated	N/A		<1,00.000	3			N/A		N/A		3				
Cost Factor	Total C										3				
FINAL SCOR	NAL SCORE: = A + B + C Identification Level of Significance														

Reviewed by:
(EMS Coordinator)
Signature

Remarks: Action program required to replace equipment with CFCs and ensure further decrease in emission of R11 and R12.

Reviewed by:
(EMS Coordinator)
Date

EMS no.: 4.3.1

Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) E

Environmental Aspect Significance Evaluation Matrix

SOURCE: A5. Plastics Dosing Cups Manufacturing Plant	ACTIVITY: Manufacturing	DATE: mm/dd/yyyy	PRODUCT: Plastics Dosing Cups	Plastics Dos	SERVICES: sing Cups Manufacturi	ng
LOCATION: Near the Administration B	Block	Plastics Do				
ENVIRONMENTAL ASPI	ECT	O	IMPACT -VE	IMPACT +VE	IMPACT CODE	
B5. Controlled and uncontremissions to atmosphere	• Plasti • The d • High- as a r	osing cups are p density polyeth	nay happen ased and stored in a secured store provided with syrups and suspensions ylene and low-density polyethylene are used ch is food grade nonharmful	_	No impact Air pollution prevention	PI-007 PI-001
C5. Controlled and uncontrolled discharges to water	olled • N/A			_	Marine water prevention	PI-002

D5. Contamination of land	• N/A	_	Land preservation	PI-005
E5. Solid waste	The following solid waste results from plastic dosing cups manufacturing process • Discarded dosing cups, paper bag, and shrink-wrap plastic	_	_	_
F5. Use of raw materials and other natural resources	Materials used are converted into finished products Process losses are NIL	_	Resource optimization	PI-113
G5. Use of energy	Energy is resourced from local electricity department, insignificant	Natural resource utilization	No impact	PI-007
H5. Use of water	• N/A	_	No impact	PI-007
I5. Noise, odor, dusts, vibration, and visual impact	The overall plastic dosing cups process is self-contained. No dust is produced The packaging process is noisy but within 90 db., which is satisfactory	_	_	_
J5. Effects on ecosystems	The overall system is satisfactory (under control) and does not lead to major threats to the economic system	_	No impact	PI-007
K5. Upstream effects—energy, water, and raw materials	The dosing cups in circulation in public should dispose for recyclers	Waste generation	_	NI-009
L5. Downstream effects	The dosing cups in circulation in public should dispose for recyclers	Waste generation	_	NI-009
M5. Past effects	The dosing cups in circulation in public should dispose for recyclers	Waste generation	_	NI-009
N5. Future effects	The dosing cups in circulation in public should dispose for recyclers	Waste generation	_	NI-009
O5. Selection test	• N/A	• N/A	• N/A	_
P5. Environmental impact evaluation	As above	As above	As above	_
Q5. Identification of level of significance	As follows	As follows	As follows	_

Key: 0 = Insignificant, 1–20 = Slightly significant, 21–35 = Significant, 36–Max. = Highly significant, PI = Positive impact code, NI = Negative impact.

A: Ranking of Environmental Effects Under Normal Operation Conditions														
	Conditions/Score Weighting Fa													
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	or Total		Remarks	
Legislation	Existing Local official legislation No. 16 Personal Protection Equipment Local official information on Appendix 1 1.1 Regulation on air pollution control from stationary sources 1.2 Occupational health & safety regulation 1.3 Noise control regulation	Impending				None	3	3×	2	6	а			
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental • Waste generation dust • Air pollution • Metal sheet	1	No detrimental		1×	3	3	ь		
Interested parties	Considerable interest • Staff awareness and safety • Local legislation	3	Moderate interest		Little interest		No interest		3×	2	6	с		
Quantity	High Medium Low 1 Nil × 3 Insignificant waste 0× 3													
Normal operati	ng conditions total = (a + b + c + d)		Total A								15			

			B: Ranking of	Envir	onmental Effect u	nder	other Opera	ting	Conditio	on	s				
					Conditions/Sc	ore							To	tal	
Elements	Condition	12	Cond	lition		6	Condition	3			Condition	0			Remarks
Abnormal operations	_		Increased environment Not using mask maafter long exposure	y lead	to health & safety		No Change	3	Reduced	d e	environmental impact	0	6	a	
Accident / emergency			Increased environmentAccidental fire (resiAdequate fire fight	in)		6	No change	3	Reduced	d€	environmental impact	0	6	b	
Past activities	Evident/ requires action —		Possible damage/diffic	ult to	evaluate		_		No dam	ag	5e	0	0	С	
Planned activities			Increased environment	al imp	pact		No change		• Plan	ne	environmental impact ed activities reduce num waste	0	0	d	
Other operation	ng conditions total	scoı	e = (a+b+c+d)	Total	В		•						12		
			C: (Cost F	actor Ranking of	Envi	ronmental Ef	fect	s						
Elements	Very high		4 High	3	Medium		2 Lo	ow	1	1	None	0	Tota	ıl	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$						0		
Estimated	N/A		N/A		N/A		Applicab <10,000 US\$	le	1		N/A		1		
Cost Factor Total C												1			
FINAL SCOR	E: = A + B + C	Iden	tification Level of Signi	ficano	ee								28		

Remarks: Action program required	to increase public awareness to promote pollution preve	entive and encourage recycling
Reviewed by:		
(EMS Coordinator)	Signature	Date

EMS no.: 4.3.1 Issue date: mm/dd/yyyy

Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) F

Environmental Aspect Significance Evaluation Matrix

SOURCE: A6. Aluminum Caps Manufacturing Plant	ACTIVITY: Manufacturing	DATE: mm/dd/yyyy	PRODUCT: Aluminum Caps		SERVICES: Caps Manufacturing	.
LOCATION: Near the administration b	olock	Alumin				
ENVIRONMENTAL ASP	ECT	O	THER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
B6. Controlled and uncont emissions to atmosphere		process does not sphere	lead to controlled or uncontrolled emission to	_	No impactAir pollution prevention	PI-007 PI-001
C6. Controlled and uncont	rolled • None	:		_	Marine water conservation	PI-002
D6. Contamination of land	• None	:		_	Land conservation	PI-005

E6. Solid waste	The following solid waste results from the process Rejected aluminum caps Waste aluminum sheets Aluminum dust Above materials are sold to local buyers and contractors for recycling	_	_	_
F6. Use of raw materials and other natural resources	Materials used are converted into finished products Losses are insignificant	Resources utilization	_	NI-010
G6. Use of energy	Energy is resourced from local electricity department, insignificant savings are achieved by planned activities	Natural resource utilization	Energy conservation	PI-112
H6. Use of water	• N/A	_	No impact	PI-007
I6. Noise, odor, dusts, vibration, and visual impact	The overall process is self-contained. No significant dust is produced The process is noisy; staff use hearing protection & safety mask	Health & safety	_	NI-006
J6. Effects on ecosystems	The overall system is satisfactory (under control) and does not lead to major threats to the ecology	Consumption of natural resources	_	NI-010
K6. Upstream effects—energy, water, and raw materials	Aluminum shortage, consumption of reserves	Consumption of natural resources	_	NI-010
L6. Downstream effects	Aluminum waste generation	_	Increased recycling	PI-009
M6. Past effects	Aluminum waste generation	_	_	_
N6. Future effects	Aluminum waste generation	_	_	_
O6. Selection test	• N/A	• N/A	• N/A	_
P6. Environmental impact evaluation	As above	As above	As above	_
Q6. Identification of level of significance	As follows	As follows	As follows	_

Key: 0 = Insignificant, 1–20 = Slightly significant, 21–35 = Significant, 36–Max. = Highly significant, PI = Positive impact code, NI = Negative impact.

	A: Ranking of Environmental Effects under Normal Operation Conditions													
			Condition	s/S	core				Weig	hting Fa	ctor			
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	To	tal	Remarks	
Legislation	Existing Local legislation No. 16 Personal Protection Equipment Local official information on Appendix 1 1.1 Regulation on air pollution control from stationary sources 1.2 Occupational health & safety regulation 1.3 Noise control regulation Local Guidelines No. 52: Metal finishing industries		Impending				None	3	3×	2	6	а		
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental		No detrimental None	0	0×	3	0	b		
Interested parties	Considerable interest • Personnel safety • Local legislation 3 Moderate interest interest Little interest No interest 0 3									2	6	С		
Quantity	High		Medium		Low	1	Nil • Nonquantifiable	0	0×	3	0	d		
Normal operati	ing conditions total = (a + b + c + d)		Total A								12			

	B: Ranking of Environmental Effect under other Operating Conditions																
					Condi	tions	Score/	:							То	tal	
Elements	Condition	12	Condi	tion		6	С	ondi	tion	3		(Condition	0			Remarks
Abnormal operations	_		Increased environme	ental imp -	oact		No change • Not kno			3	Reduced	vironmental impact		3	а		
Accident/ emergency	emergency • Accidental cuts due to unsafe handling health & safety														6	b	
Past activities	Evident/ requires action —		Possible damage/dim	fficult to	evaluate			_	-		No dam • Not	0	vn	0	0	С	
Planned activities			Increased environme	ental imp	oact		No	chang	ge	3	• Plan	ned	vironmental impact activities will reduce safety impact	0	0	d	
Other Operati	ing Conditions To	al So	core = (a + b + c + d)	Tot	al B										9		
			(C: Cost I	actor Ranl	king	of Env	viron	mental	Effe	ects						
Elements	Very High		4 High	3	Me	dium		2		Lo	w	1	None	0	Tota	al	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 U	JS\$			<10,00	0 US	5\$				C		
Estimated	Stimated N/A N/A N/A Applicable 1 N/A 1 N/A 1 N/A													1			
Cost Factor Total C													1				
FINAL SCOR	E: = A + B + C	Iden	tification Level of Sig	gnifican	ce										22		

Remarks: <u>Action program required to</u>	increase public awareness for safe disposal and end	courage recyling
Reviewed by:		
EMS Coordinator)	Signature	Date

EMS no.: 4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) G

Environmental Aspect Significance Evaluation Matrix

SOURCE: A7. Transportation	ACTIVITY: Shipping	DATE: mm/dd/yyyy	PRODUCT: All Products	SERVICES: N/A		
LOCATION ENVIRONMENTAL ASP	ЕСТ		AREA: nside and Outside HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
B7. Controlled and uncont Emissions to atmosphere	Exhau Partic Nitro The v efficie All ve of reg Daily	ust, emission, ex culate in air gen oxides ehicles are subje ency ehicles are inspe gistration by loca	ect to regular maintenance to achieve max. cted for exhaust emission yearly at the time	Health & safety Acid rain Global warming Smoke	_	NI-006 NI-112 NI-002 NI-006

C7. Controlled and uncontrolled	Training of drivers is conducted to ensure reduction in fuel consumption Planning & organized vehicles movement inside and outside The oil is only replaced at service station and disposed	_	Marine water	PI-002
discharges to water	of through local municipality or concerned station		conservation	
D7. Contamination of land	The vehicles are inspected on continuous basis for leakages of oil which is insignificant	_	Conservation of natural flora and fauna Preservation of land	PI-004 PI-005
E7. Solid waste	Following solid waste results from the vehicles • Used batteries • Batteries are handed over to local municipality for safe disposal • Engine oil handed over to gas station	_	Pollution prevention Health & safety	PI-001 PI-006
F7. Use of raw materials and other natural resources	Diesel, petrol, and engine oil	Resource utilization	_	NI-111
G7. Use of energy	Use of energy is insignificant	Natural resource utilization	Energy conservation	PI-112
H7. Use of water	Insignificant amount of water is used in radiators	_	No impact	PI-007
I7. Noise, odor, dusts, vibration, and visual impact	The transportation process is noisy but insignificant Odor is kept insignificant through servicing	_	Health & safety Pollution prevention	PI-113 PI-001
J7. Effects on ecosystems	Inadequate organization may result in adverse effect	Deterioration of ecosystem	_	NI-112

SOURCE: A7. Transportation		IVITY: pping	DATE: mm/dd/yyyy	PRODUCT: All Products	S	ERVICES: N/A	
LOCATION			I	AREA: nside and Outside			
ENVIRONMENTAL ASP	ЕСТ		OTI	HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
K7. Upstream effects—ene water, raw materials	· .				Resources utilization Threat to health & safety Energy	_	NI-010 NI-006 NI-113
L7. Downstream effects		• Natur	al product utiliz	zation	Health & safety	_	NI-005
M7. Past effects		• Lack o	of maintenance	and services	Health & safety	_	NI-006
N7. Future effects		• Reduc	ce air pollution		_	Health & safety Pollution prevention	PI-113 PI-001
O7. Selection test		• N/A			• N/A	_	_
P7. Environmental impact evaluation	*				As above	_	_
Q7. Identification of level of significance	Q7. Identification of level of significance • As follows				As follows	_	_

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ran	king	of Environmental	Eff	ects under Nor	mal	Operation Condition	s					
			Conditions/S	core	!				Weig	hting Fa	ctor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	То	tal	Remarks
Legislation	Existing Local legislation No. 16 Personal Protection Equipment Local official information bulletin. Appendix 1, 1.1 Regulation on air pollution control from stationary sources Local legislations No. 5: Oil spill response & preparation No. 29: Requirements for the discharge of waste gases, fumes and dust to atmosphere. 1.2 Noise control regulation	3	Impending				None		×	2	6	а	
Environmental damage	Known detrimental		Possible detrimental • Ozone depletion • Air pollution • Health & safety		Limited detrimental		No detrimental None	0	2	3	6	b	
Interested parties	Considerable interest Local legislation Health & Safety	3	Moderate interest		Little interest		No interest		3×	2	6	С	
Quantity	High	3	Medium		Low	1 1	Nil Nil (not quantifiable)	0	0×	3	0	d	
Normal Operat	ing Conditions Total = $(a + b + c + c)$	d)	Total A								18		

			B: Ranking of	Envir	onme	ntal	Effect unde	er ot	her Ope	erati	ng Condi	ition	s				
					Co	ondi	ions/Score								То	tal	
Elements	Condition	12	Condition			6	Cone	ditio	n	3		(Condition	0			Remarks
Abnormal operations	_		Increased environment • No routine service	al imp	act	6	No Chang	ge			Reduced	d env	rironmental impact		6	а	
Accident / emergency			Increased environment • Accidental fire may air pollution			6	No chang	e			Reduced	d env	rironmental impact		6	b	
Past activities	Evident/ requires action —		Possible damage/diffice evaluate			Lack of and pl operat	anne	ed	3	No dam	age			3	с		
Planned activities			Increased environment	al imp	act		No chang	e		3	• Plan	ned	rironmental impact service & ance & organization	0	0	d	
Other Operati	ng Conditions Tot	al Sc	ore = (a + b + c + d)	Tot	al B										15		
			C: (Cost F	actor	Ranl	king of Env	iron	mental	Eff	ects						
Elements	Very High	4	1 High	3		Me	dium	2		Lo	w	1	None	0	Tot	al	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,0 US\$	000			<10,00 US\$	00					()	
Estimated	N/A		N/A		N/A	1			N/A				N/A		()	
Cost Factor	Total C						·								()	·
FINAL SCOR	E: = A + B + C	Iden	tification Level of Signi	ficanc	e										33	3	

Remarks: Action program required to educate	drivers and review records for the optimizat	tion of oil, fuel, and diesel consumption.
Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.1 (1) H

Environmental Aspect Significance Evaluation Matrix

SOURCE: A8. Laundry	ACTIVITY:	DATE: mm/dd/yyyy	PRODUCT: Washing of Lab Coats and Uniforms	SERVICES: Steam Generation							
LOCATION: Washing Room			AREA: Laundry								
ENVIRONMENTAL ASP	ECT	ОТІ	HER INFORMATION	IMPACT –VE	IMPACT +VE	IMPACT CODE					
B8. Controlled and uncont Emissions to atmosphere	gov • The	rning of staff equipment used i	ns are used for washing of internal is electrical two washes and one dryer or uncontrolled emission	_	No impact Air pollution prevention	PI-007 PI-001					
				_	Marine water conservation	PI-002					

SOURCE: A8. Laundry	ACTIV	VITY:	DATE: mm/dd/yyyy	PRODUCT: Washing of Lab Coats and Uniforms		SERVICES: m Generation	
LOCATION: Washing Room			3333	AREA: Laundry			
ENVIRONMENTAL ASP	ECT		ОТІ	HER INFORMATION	IMPACT –VE	IMPACT +VE	IMPACT CODE
D8. Contamination of land	•	The left	tover water is 1	not drained in the land	_	• Land conservation	PI-005
E8. Solid waste	•	• Solid w	ater is in disso	lved form in waste water	_	No impact	PI-007
F8. Use of raw materials ar other natural resources		enviror	nmental friendl	re used for washing which are y gnificant as quantities are standardized	_	Health & safety Ozone preservation	PI-113 PI-010
G8. Use of energy	•	• Use of	energy is insig	nificant	Natural resource utilization	No impact	PI-007
H8. Use of water	•	• Water o	consumption is	according to the washing quantities	_	Resource optimization	PI-113
I8. Noise, odor, dust, vibratand visual impact				self contained. No dust is produced. ut within 90 db which is satisfactory.	_	No impact	PI-007
J8. Effects on ecosystems	•		•	satisfactory (under control) and does not the economic system.	_	No impact	PI-007

K8. Upstream effects—energy, water, raw materials	Energy and raw material consumption, insignificant	_	No impact	PI-007
L8. Downstream effects	Energy and raw material consumption, insignificant	_	No impact	PI-007
M8. Past effects	Use of bleaching agents	Ozone depletion	_	NI-007
N8. Future effects	Use of environmental-friendly cleaning agents	_	Ozone conservation	NI-112
O8. Selection test	• N/A	• N/A	• N/A	_
P8. Environmental impact evaluation	As above	As above	As above	_
Q8. Identification of level of significance	As follows	As follows	As follows	_

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ran	king	of Environmental	Eff	ects under Nor	mal	Operation Condition	s					
			Conditions/S	core	!				Weig	hting Fa	ctor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	To	tal	Remarks
Legislation	Existing Local official legislation No. 16 Personal Protection Equipment Local official information bulletin. Appendix 1, 1.2 Regulation on the disposal of waste water into marine environment. Local information Appendix 1 1.4 Regulation on Occupational health & safety regulation 1.1 Noise control regulation Local legislation No. 64: Safety, health & environmental requirements for laundry operation	3	Impending				None	3	3×	2	6	a	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental		No detrimental None	0	0×	3	0	b	
Interested parties	Considerable interest Local legislation Health & safety	3	Moderate interest		Little interest		No interest None	0	3×	2	6	с	
Quantity	High		Medium		Low		Nil Nil	0	0×	3	0	d	
Normal Operat	ing Conditions Total = $(a + b + c + a)$	d)	Total A								12		

			B: Ranking of	Envi	ronmental Eff	ect u	nder ot	her Ope	erati	ng Condi	tion	s				
					Condition	ıs/Sc	ore							To	tal	
Elements	Condition	12	Condit	ion		6	Cond	lition	3		(Condition	0			Remarks
Abnormal operations	_		Increased environment • Using chlorinated be cleaning	,		6	No ch	ange		Reduced	l env	vironmental impact		6	а	
Accident / emergency			Increased environment Overflow of holding	,		6	No cha	No change			l env	vironmental impact		6	b	
Past activities	Evident/ requires action		Possible damage/diffice Use of bleaches Ozone depletion	cult to	evaluate	6	-	_		No dama	age			6	С	
Planned activities			Increased environment	increased environmental impact					3		disp	vironmental impact posal of waste water a safety	3	3	d	
Other Operati	ng Conditions To	tal Sc	ore = (a + b + c + d)	To	tal B				-					21		
			C:	Cost 1	Factor Rankin	g of	Enviror	mental	Effe	ects						•
Elements	Very High		4 High	3	Mediu	m	2		Lo	w	1	None	0	Tot	al	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$,		<10,00	0 US	S\$				()	
Estimated	N/A		N/A		N/A			N/A				N/A		()	
Cost Factor	Total C				•		•							()	
FINAL SCOR	E: = A + B + C	Iden	tification Level of Sign	ifican	ce									33	3	
Remarks: No a	ction program req	uire	l. Operational controls	are ac	lequate.											
Reviewed by:									_							
EMS Coordina	ator)	Signature Date														

EMS no.: 4.3.1 Issue date: mm/dd/yyyy Revision no.: New

Initiator signature

Attachment no. 4.3.1(1) I

Environmental Aspect Significance Evaluation Matrix

SOURCE: A9. Kitchen	ACTIVITY: Cooking	DATE: mm/dd/yyyy	PRODUCT: N/A		SERVICES: Catering						
LOCATION: Cafeteria			AREA: Administration								
ENVIRONMENTAL ASPECT			HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE					
B9. Controlled and uncont Emissions to atmosphere	1	iid petroleum gas	is used for cooking, insignificant	_	No impact	PI-007					
C9. Controlled and uncont discharges to water	carı	ying minimal foo	t, the equipments are washed with water d residues. The water is sent to treatment d used for gardening around the plant.	_	Conservation of marine water Recycling	PI-002 PI-009					
for disposal			anded over to local municipality o contains oil in washing, increasing ent plant	_	Health & safety Land conservation	PI-113 PI-005					

E9. Solid waste	Following solid waste results from cooking process:	_	Health & safety	PI-113
	Plastic bags Leftover food		Pollution prevention	PI-001
	Cartons Used oil (disposed by local			
	Rejected kitchenware municipality)			
	Above materials are sold to local buyers & contractor for recycling.			
F9. Use of raw materials and	Materials used are converted into ready-to-use food	_	 Resource optimization 	PI-113
other natural resources	Cooking losses are insignificant			
	Planned operations ensure optimization			
G9. Use of energy	Both electrical energy & gas is used in cooking which is	_	No impact	PI-007
	insignificant			
H9. Use of water	Water consumption is according to the quantities required for	_	Recycling	PI-009
	cooking or washing		 Good housekeeping, 	PI-008
	The waste water is 100% recycled		gardening around the	
			plant.	
I9. Noise, odor, dusts, vibration	The overall cooking process is self-contained. No dust is	_	No impact	PI-007
and visual impact	produced			
	Adequate exhaust system removes odor			
J9. Effects on ecosystems	The overall system is satisfactory (under control) and does not	_	No impact	PI-007
	lead to major threat to the ecosystem			
K9. Upstream effects—energy,	Not applicable	_	_	-
water, raw materials				
L9. Downstream effects	Insignificant, but staff training is required on health and safety	Health &	_	NI-006
	and safe food processing	safety		
M9. Past effects	Insignificant	_	_	
N9. Future effects	Insignificant	_	_	_
O9. Selection test	Not applicable	_	_	_
P9. Environmental impact	As above	As above	As above	_
evaluation				
Q9. Identification of level of	As follows	As follows	As follows	_
significance				

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ranking of Environmental Effects under Normal Operation Conditions													
			Conditions/S	core	:				Weig	thing Fa	ctor			
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	To	Total Rema		
Legislation	Existing Local legislation No. 16 Personal Protection Equipment Local legislation, Appendix 3 No. 65: Liquefied petroleum cylinders No. 38: Health & safety in kitchen & food preparation areas	3	Impending				None	3	3×	2	6	а		
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental		No detrimental None	0	0×	3	0	b		
Interested parties	Considerable interest • Personnel health & safety • Legislation	3	Moderate interest		Little interest		No interest None		3×	2	6	С		
Quantity	High		Medium		Low Solid waste: Insignificant	1	Nil		1×	3	3	d		
Normal Operat	al Operating Conditions Total = $(a + b + c + d)$ Total A													

B: Ranking of Environmental Effect under other Operating Conditions												
			Conditions/So	core					То	tal		
Elements	Condition	12	Condition	6	Condition	3	Condition	0			Remarks	
Abnormal operations	_		Increased environmental impact • Unsafe disposal of leftover food		No Change		Reduced environmental impact		6	а		
Accident / emergency	Food contamination may cause health & safety problem	12	Increased environmental impact		No change		Reduced environmental impact	0	12	b		
Past activities	Evident/Requires action —		Possible damage/difficult to evaluate —		_		No damage • No damage	0	0	с		
Planned activities			Increased environmental impact		No change		Reduced environmental impact • Maintenance of waste reduce impact	0	0	d		
Other Operating Conditions Total Score = $(a + b + c + d)$ Total B												

C: Cost Factor Ranking of Environmental Effects												
Elements	Very High	4	High	3	Medium	2	Low	1	None	0	Total	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0	
Estimated	N/A		N/A		N/A		N/A		N/A		0	
Cost Factor	Cost Factor Total C											
FINAL SCORE: = A + B + C Identification Level of Significance											33	

Remarks: The kitchen operations are satisfact	ory and require more operational con-	<u>ttrol</u>	
Reviewed by: (EMS Coordinator)	Signature	Date	

Attachment no. 4.3.1 (1) J

Environmental Aspect Significance Evaluation Matrix

SOURCE: A10. Civil Works & Maintenance	ACTIVITY: Construction	DATE: mm/dd/yyyy	PRODUCT: N/A	Carpentry/Fabrication/ C	Manufacturing	
LOCATION: Maintenance		Workshop	AREA: o and Cement Mixing Plant			
ENVIRONMENTAL ASP	ECT	ОТІ	HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
B10. Controlled and uncontrolled emissions to atmosphere	Wood Adhe Main preca Iron Ceme	esive glues, thing tenance worksh autions workshop, steel ent mixing plant	ners are used in insignificant amounts ops, all machines are used with safety bars are cut for civil construction works is used at the time of construction only protective equipments are used	 Health & safety Fire hazard Ozone depletion 	No impact	NI-006 NI-114 NI-007

C10. Controlled and uncontrolled discharges to water	Not applicable	_	No impact	PI-007
D10. Contamination of land	Oil and fuel used for the civil work machinery/vehicles. The overall system is under control due to better maintenance of machines/vehicles and does not lead to major threat to the land contamination	_	No impact	PI-007
E10. Solid waste	Concrete Damage blocks Wooden scrap Empty aluminum cans Above materials are sold to local buyers & contractor for recycling	_	Resources utilization	PI-113
F10. Use of raw materials and	Materials used are converted into finished products	_	Resource	PI-113
other natural resources	Losses are insignificant		optimization	
G10. Use of energy	Electrical energy consumption is insignificant	_	No impact	PI-007
H10. Use of water	Insignificant amount is used for cement mixing	_	No impact	PI-007
I10. Noise, odor, dusts, vibration and visual impact	Civil works are conducted in open space and noise is insignificant Housekeeping is satisfactory	_	No impact	PI-007
J10. Effects on ecosystems	The overall system is under control and does not lead to major threat to the ecosystem	_	No impact	PI-007
K10. Upstream effects—energy, water, raw materials	Insignificant	_	No impact	PI-007
L10. Downstream effects	Insignificant	_	No impact	PI-007
M10. Past effects	Insignificant	_	No impact	PI-007
N10. Future effects	Insignificant	_	No impact	PI-007
O10. Selection test	Not applicable	Not applicable	Not applicable	_
P10. Environmental impact evaluation	As above	As above	As above	_
Q10. Identification of level of significance	As follows	As follows	As follows	_

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ranking of Envir	onn	nental Effects u	ınde	er Normal Ope	rati	ion Conditions						
	Co	ndi	tions/Score						Weigl	nting Fac	tor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	То	tal	Remarks
Legislation	Existing	3	Impending				None	3	3×	2	6	а	
	Local legislation No. 16												
	Personal Protection Equipment												
	Local information Appendix												
	1.1 Regulation on air pollution control from stationary source												
	1.2 Occupational health & safety regulation												
	1.3 Noise control regulation												
	Local guidelines												
	No. 25: First aid												
	No. 52: Metal finishing industry												
	No. 29: Requirement for the discharge of waste												
	gases fumes and dust to the atmosphere.												
	No. 6: Industries compound gas cylinders												
	No. 14: Personal protective equipment—head protection												
	No. 15: Personal protective equipment—eye &												
	face protection												
	No. 20: Personal protective equipment												
	Fall protection/ safety lines.												
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental		No detrimental None	0	0×	3	0	b	
Interested	Considerable interest	3	Moderate		Little interest		No interest	0	3×	2	6	С	
parties	Health & safety		interest				None						
_	Legislation												
Quantity	High		Medium		Low	1	Nil		1×		3	d	
					Solid waste:					3			
					Insignificant								
Normal Operat	ing Conditions Total = $(a + b + c + d)$ Total	Α	•			•	•		•		15		

			Conditions/S	Scor	·e				Total		
Elements	Condition	ition 12 Condition 6 Condition 3 Co									Remarks
Abnormal operations	_		Increased environmental impact		No change No Change Unknown	3	Reduced environmental impact	0	3	а	
Accident / emergency		12	Increased environmental impact • Threat to health & safety	6	No change		Reduced environmental impact	0	6	b	
Past activities	Evident/requires action —		Possible damage/difficult to evaluate —		_		No damage • No damage	0	0	С	
Planned activities			Increased environmental impact		No change	3	Reduced environmental impact • Planned inspection	0	0	d	
Other Operating Conditions Total Score = $(a + b + c + d)$ Total B											

	C: Cost Factor Ranking of Environmental Effects												
Elements	Very High	4	High	3	Medium	2	Low	1	None	0	Total	Remarks	
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0		
Estimated	N/A		N/A		N/A		N/A <10,000 US\$		N/A		1		
Cost Factor	Cost Factor Total C												
FINAL SCOR	FINAL SCORE: = A + B + C Identification Level of Significance												

Remarks: Action program required for safety and environmental awareness of employees and resourcing of more safety equipment

Reviewed by:
(EMS Coordinator) Signature Date

Attachment no. 4.3.1 (1) K

Environmental Aspect Significance Evaluation Matrix

SOURCE: A11. Tablets Processing	ACTIVITY: Tableting	DATE: mm/dd/yyyy	PRODUCT: All Tablet Products	SERVICES: N/A						
LOCATION: Plants		Manufactu	AREA: ring & Packaging Solids							
ENVIRONMENTAL ASPE	ЕСТ	ОТНЕ	R INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE				
B11. Controlled and uncontrolled emissions to atmosphere	The table atmosp	01	not lead to controlled emission to the	_	Pollution prevention	PI-001				
C11. Controlled and uncontrolled discharges to water	wate treat plant • The	r-carrying chemica ment plant for recy : water discharge is o otal amount of wa	the equipments are washed with I residues. The water is sent to the cling and used for gardening around the controlled and recycled 100% ste water recycled in year 2000 was	_	Marine water conservation Resource optimization	PI-002 PI-113				

SOURCE: A11. Tablets Processing	ACTIVIT Tabletin		PRODUCT: All Tablet Products	5	SERVICES: N/A	
LOCATION: Plants		Manufactu	AREA: ring & Packaging Solids			
ENVIRONMENTAL ASPE	ЕСТ	отні	ER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
D11. Contamination of land	I The t	ableting process does	not lead to land contamination	_	No impact	PI-007
E11. Solid waste	• F • F • C	mpty steel drums lastic bags artons .luminum seals	ts from tableting process: • Empty plastic bottles • Rejected bulk materials • Damage PP caps • PVC rolls local buyers & contractor for recycling	_	_	_
F11. Use of raw materials at other natural resources			verted into finished products nificant approximately 1–3%	_	Resource optimization	PI-009
G11. Use of energy	υ	se is insignificant as it	m RAK electricity department, energy is subject to production orders minimize the energy consumption	Natural Resource utilization	Energy conservation	PI-112
H11. Use of water	i	Vater consumption is insignificant and is used he waste water is 100°		_	Good housekeeping, gardening around the plant	PI-008
I11. Noise, odor, dusts, vibr and visual impact	• T	ust is produced and the he exhaust system ens	ocess is self-contained. No significant ne staff wear masks sures adequate removal of process dust is noisy but within 65 db. which is	_	Health & safety Pollution prevention	PI-113 PI-001

J11. Effects on ecosystems	Not applicable	_	_	_
K11. Upstream effects—energy, water, raw materials	Increased production will lead to increased consumption of raw materials energy and water	Resource utilization	_	NI-110
L11. Downstream effects	• N/A	Resource utilization	_	NI-110
M11. Past effects	Old machines were not adequately equipped with dust extraction systems	Health & safety Air pollution	_	NI-006 NI-114
N11. Future effects	The tableting operations are safe and have no threats in future operations	_	Health & safetyAir pollution prevention	NI-113 PI-001
O11. Selection test	• N/A	• N/A	• N/A	_
P11. Environmental impact evaluation	As above	As above	As above	_
Q11. Identification of level of significance	As follows	As follows	As follows	_

Key: 0 = Insignificant, 1–20 = Slightly significant, 21–35 = Significant, 36–Max. = Highly significant, PI = Positive impact code, NI = Negative impact.

A: Ranking of Environmental Effects under Normal Operation Conditions													
		Co	onditions/Score	•					Weigh	nting Fac	ctor		
Elements	Condition	3	Condition	2	2 Condition		Condition	0	Multiply	Factor	То	tal	Remarks
Legislation	Existing Local legislation No. 16 Personal Protection Equipment Local information bulletin, Appendix 1, 1.1 Regulation on the disposal of waste into marine environment Local official information Appendix 1 1.2 Regulation on air pollution control from stationary sources 1.3 Occupational health & safety regulation 1.4 Protected areas regulations	3	Impending				None		×	2	6	а	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental		No detrimental • Controlled no impact	0	0×	3	0	b	
Interested parties	Considerable interest • Staff health & safety	3	Moderate interest		Little interest		No interest None		3×	2	6	С	
Quantity	High		Medium		Low • Dust is controlled by using filters	1	Nil		1×	3	3	d	
Normal Operat	ing Conditions Total = $(a + b + c + d)$ T	ota	l A								15		

				B: Ranking of	Envir	onmental Effect und	ler o	ther Operatio	ıg C	onditions	6				
						Conditions/Scor	re						Т	otal	
Elements	Condition		12	(Condi	tion	6	Condition	3		Condition	0			Remarks
Abnormal operations	_			Increased enviro		ital impact lifferential in rooms	6	No Change		Reduced	l environmental impa	ct	6	а	
Accident/ emergency				Increased environments Filters leakage Rupture in de	ge	•	6	No change		Reduced	environmental impa	ct	6	b	
Past activities	Evident/Requires ad —	ction		Possible damage • Health & saf		icult to evaluate	6	_		No dama	age		6	С	
Planned activities				Increased enviro	nmen	ital impact		No change		• Mair	l environmental impa ntenance of waste wat ment plant.		0	d	
Other Operati	ng Conditions Total	Score	= (a	+b+c+d)	Tota	al B							15		
				C: 0	Cost F	actor Ranking of En	viro	nmental Effe	cts						
Elements	Very High	4		High	3	Medium	2	Lov	v	1	None	0	Tot	al	Remarks
Cost	<1,000,000 US\$		<1,0 US\$	00.000		<50,000 US\$		<10,000 US\$)	
Estimated	N/A		N/A	A		N/A		N/A			N/A)	
Cost Factor	Total C)	
FINAL SCOR	$E: = A + B + C \qquad Id$	entifi	catio	n Level of Signif	icanc	e							3.	3	
Remarks: Action	on program required	l conn	ect n	ew plant waste v	vater	to existing waste wa	ter t	reatment pla	<u>nt</u>						

	•	Ü	•	1	O	1	
Reviewed by:							
EMS Coordinat	or)			Signa	ature		Date

EMS no.: 4.3.1

Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) L

Environmental Aspect Significance Evaluation Matrix

SOURCE: A12. Capsules Processing	ACTIVITY: Capsulation	DATE: mm/dd/yyyy	PRODUCT: All Capsules	SERVICES: N/A						
LOCATION: Plants		Manu	AREA: facturing & Packaging							
ENVIRONMENTAL ASPI	ECT	ОТН	IER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE				
B12. Controlled and uncontrolled emissions to atmosphere			oes not lead to controlled emission to the	_	Pollution prevention	PI-001				
C12. Controlled and uncontrolled discharges to water	o water treatr plant	carrying chemic	tion, the equipments are washed with cal residues. The water is sent to the cycling and used for watering around the s controlled	_	Marine water conservation	PI-002				
D12. Contamination of land	d The caps	ılation process d	oes not lead to land contamination	_	No impact	PI-007				

E12. Solid waste	Following solid waste results from the capsulation process: • Empty steel drums • Empty plastic bottles • Plastic bags • Rejected bulk materials • Cartons • Damage PP caps • Aluminum seals • PVC rolls Above materials are sold to local buyers & contractor for recycling	_	_	_
F12. Use of raw materials and other natural resources	Materials used are converted into finished products Process losses are insignificant, approximately 1-3%	_	Resources optimization	PI-113
G12. Use of energy	Energy is resourced from local electricity department, energy use is insignificant as it is subject to production orders Planned manufacturing minimize the energy consumption	Natural resource utilization	Energy conservation	PI-007
H12. Use of water	During processing water is not only used for cleaning of equipments The waste water is 100% recycled	_	Good housekeeping, gardening around the plant Waste water recycling	PI-008 PI-009
I12. Noise, odor, dusts, vibration, and visual impact	The overall capsulation process is self-contained. No significant dust is produced staff wear mask The packaging process is noisy but within 65 db which is satisfactory	_	Health & safety Pollution prevention	PI-113 PI-001
J12. Effects on ecosystems	• N/A	_	_	NI-007
K12. Upstream effects—energy, water, and raw materials	Increased production will lead to increase consumption of raw materials energy and water	Resource utilization	_	_
L12. Downstream effects	• N/A	Resource utilization	No impact	PI-007
M12. Past effects	Old capsulation was not adequately equipped with dust extraction systems	Health & safety Air pollution	_	NI-006 NI-114

SOURCE: A12. Capsules Processing	ACTIVITY: Capsulation	DATE: mm/dd/yyyy	PRODUCT: All Capsules	SE	RVICES: N/A	
LOCATION:		, ,,,,,	AREA: facturing & Packaging			
			HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
N12. Future effects • The capsulation operations are safe and have n future operations			ntions are safe and have no threats in	_	Health & safety Pollution prevention	NI-113 PI-001
O12. Selection test	• N/A			• N/A	• N/A	_
P12. Environmental impact evaluation	P12. Environmental impact • As above			As above	As above	_
Q12. Identification of level significance	of • As fol	llows		As follows	As follows	_

Key: 0 = Insignificant, 1–20 = Slightly significant, 21–35 = Significant, 36–Max. = Highly significant, PI = Positive impact code, NI = Negative impact.

	A: Ra	nkir	g of Environm	ent	al Effects under Norn	ıal (Operation Conditions						
			Conditi	ons	s/Score				Weig	hting Fa	ctor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	To	tal	Remarks
Legislation	Existing Local legislation No. 16 Personal Protection Equipment Local information bulletin, Appendix 1, 1.1 Regulation on the disposal of waste into marine environment. 1.2 Regulation on air pollution control from stationary sources 1.3 Occupational health & safety regulation 1.4 Protected areas regulations	3	Impending				None	3	3×	2	6	a	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental • Air pollution	1	No detrimental None		1×	3	3	b	
Interested parties	Considerable interest • Staff health & safety • Air pollution	3	Moderate interest		Little interest		No interest None	0	3×	2	6	с	
Quantity	High		Medium		Low	1	Nil Dust: Not quantifiable	0	0×	3	0	d	
Normal Operat	ing Conditions Total = $(a + b + c + c)$	- d)	Total A								15		

			B: Ranking o	f Envi	ronmental l	Effec	t under ot	he	er Ope	rati	ng Condit	tion	5				
					Condit	ions/	Score								То	tal	
Elements	Condition	12	Conditi	on		6	6 Condition		3	Condition		Condition	0			Remarks	
Abnormal operations	_		Increased environmen • Dust extraction sys			6	No Char	nge	e		Reduced	env	ironmental impact		6	а	
Accident / emergency			Increased environmen • Dust collection sys			6	No chan	ge	2	3	Reduced	env	ironmental impact		6	b	
Past activities	Evident/ requires action —		Possible damage/diffi • Health & safety • Air pollution	cult to	evaluate	6	_	-			No dama	age			6	С	
Planned activities			Increased environmen	tal im _j	pact		No chan	ge	2				ironmental impact maintenance	0	0	d	
Other Operati	ing Conditions To	tal Sc	ore = (a + b + c + d)	То	tal B										18		
			C:	Cost 1	Factor Rank	ing	of Environ	ım	nental 1	Effe	ects						
Elements	Very High	4	4 High	3	Med	liun	ı 2			Lo	W	1	None	0	Tot	al	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$				<10,000 US\$)					()	
Estimated	N/A		N/A		N/A			ı	N/A				N/A		C)	
Cost Factor	Total C														()	
FINAL SCOR	E: = A + B + C	Iden	tification Level of Sigr	ifican	ce										33	3	
Remarks: Year	ly orientation of st	aff o	n health & safety and p	reven	tion of poll	ıtion											
Reviewed by: (EMS Coordina	ator)		Sig	nature	<u> </u>	_				_	1	Date					

Attachment no. 4.3.1 (1) M

Environmental Aspect Significance Evaluation Matrix

SOURCE: A13. Powders Processing			DATE: mm/dd/yyyy	PRODUCT: Powders for Suspension	SE	SERVICES: N/A							
LOCATION: Plants	LOCATION: Plants AREA: Manu			lanufacturing & Packaging									
ENVIRONMENTAL ASP	ЕСТ		ОТІ	HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE						
B13. Controlled and • The power				rocess does not lead to controlled or n to the atmosphere	_	Pollution prevention	PI-001						
C13. Controlled and uncontrolled discharges t water		water treatm	carrying chemic	filling, the equipments are washed with al residues. The water is sent to the cycling and used for gardening purposes controlled	_	Marine water conservation	PI-002						
D13. Contamination of land • The powders filling proce contamination		rocess does not involve direct land	_	No impact	PI-007								

SOURCE: A13. Powders Processing	ACTIVITY: PPS Mfg.	DATE: mm/dd/yyyy	PRODUCT: Powders for Suspension	SE	RVICES: N/A	
LOCATION: Plants		AREA: M	lanufacturing & Packaging			
ENVIRONMENTAL ASP	ECT	OTI	HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
E13. Solid waste	EmpiPlastiCartoAlum	y steel drums c bags ons ninum seals	ults from powders filling process: • Empty plastic bottles • Rejected bulk materials • Damage PP caps • PVC rolls to local buyers & contractor for recycling	_	_	_
F13. Use of raw materials a other natural resources	I	rials used are cor ss losses are insi	nverted into finished products gnificant	Natural resource utilization	Resources optimization	PI-113
G13. Use of energy	• The a	mount used is re	om Local electricity department ciprocal to output ctivities are encouraged to prevent electrical	Natural resource utilization	Energy conservation	PI-113
H13. Use of water		r is used only for vaste water is 100	O	_	Good housekeeping, gardening purposes Waste water recycling	PI-008
I13. Noise, odor, dusts, vibration, and visual imp	act signi • The p	icant dust is pro	illing process is self contained. No duced and staff wear masks s is noisy but within 60 db which is	_	Health & safety Pollution prevention	PI-113 PI-001

J13. Effects on ecosystems	Not applicable	_	_	_
K13. Upstream effects—energy, water, and raw materials	Increased production will lead to increased consumption of energy and water & materials	Resource utilization	_	_
L13. Downstream effects	Consumption of natural resources	Resource utilization	No impact	NI-010
M13. Past effects	Old powder filling machines were not fitted with dust extraction systems	Health & safety Air pollution	_	NI-006 NI-114
N13. Future effects	The new powders filling machines are safe and have adequate dust extraction	_	Health & safety Pollution prevention	NI-113 PI-001
O13. Selection test	• N/A	• N/A	• N/A	_
P13. Environmental impact evaluation	As above	As above	As above	_
Q13. Identification of level of significance	As follows	As follows	As follows	_

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ra	nkin	g of Environm	ent	al Effects Under Norn	nal (Operation Conditions						
			Conditi	ons	s/Score				Weig	hting Fa	ctor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	То	tal	Remarks
Legislation	Existing Local legislation No. 16 Personal Protection Equipment Local information bulletin, Appendix 1, 1.1 Regulation on the disposal of waste into marine environment. 1.2 Regulation on air pollution control from stationary sources 1.3 Occupational health & safety regulation 1.4 Protected areas regulations	3	Impending				None	3	3×	2	6	a	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental • Air pollution	1	No detrimental None		1×	3	3	b	
Interested parties	Considerable interest • Staff health & safety • Air pollution	3	Moderate interest		Little interest		No interest None		3×	2	6	С	
Quantity	High		Medium	2	Low	1 1	Nil Not quantifiable	0	0×	3	0	d	
Normal Operat	ing Conditions Total = $(a + b + c + c)$	- d)	Total A								15		

					Condit	ions/	Score								To	tal	
Elements	Condition	12	Conditi	on		6	Co	ndi	tion	3		(Condition	0			Remarks
Abnormal operations	_		Increased environmen • Dust extraction sys			6	No ch	nang	зе	3	Reduced	env	rironmental impact		6	а	
Accident / emergency			Increased environmen • Dust collection sys			6	No ch	hang	ge		Reduced	env	vironmental impact		6	b	
Past activities	Evident/ requires action —		Possible damage/diffi • Health & safety • Air pollution	cult to	evaluate	6		_			No dama	ige			6	С	
Planned activities			Increased environmen	tal imp	oact		No ch	hang	ge				vironmental impact maintenance.	3	3	d	
Other operation	ng conditions tota	l scor	e = (a+b+c+d)	Total	В		•								21		
			C:	Cost F	actor Rank	ing (of Envi	iron	mental	Effe	ects						
Elements	Very High	4	4 High	3	Med	ium	ı	2		Lo	w	1	None	0	Tot	al	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$				<10,000 US\$	0					()	
Estimated	N/A		N/A		N/A				N/A				N/A		()	
Cost Factor	Total C						·								()	
FINAL SCOR	E: = A + B + C	Iden	tification Level Of Sign	ifican	ce										36	5	

Date

Signature

Reviewed by: (EMS Coordinator)

Attachment no. 4.3.1 (1) N

Environmental Aspect Significance Evaluation Matrix Prepared by: Concerned Manager

SOURCE: A14. ACTIVITY: DATE: PRODUCT: mm/dd/yyyy SERVICES: N/A Semisolids Processing Semisolid Mfg. All Creams, Ointments, and Suppositories AREA: Manufacturing and Packaging LOCATION: Plant VI IMPACT IMPACT IMPACT ENVIRONMENTAL ASPECT OTHER INFORMATION -VE+VECODE • The semisolid products processing does not lead to controlled or B14. Controlled and Pollution PI-001 uncontrolled emissions to uncontrolled emission to atmosphere prevention atmosphere C14. Controlled and • At the end of semisolid processing, the equipments are washed Marine water PI-002 with water carrying chemical residues. The water is sent to the uncontrolled discharges to conservation treatment plant for recycling and used for gardening purposes Recycling PI-009 water · The water discharge is controlled • The semisolid manufacturing process does not involve direct land D14. Contamination of land No impact PI-007 contamination

E14. Solid waste	Following solid waste results from tabletting process: • Empty steel drums • Rejected bulk materials • Plastic bags • Aluminum tubes • Cartons • Aluminum seals Above materials are sold to local buyers & contractor for recycling	_	Recycling	PI-009
F14. Use of raw materials and other natural resources	Materials used are converted into finished products Process losses are insignificant	_	Resources optimization	PI-113
G14. Use of energy	Energy is resourced from local electricity department, organized production energy consumption	_	Energy optimization	PI-112
H14. Use of water	The only water consumed for cleaning of equipment The waste water is 100% recycled	_	Good housekeeping, gardening purposes Recycling	PI-008
I14. Noise, odor, dusts, vibration, and visual impact	The overall semisolid processing is self-contained. No dust is produced The packaging process is noisy but within 90 db which is satisfactory	_	No impact	PI-007
J14. Effects on ecosystems	The overall system is satisfactory (under control) and does not lead to major threat to the economic system	_	No impact	PI-007
K14. Upstream effects—energy, water, and raw materials	• N/A	_	No impact	PI-007
L14. Downstream effects	• N/A	_	_	_
M14. Past effects	Fats discharged in local sewage	Marine water pollution	_	NI-115

SOURCE: A14. Semisolids Processing	ACTIV Semisolio		DATE: mm/dd/yyyy	PRODUCT: All Creams, Ointments, and Suppositories	SERVICES: N/A					
LOCATION: Plant VI			AREA: Ma	anufacturing and Packaging						
ENVIRONMENTAL ASP	ЕСТ		OTI	HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE			
N14. Future effects	•		mi-solid manuf in future opera	acturing operations are safe and have no utions	_	Marine water conservation	PI-002			
O14. Selection test	D14. Selection test • N/A					• N/A	_			
P14. Environmental impact evaluation • As above					As above	As above	_			
Q14. Identification of level significance	of •	As follo	ows	As follows	As follows	_				

Key: 0 = Insignificant, 1–20 = Slightly significant, 21–35 = Significant, 36–Max. = Highly significant, PI = Positive impact code, NI = Negative impact.

A: Ranking of Environmental Effects Under Normal Operation Conditions													
	Conditions/Score										Weighting Factor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	То	tal	Remarks
Legislation	Existing Local legislation No. 16 Personal Protection Equipment Local information bulletin, Appendix 1, 1.2 Regulation on the disposal of waste water into marine environment Local information Appendix 1 1.3 Regulation on air pollution control from stationary sources 1.4 Occupational health & safety regulation 1.5 Noise control regulation	3	Impending				None	3	3x	2	6	a	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental	1	No detrimental None	0	0×	3	0	b	
Interested parties	Considerable interest • Staff health & safety	3	Moderate interest	2	Little interest		No interest		3×	2	6	с	
Quantity	High		Medium		Low	1 1	Nil Not quantifiable	0	0×	3	0	d	
Normal operating conditions total = $(a + b + c + d)$ Total A								12					

					Conditi	ions/	Score								То	tal	
Elements	Condition	12	Condition	n		6	С	ondi	tion	3		(Condition	0			Remark
Abnormal operations	_		Increased environment	al imp	act		No c		ge nange	3	Reduced	env	rironmental impact	3	3	а	
Accident / emergency			Increased environment • Discharge of manu			6	No c	hang	ge		Reduced	env	rironmental impact	3	6	b	
Past activities	Evident/ requires action		Possible damage/diffic • Marine water pollu		evaluate	6		_			No dama	age		0	6	С	
Planned activities			Increased environment	ncreased environmental impact						3	Plan	ned	rironmental impact maintenance will npacts	3	3	d	
Other operation	ng conditions total	l scor	e = (a+b+c+d)	Total	В									•	18		
			C:	Cost F	actor Rank	ing (of Env	iron	mental	Effe	ects						
Elements	Very High		4 High	3	Med	ium		2		Lov	w	1	None	0	Tota	al	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50, US\$					<10,0 JS\$	000				C)	
Estimated	N/A		N/A		N/A	4			ı	N/A			N/A		C	,	
Cost Factor	Total C										<u> </u>				C		
FINAL SCOR	E: = A + B + C	Iden	tification level of signif	icance	!										30	,	

Signature	Date
	Signature

Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) O

Environmental Aspect Significance Evaluation Matrix

SOURCE: A15. Liquid Processing	Li Proc	TIVITY: quid cessing Mfg.	DATE: mm/dd/yyyy	PRODUCT: All Syrups, Suspensions, and Drops	SEI	RVICES: N/A	
LOCATION: Plants			AREA: Mar	nufacturing and Packaging			
ENVIRONMENTAL ASP	PECT		отн	ER INFORMATION	IMPACT-VE	IMPACT +VE	IMPACT CODE
B15. Controlled and uncontrolled emissions to atmosphere	О	not lea		anufacturing & packaging process does or uncontrolled emission to the	_	Pollution prevention	PI-001
C15. Controlled and uncontrolled discharges water	to	are wa sent to purpo	ashed with water the treatment p	nanufacturing processes, the equipments carrying chemical residues. The water is lant for recycling and used for gardening controlled	_	Marine water conservation	PI-002

SOURCE: A15. Liquid Processing	ACTIVITY: Liquid Processing Mfg.	DATE: mm/dd/yyyy	PRODUCT: All Syrups, Suspensions, and Drops		SERVICES: N/A	
LOCATION: Plants		AREA: Ma	nufacturing and Packaging			
ENVIRONMENTAL ASP	ЕСТ	ОТН	ER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
D15. Contamination of lan		quids manufactu mination	ring process does not involve direct land	_	No impact	PI-007
E15. Solid waste	EmptPlastiCartoAlum	y steel drums c bags ns inum seals	ults from liquid process: • Empty plastic bottles • Rejected bulk materials • Damage PP caps • PVC rolls o local buyers & contractor for recycling	_	_	_
F15. Use of raw materials a other natural resources		rials used are con ss losses are insig	verted into finished products gnificant 1–3%	_	Resources optimization	PI-113
G15. Use of energy	-	gy is resourced fro nificant due to pla	om local electricity department. anned activities	_	Energy conservation	PI-112
H15. Use of water	washi	is used for proce ing of equipment vaste water is 100		_	Irrigation	PI-008
I15. Noise, odor, dusts, vibration, and visual imp	eact signif	icant dust is prod	ressing process is self-contained. No duced s is noisy but within 90 db which is	_	No impact	PI-007

J15. Effects on ecosystems	The overall system is satisfactory (under control) and does not lead to major threat to the eco system	_	No impact	PI-007
K15. Upstream effects—energy, water, and raw materials	Increased production will lead to increased consumption of energy and water & materials	_	No impact	PI-007
L15. Downstream effects	• N/A	_	_	_
M15. Past effects	Washing discharged to local sewage	Marine water pollution	_	NI-115
N15. Future effects	The liquids manufacturing operation are safe and have no threats in future operations	_	Marine water pollution	PI-002
O15. Selection test	• N/A	• N/A	• N/A	_
P15. Environmental impact evaluation	As above	As above	As above	_
Q15. Identification of level of significance	As follows	As follows	As follows	_

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ra	nkin	g of Environm	ent	al Effects Under Norn	nal	Operation Condition	ns					
			Conditi	ions	s/Score				Weig	hting Fa	ctor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	То	tal	Remarks
Legislation	Existing Local legislation No. 16 Personal Protection Equipment Local information bulletin, Appendix 1, 1.1 Regulation on the disposal of waste into marine environment. 1.2 Regulation on air pollution control from stationary sources 1.3 Occupational health & safety regulation 1.4 Protected areas regulations	3	Impending				None	3	3×	2	6	а	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental	1	No detrimental None	0	0×	3	0	b	
Interested parties	Considerable interest • Staff health & safety	3	Moderate interest		Little interest		No interest None		3×	2	6	с	
Quantity	High		Medium		Low Solid waste: Insufficient	1 1	Nil Dust: Not quantifiable	0	0×	3	0	d	
Normal operati	ng conditions total = (a + b + c + a)	l)	Total A								12		

			B: Ranking of	LIIVII				пст Оре	LIUII	ng Conui				-		Ι
					Con	ditions/Sco	re						1	To	tal	-
Elements	Condition	12	Condition		6	Co	nditio	n	3		(Condition	0			Remarks
Abnormal operations	_		Increased environmen	tal impa	act	No chan Not		wn	3	Reduced	env	rironmental impact	3	3	а	
Accident / emergency			Increased environmen	tal impa	act	No chan • Man vesse	ufactu	ring harge	3	Reduced	env	rironmental impact	3	3	b	
Past activities	Evident/ requires action —		Possible damage/difficevaluate	cult to		Discharg sewage		cal	3	No dama	age		0	36	с	
Planned activities			Increased environmen	tal impa	act	No chan	ge		3			rironmental impact waste water treatment	3	3	d	
Other operation	ng conditions total	scor	e = (a+b+c+d)	Total l	В									21		
			C:	Cost Fa	ctor Ra	nking of E	nviror	mental	Effe	ects						
Elements	Very High	4	High	3	N	ledium	2		Lo	w	1	None	0	Tot	al	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$)		<10,00 US\$	00					()	
Estimated	N/A		N/A		N/A			N/A				N/A		()	
Cost Factor	Total C	•					•	•						()	
FINAL SCOR	E: = A + B + C	Iden	tification level of signif	ficance										24	1	
Remarks: Year	ly orientation of st	aff or	health & safety and p	reventi	on of po	ollution		_								
Reviewed by:	ator)			ature					_		Date					

EMS no.: 4.3.1 Issue date: mm/dd/yyyy Revision no.: New

Initiator signature

Attachment no. 4.3.1 (1) P

Environmental Aspect Significance Evaluation Matrix

SOURCE: A16. Sterile Processing		TIVITY:	DATE: mm/dd/yyyy	PRODUCT: All Terminally and Aseptically Sterilized Products, Ready-to-Use Syringes and Lyophilized Products		SERVICES: N/A					
LOCATION: Plant II				AREA							
ENVIRONMENTAL ASP	ECT		ОТН	ER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE				
B16. Controlled and uncontrolled emissions to atmosphere)	I	e process does no n to the atmosph	ot lead to controlled or uncontrolled ere	_	Pollution prevention	PI-001				
C16. Controlled and uncontrolled discharges t water	co .	with with with treatn	water carrying ch nent plant for rec vater discharge is	rocessing, the equipments are washed nemical residues. The water is sent to the cycling and used for gardening purposes s controlled afety equipment	_	Recycling Marine water conservation	PI-009 PI-002				

D16. Contamination of land	The sterile processing does not involve direct land contamination	_	Recycling Irrigation	PI-009 PI-008
E16. Solid waste	Following solid waste results from tabletting process: • Empty steel drums • Broken empoules/vials/syringes • Plastic bags • Rejected bulk materials • Rubber stoppers • Aluminum seals Above materials are sold to local buyers & contractor for recycling. The quantities are exceptionally low.	_	Recycling	PI-009
F16. Use of raw materials and other natural resources	Materials used are converted into finished products Process losses are insignificant 1–3%	_	Resource optimization	PI-113
G16. Use of energy	Energy is resourced from local electricity department Energy consumption is optimized through adequate planning	Natural resource utilization	Energy conservation	PI-112
H16. Use of water	Water consumption is according to the production, orders The waste water is 100% recycled	_	Recycling Pollution prevention	PI-009 PI-001
I16. Noise, odor, dusts, vibration and visual impact	The overall process is self-contained. No significant dust is produced The filling process is noisy but within 90 db which is satisfactory	_	No impact	PI-007
J16. Effects on ecosystems	The overall system is satisfactory (under control) and does not lead to major threat to the ecosystem	_	No impact	PI-007
K16. Upstream effects—energy, water, raw materials	• N/A	_	No impact	PI-007
L16. Downstream effects	• N/A	_	No impact	PI-007
M16. Past effects	• N/A	_	No impact	PI-007
N16. Future effects	The sterile operations are safe and have no threats in future operations	_	No impact	PI-007

SOURCE: A16. Sterile	ACT	ΓΙVΙΤΥ:	DATE:	PRODUCT: All Terminally and Aseptically Sterilized Products, Ready-to-Use Syringes and Lyophilized			
Processing	Steri	ile Mfg.	mm/dd/yyyy	Products		SERVICES: N/A	
LOCATION Plant II				AREA			
ENVIRONMENTAL ASP	ЕСТ		ОТН	ER INFORMATION	IMPACT-VE	IMPACT +VE	IMPACT CODE
O16. Selection test		• N/A			• N/A	• N/A	_
P16. Environmental impac	t	As abo	ove		As above	As above	_
Q16. Identification of level significance	of	• As fol	lows		As follows	As follows	_

Key: 0 = Insignificant, 1–20 = Slightly significant, 21–35 = Significant, 36–Max. = Highly significant, PI = Positive impact code, NI = Negative impact.

	A: Ranking of I	Env	ironmental Effe	ects	under Normal O)pei	ration Conditions						
		(Conditions/Scor	e					Weigl	nting Fac	tor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	To	tal	Remarks
Legislation	Existing Local legislation No. 16 Personal protection equipment Local information bulletin, Appendix 1, 1.2 Regulation on the disposal of waste water into marine environment Local information Appendix 1 1.3 Regulation on air pollution control from stationary sources 1.4 Occupational health & safety regulation 1.5 Noise control regulation	3	Impending				None	3×	3×	2	6	а	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental		Not detrimental None	0	0×	3	0	b	
Interested parties	Considerable interest • Staff health & safety	3	Moderate interest		Little interest		No interest		3×	2	6	с	
Quantity	High		Medium		Low • Low waste	1	Nil	0	1×	3	3	d	
Normal operati	ng conditions total = $(a + b + c + d)$ Total	al A	1								15		

			B: Ranking of E	Enviro	nmental Effect und	er ot	her Ope	rati	ng Conditio	ons	1					
					Conditions/Scor	e								Tota	al	
Elements	Condition	12	Condition		Conditi	on		3			Condition	0]	Remarks
Abnormal operations	_		Increased environmental impact	1	No change • Unknown			3	Reduced er	nv	ironmental impact	C	1	3	а	
Accident / emergency			Increased environmental impact	1	No change • Accidental op solution prep			3	Reduced er	nv	ironmental impact	С	1	3	b	
Past activities	Evident/ requires action —		Possible damage/difficu to evaluate —	ılt	_				No damag	e		C)	С	
Planned activities			Increased environmental impact	1	No change				Waste v	wa	ironmental impact ster recycling will rrigation	3		3	d	
Other operating	ng conditions total	scor	e = (a+b+c+d) T	otal I	3									9		
			C: Co	ost Fa	ctor Ranking of Env	viror	mental	Effe	ects							
Elements	Very High	4	High	3	Medium	2		Lo	w 1	1	None	0	To	tal	R	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$)						0		
Estimated	N/A		N/A		N/A		N/A				N/A			0		
Cost Factor	Total C	•												0		
FINAL SCOR	E: = A + B + C	lden	ification level of signific	ance										24		
Remarks: Yearl	y orientation of sta	iff or	health & safety and pre	venti	on of pollution											

Remarks: 1earry orientation or start	on health & safety and prevention of pollution	
Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) Q

Environmental Aspect Significance Evaluation Matrix

SOURCE: A17. Sterile Powder Filling	ACTIVITY: Sterile Filling	DATE: mm/dd/yyyy	SERVICES: N/A							
LOCATION: Plant II			AREA							
ENVIRONMENT	TAL ASPECT	ОТН	HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE				
B17. Controlled at emissions to the		The sterile process does emission to the atmosp	not lead to controlled or uncontrolled ohere	_	Pollution prevention	PI-001				
C17. Controlled and uncontrolled discharges to water The water discharge is controlled Staff wears adequate safety equipments		At the end of sterile with water carrying the treatment plant purposes	_	Recycling Marine water conservation	PI-009 PI-002					

SOURCE: A17. Sterile Powder Filling	ACTIVITY: Sterile Filling	DATE: mm/dd/yyyy	PRODUCT: Sterile Powder Filling		SERVICES: N/A	
LOCATION: Plan	nt II		AREA			
ENVIRONMENT	TAL ASPECT	ОТІ	HER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
D17. Contaminati	on of land	The sterile processin contamination	g does not involve direct land	_	Recycling Irrigation	PI-009 PI-008
E17. Solid waste		Empty steel drums Broken ampoules/v Plastic bags Cartons Rubber stoppers Aluminum seals Rejected bulk mater Few of the above mater for recycling. The rejected		_	Recycling	PI-009
F17. Use of raw m	naterials and other es	Materials used are c Process losses are ir	converted into finished products asignificant 1–3%	_	Resource optimization	PI-113
1 07			from local electricity department n is optimized through adequate	Natural resource utilization	Energy conservation	PI-112
H17. Use of water	r	Water consumption The waste water is	is according to the production, orders 100% recycled	_	Recycling Pollution prevention	PI-009 PI-001

II7. Noise, odor, dust, vibration, and visual impact	 The overall process is self-contained. No significant dust is produced The filling process is noisy but within 90 db which is satisfactory 	_	No impact	PI-007
J17. Effects on ecosystems	The overall system is satisfactory (under control) and does not lead to major threat to the ecosystem	_	No impact	PI-007
K17. Upstream effects—energy, water, raw materials	• N/A	_	No impact	PI-007
L17. Downstream effects	• N/A	_	No impact	PI-007
M17. Past effects	• N/A	_	No impact	PI-007
N17. Future effects	The sterile operations are safe and have no threats in future operations	_	No impact	PI-007
O17. Selection test	• N/A	• N/A	• N/A	_
P17. Environmental impact evaluation	As above	As above	As above	_
Q17. Identification of level of significance	As follows	As follows	As follows	_

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

			Condition	ıs/S	core				Weig	hting Fa	ctor		
Elements	Condition		Condition	2	Condition	1	Condition	0	Multiply	Factor		tal	Remarks
Legislation	Existing local legislation No. 16 Personal protection equipment Local information bulletin, Appendix 1, 1.2 Regulation on the disposal of waste water into marine environment Local information Appendix 1 1.3 Regulation on air pollution control from stationary		Impending				None	3	3×	2	6	а	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental		No detrimental	0	0×	3	0	b	
Interested parties	Considerable interest • Staff health & safety	3	Moderate interest		Little interest		No interest		3×	2	6	С	
Quantity	High		Medium		Low • Low waste	1	Nil	0	1×	3	0	d	
Normal Operat	ing Conditions Total = $(a + b + c + d)$)	Total A			•	•		•		15		

	B: Ranking of Environmental Effect under other Operating Conditions												
		Conditions/Score											
Elements	Condition	12	Condition	6	Condition	3	Condition	0			Remarks		
Abnormal operations	_		Increased environmental impact —		No change • Unknown	3	Reduced environmental impact	0	3	а			
Accident/ emergency			Increased environmental impact	6	No change • Accidental cuts due to unsafe handling health & safety	3	Reduced environmental impact	0	3	b			
Past activities	Evident/ requires action —		Possible damage/difficult to evaluate —		_		No damage • None	0	0	с			
Planned activities			Increased environmental impact		No change		Reduced environmental impact • Waste recycling will result in irrigation	3	3	d			
Other operation	ng conditions total	sco	ce = (a + b + c + d) Total B						9				

	C: Cost Factor Ranking of Environmental Effects													
Elements	Very High	4	High	3	Medium	2	Low	1	None	0	Total	Remarks		
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0			
Estimated	N/A		N/A		N/A		N/A	1	N/A		0			
Cost Factor	Total C										0			
FINAL SCOR	INAL SCORE: = A + B + C Identification level of significance										24			

Remarks: Yearly orientation of staff on health &	safety and prevention of pollution	
Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy Revision no.: New

Initiator signature

Attachment no. 4.3.1 (1) R

Environmental Aspect Significance Evaluation Matrix

SOURCE:	ACTIVITY: Testing	DATE:	PRODUCT:		SERVICES:	
A18. QC Lab & PDL Lab	Formulation	mm/dd/yyyy	N/A		N/A	
LOCATION: Plant			AREA: Administration Building			
ENVIRONMENTAL ASP	ЕСТ		OTHER INFORMATION	IMPACT –VE	IMPACT +VE	IMPACT CODE
B18. Controlled and uncontrolled emissions to atmosphere	o the prod • The used • The for d	ucts cossible emissior for testings are i chlorinated solve isposal by local r	nts used are identified and collected separately	_	Health & safety Pollution prevention Ozone conservation	PI-113 PI-001 PI-112

SOURCE: A18. QC Lab & PDL	ACTIVITY: Testing	DATE:	PRODUCT:		SERVICES:	
Lab	Formulation	mm/dd/yyyy	N/A		N/A	1
LOCATION: Plant		ARI	EA: Administration building			
ENVIRONMENTAL ASP	ECT	(OTHER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
C18. Controlled and uncontrolled discharges water	to waste	other than VOC ed in controlled	of the experiments in QC & PDL lab. the liquid is and chlorinated compounds are diluted and system for treatment by waste water treatment	-	Marine water conservation	PI-002
D18. Contamination of lan		C lab & PDL lab	, solid waste is transferred to local municipality for	_	Pollution prevention	PI-001
E18. Solid waste	Empt Plasti Carto Alum Disponed Biolog	y plastic bottles c bags ns inum seals osable shoe & covers gical waste	alts from lab operations: Repeated finished products Rejected bulk materials PP caps PVC blisters Volatile organic solvents/local municipality Chlorinated solvents/local municipality olocal buyers & contractor for recycling except materials for safe disposal by local municipality	_	Pollution prevention Ozone conservation	PI-001 PI-112
F18. Use of raw materials other natural resources		nicals are used fo unts consumed a	r testing and controlled according to test methods re insignificant	_	Resource optimization	NI-113
G18. Use of energy	Electr	ical consumption	n of lab equipment is insignificant	_	No impact	PI-007
H18. Use of water			according to the testing requirements)%. Amount of water consumed is insignificant	-	Good housekeeping, gardening around the plant	PI-008

I18. Noise, odor, dusts, vibration, and visual Impact	The overall lab operations are self-contained. No significant impact is produced	_	Health & safety	PI-113
J18. Effects on ecosystems	 The overall system is satisfactory (under control) and does not lead to major threat to the ecosystem 	_	No impact	PI-007
K18. Upstream effects—energy, water, and raw materials	 Generation of lab waste results in spite of safe disposal increase in pollution and may affect health 	Health & safety	_	NI-006
L18. Downstream effects	• N/A	_	No impact	PI-007
M18. Past effects	Discharge of lab waste water to local sewage	Marine water pollution	No impact	NI-115
N18. Future effects	The tableting operations are safe and have no threats in future operations	_	Marine water conservation	PI-002
O18. Selection test	• N/A	• N/A	• N/A	_
P18. Environmental impact evaluation	As above	As above	As above	
Q18. Identification of level of significance	As follows	As follows	As follows	_

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ranking	of E	Environmental	Effe	cts under Normal Ope	rati	on Conditions						
			Conditions/S	cor	e				Weigh	nting Fac	tor		
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	To	tal	Remarks
Legislation	Existing Local legislation No. 16 personal Protection Equipment Local information bulletin, Appendix 1, 1.1 Regulation on the disposal of waste water into marine environment Local information Appendix 1 1.2 Regulation on air pollution control from stationary 1.3 Occupational health & safety regulation Environmental protection & safety guidelines No. 29: Requirements for the discharge of waste gases fumes & dust to atmosphere No. 20: Personal protective equipment No. 58: Policy on the control of ozone deleting substance		Impending				None	3	3×	2	6	a	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimentalOzone deletionAir pollution	1	No detrimental None		1×	2	3	b	
Interested parties	Considerable interest • Staff health & safety • Legislation	3	Moderate interest		Little interest		No interest None		3×	2	6	С	
Quantity	High		Medium		Low • Low	1	Nil		1×	3	3	d	
Normal operati	ng conditions total = $(a + b + c + d)$	To	otal A			•	•	-			18		

			B: Ranking of Environmental	Effec	t under other Op	erati	ng Conditions						
		Conditions/Score											
Elements	ements Condition 12		Condition	ition 6		3	Condition	0			Remarks		
Abnormal operations	_		Increased environmental impact • Unorganized disposal of waste —	6	No change	3	Reduced environmental impact		6	а			
Accident/ emergency			Increased environmental impact • In case of natural disaster	6	No change	3	Reduced environmental impact		6	b			
Past activities	Evident/ requires action —	Evident/ Possible damage/difficult to evaluate		6	_		No damage • None	0	6	С			
Planned activities			Increased environmental impact		No change		Reduced environmental impact • Safe disposal waste	0	0	d			
Other operating conditions total score = $(a + b + c + d)$ Total B													

	C: Cost Factor Ranking of Environmental Effects												
Elements Very High 4 High 3 Medium 2 Low 1 None												Remarks	
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0		
Estimated	N/A		N/A		N/A		N/A	1	N/A		0		
Cost Factor	Cost Factor Total C												
FINAL SCOR	FINAL SCORE: = A + B + C Identification level of significance												

Remarks: Orientation and training of lab and	d PDL staff on safety and environment	
Reviewed by:		
(EMS Coordinator)	Signature	Date

Initiator signature

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.3.1 (1) S

Environmental Aspect Significance Evaluation Matrix

SOURCE:	ACTIVIT	Y: DATE:	PRODUCT:		SERVICES:			
A19. Stores	Storage	mm/dd/yyyy	N/A	N/A				
LOCATION:								
Plant		AREA	A: Inside and Outside the Factory					
	IMPACT	IMPACT	IMPACT					
ENVIRONMENTAL ASP	ECT		OTHER INFORMATION	-VE	+VE	CODE		
B19. Controlled and uncon	trolled Th	e following materials	do no lead to controlled or uncontrolled emission	_	Pollution	PI-001		
emissions to atmosphere	fı	om stores operation			prevention			
	•	Raw materials/bull	chemicals					
	•	Packaging materials	3					
	•	Finished products						
	•	Flammables						
	Hazardous chemica	ls						
	•	Cold store						
	•	Materials safety dat						

SOURCE: A19. Stores	ACTI Stor	VITY:	DATE: mm/dd/yyyy	PRODUCT: N/A		SERVICES: N/A	
LOCATION: Plant			AREA				
ENVIRONMENTAL ASP	ECT			OTHER INFORMATION	IMPACT -VE	IMPACT +VE	IMPACT CODE
C19. Controlled and uncondischarges to water	itrolled	• No	controlled or un	controlled discharge are made from stores	_	Marine water conservation	PI-002
D19. Contamination of lan	d	• The	above materials	do not contaminate	_	Land conservation	PI-005
E19. Solid waste		EmjPlasCarAluReje	oty steel drums itic bags tons minum seals ected raw materi	esults from store process: Rejected finished products/local municipality Used pallets als/local municipality sold to local buyers & contractors for recycling	_	Health & safety Pollution prevention	PI-113 PI-001
F19. Use of raw materials a other natural resources	ınd	• Was	te pallets are pu	rchased	_	 Resource optimization 	PI-113
G19. Use of energy		con	rgy is resourced ditioning to high perature optima	_	NI-115		
H19. Use of water		• Wat	er is used only f	or cleaning purposes, insignificant amount	_	Good housekeeping, gardening purposes	PI-008

I19. Noise, odor, dusts, vibration, and visual impact	 The forklift used are battery operated and lead to characteristics odor, insignificant amount 	_	No impact	PI-007
J19. Effects on ecosystems	The overall system is satisfactory (under control) and does not lead to major threat to the ecosystem	_	No impact	PI-007
K19. Upstream effects—energy, water, raw materials	• N/A	_	No impact	PI-007
L19. Downstream effects	• N/A	_	No impact	PI-007
M19. Past effects	• N/A	_	No impact	PI-007
N19. Future effects	The store operations are safe and have no threats in future operations	_	No impact	PI-007
O19. Selection test	• N/A	• N/A	• N/A	
P19. Environmental impact evaluation	As above	As above	As above	_
Q19. Identification of level of significance	As follows	As follows	As follows	

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ran	king	of Environmental	Eff	ects under Normal Op	era	tion Conditions						
			Conditions/	Sco	re				Weig	hting Fa	actor		
Elements	Condition	3	Condition 2 Condition 1 Condition		0	Multiply	Factor	То	tal	Remarks			
Legislation	Existing Local legislation No. 16 Personal protection equipment Local information bulletin, Appendix 1, 1.1 Regulation on air pollution control from stationary sources. 1.2 Occupational health & safety regulation		Impending				None		0×	2	0	а	
Environmental damage	Known detrimental		Possible detrimental		Limited detrimental Ozone deletion Air pollution		No detrimental None	0	0×	3	0	b	
Interested parties	Considerable interest • Local legislation	3	Moderate interest		Little interest		No interest None		3×	2	6	С	
Quantity	High		Medium • Insignificant	2	Low • Solid waste insignificant	1	Nil		1×	3 3	6	d	
Normal operation	ng conditions total = (a + b + c + d)		Total A		•	•			•	•	12		

			B: Ranking of Environmental I	Effec	t under other Op	erati	ng Conditions				
			Conditi	ions/	Score				То	tal	
Elements	Condition	Condition 12 Condition 6 Condition 3 Condition 0								Remarks	
Abnormal operations	_		Increased environmental impact Unsafe handling or transfer to weighing area —	6	No change		Reduced environmental impact	0	6	а	
Accident/ emergency			Increased environmental impact	6	No change		Reduced environmental impact	0	6	b	
Past activities	Evident/ Requires action		Possible damage/difficult to evaluate	6	_		No damage • None	0	6	с	
Planned activities			Increased environmental impact		No change		Reduced environmental impact • Planned inspection & safe handling	0	0	d	
Other operation	ng conditions total	scoı	ce = (a + b + c + d) Total B						18		

	C: Cost Factor Ranking of Environmental Effects												
Elements Very High 4 High 3 Medium 2 Low 1 None													
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0		
Estimated	N/A		N/A		N/A		N/A		N/A		0		
Cost Factor Total C													
FINAL SCOR	FINAL SCORE: = A + B + C Identification Level Of Significance												

Remarks: Orientation an	id training of stores staff on safety and environment	
Reviewed by:		
(EMS Coordinator)	Signature	Date

Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) T

Environmental Aspect Significance Evaluation Matrix

SOURCE: A20. Administration		IVITY:	DATE:	PRODUCT: N/A		SERVICES: N/A	
A20. Administration	Koutine	Operation mm/dd/yyyy N/A				IN/A	
LOCATION:			AREA:				
Offices			Plant I, II, III, & Admir	nistration			
					IMPACT	IMPACT	IMPACT
ENVIRONMENTAL AS	SPECT		OTHER INFORMA	TION	-VE	+VE	CODE
B20. Controlled and unco		• N/A			_	Pollution preservation	P1-001
C20. Controlled and uncodischarges to water	ontrolled	Sewage c	ontrol and recycled		_	Marine water conservation	PI-002
D20. Contamination of la	and	Adminis contamir	tration operations do not lation	lead to land	_	Land conservation	PI-005
E20. Solid waste		Following so	lid waste results from adr	ministration routine	Recourse utilization	_	

SOURCE:	ACT	CTIVITY: DATE: PRODUCT:		SERVICES:					
A20. Administration	Routine	Operation	mm/dd/yyyy	N/A		N/A			
LOCATION:			AREA:						
Offices			Plant I, II, III, & Admir	nistration					
					IMPACT	IMPACT	IMPACT		
ENVIRONMENTAL AS	SPECT		OTHER INFORMA	TION	–VE	+VE	CODE		
e-waste1		Toilet wa	ste						
		Papers							
		• Carton, e	empty boxes, plastic bags,	tea cups					
		Used car	tridges, discarded monito	r, printer, CPU					
		Rejected	floppies and CDs						
F20. Use of raw material natural resources	s and other	Stationer	ies supplies, insignificant		Resource utilization	_	NI-116		
G20. Use of energy			y is used for air condition through planed maintena	0 1	_	Energy conservation	PI-112		
H20. Use of water			water is used for drinking he toilet and this water is		_	Good house keeping, gardening around the plant.	PI-008		
I20. Noise, odor, dusts, v and visual impact	ibration,	• N/A			_	No impact	_		
J20. Effects on ecosystem	ıs	Insignific	cant		_	No impact	PI-007		

K20. Upstream effects—energy, water, raw materials	• N/A	_	No impact	PI-007
L20. Downstream effects	• N/A	_	No impact	PI-007
M20. Past effects	• N/A	_	No impact	PI-007
N20. Future effects	• N/A	_	No impact	PI-007
O20. Selection test	• N/A	• N/A	• N/A	_
P20. Environmental impact evaluation	• As above	As above	_	_
Q20. Identification of level of significance	As follows	As follows	As follows	_

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ranl	king	of Environmenta	l Eff	ects under Normal Op	era	tion Conditions						
		Weighting Factor											
Elements	Condition		3 Condition		Condition	1	Condition		Multiply	Factor	Total		Remarks
Legislation	Existing Local legislation No. 16 Local information bulletin, Appendix 1, 1.1 Regulation on air pollution control from stationary sources Local legislations No. 5: Oil spill response & prepa-ration. No. 29: Requirements for the discharge of waste gases, fumes and dust to atmosphere. 1.2 Noise control regulation	3	Impending				None	3	3×	2	6	a	
Environmental damage	Known detrimental		Possible detrimental	2	Limited detrimental		No detrimental None	0	0×	3	0	b	
Interested parties	Considerable interest • Health & safety • Legislation	3	Moderate interest		Little interest		No interest		3×	2	6	С	
Quantity	High	3	Medium		Low	1 1	Nil	0	1×	3	3	d	
Normal operation	ng conditions total = (a + b + c + d)		Total A								15		

B: Ranking of Environmental Effect under other Operating Conditions												
Conditions/Score										tal		
Elements	Condition	12	Condition	Condition 6 Condition 3 Condition 0							Remarks	
Abnormal operations	_		Increased environmental impact • Unorganized waste disposal —	6	No change		Reduced environmental impact		6	а		
Accident/ emergency			Increased environmental impact • Accidental fire will lead to release CO2 and CO • Health & safety	6	No change		Reduced environmental impact		6	b		
Past activities	Evident/ requires action —		Possible damage/difficult to evaluate		_		No damage No effect		0	с		
Planned activities			Increased environmental impact		No change		Reduced environmental impact • Safe disposal reduced environment pollution	0	0	d		
Other operation	ng conditions total	sco	re = (a + b + c + d) Total B						12			

	C: Cost Factor Ranking of Environmental Effects											
Elements	Very High	4	High	3	Medium	2	Low	1	None	0	Total	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0	
Estimated	N/A		N/A		N/A		N/A	1	N/A		0	
Cost Factor Total C										0		
FINAL SCORE: = A + B + C Identification level of significance									27			

Remarks: Yearly orientation of staff to increase safety and environmental awareness									
Reviewed by:									
(EMS Coordinator)	Signature	Date							

Issue date: mm/dd/yyyy Revision no.: New Initiator signature

Attachment no. 4.3.1 (1) U

Environmental Aspect Significance Evaluation Matrix

SOURCE:	ACTIVITY:		DATE:	PRODUCT:	SERVICES:					
A21. Civil Works and	Construction		mm/dd/yyyy	N/A	Carpentry/Fabrication/ Construction/					
Construction					Cemen	t Manufacturing				
LOCATION: New Construction		AI	REA: New Construction A	Around PP Caps Plant						
					IMPACT	IMPACT	IMPACT			
ENVIRONMENTAL AS	PECT		OTHER INFOR	MATION	–VE	+VE	CODE			
B21. Controlled and unco	ontrolled emissions	• Carp	entry works		Health & safety	_	NI-006			
to atmosphere		• Wood	1		Fire hazard		NI-114			
		Adhe amou	esive glues and thinners a	re used in insignificant	Ozone depletion		NI-007			
		Maintenance workshops; all machines are used with safety precautions								
		• Iron work	workshop; steel bars are c	ut for civil construction						
		• Ceme	ent mixing plant is used a	t the time of construction						
		only								
		• Adec	quate personnel protective	e equipments are used						

SOURCE: A21. Civil Works and Construction	ACTIVITY: Construction		DATE: mm/dd/yyyy	PRODUCT: N/A	Carpentry/Fa	SERVICES: abrication/ Construct nt Manufacturing	ion/	
LOCATION: New Cons	truction	AI	REA: New Construction A	Around PP Caps Plant				
ENVIRONMENTAL AS	PECT		OTHER INFOR	MATION	IMPACT -VE	IMPACT +VE	IMPACT CODE	
C21. Controlled and unco	ontrolled	• N/A			_	No impact PI-007		
D21. Contamination of la	and	• N/A			_	No impact	PI-007	
E21. Solid waste	E21. Solid waste			uyers and contractors for	_	Resources utilization	PI-113	
F21. Use of raw materials resources	s and other natural		rials used are converted in es are insignificant	nto finished products	_	Resource optimization	PI-113	
G21. Use of energy		• Elect	rical energy consumption	is insignificant	_	No impact	PI-007	
H21. Use of water		 Insig 	nificant amount is used fo	r cement mixing		No impact	PI-007	
I21. Noise, odor, dust, vil impact	bration, and visual	Civil works are conducted in open space and noise is insignificant Housekeeping is satisfactory			_	No impact	PI-007	

J21. Effects on ecosystems	The overall system is under control and does not lead to	_	No impact	PI-007
	major threats to the ecosystem			
K21. Upstream effects—energy, water, and	Insignificant	_	No impact	PI-007
raw materials				
L21. Downstream effects	Insignificant	_	No impact	PI-007
M21. Past effects	Insignificant	_	No impact	PI-007
N21. Future effects	Insignificant	_	No impact	PI-007
O21. Selection test	• N/A	• N/A	• N/A	_
P21. Environmental impact evaluation	As above	As above	As above	_
Q21. Identification of level of significance	As follows	As follows	As follows	_

 $Key: 0 = Insignificant, 1-20 = Slightly \ significant, 21-35 = Significant, 36-Max. = Highly \ significant, PI = Positive \ impact \ code, NI = Negative \ impact.$

	A: Ranking of Envi	ron	mental Effects u	ınde	r Normal Oper	atio	n Conditions						
	Conditions/Score Weighting Fact							tor		ı			
Elements	Condition	3	Condition	2	Condition	1	Condition	0	Multiply	Factor	То	tal	Remarks
Legislation	Existing	3	Impending				None	3	3×	2	6	а	
	Local legislation												i
	No. 16												i I
	Personal Protection Equipment												i I
	Local information												i I
	Appendix												i I
	1.2 Regulation on air pollution control from												i I
	stationary source												ì
	1.2 Occupational health & safety regulation												i I
	1.2 Noise control regulation												ì
	Local Guidelines												ì
	No. 25: First Aid												i I
	No. 52: Metal finishing industry												i I
	No. 29: Requirement for the discharge of waste gases												i
	fumes and dust to the atmosphere												i I
	No. 6: Industries compound gas cylinders												ì
	No. 14: Personal protective equipment—Head												i I
	protection												i
	No. 15: Personal protective equipment—Eye & face												i I
	protection												i
	No. 20: Personal protective equipment—Fall												i I
	protection/safety lines												i
Environmental	Known detrimental		Possible		Limited		No detrimental	0	0×	3	0	b	
damage			detrimental		detrimental		None						
Interested	Considerable interest	3	Moderate		Little interest		No interest	0	3×	2	6	с	i
parties	Health & safety		interest										i
	Legislation												
Quantity	High		Medium		Low	1	Nil		1×	3	3	d	i
					Solid waste:								i
		L_			Insignificant			L					
Normal Opera	ting Conditions Total = $(a + b + c + d)$ Total	A									15		

	B: Ranking of Environmental Effect under other Operating Conditions										
		Conditions/Score							То	tal	
Elements	Condition	12	Condition	6	Condition	3	Condition	0			Remarks
Abnormal operations	_		Increased environmental impact —	6	No Change No change Unknown	3	Reduced environmental impact	0	3	а	
Accident/ emergency			Increased environmental impact • Threat to health & safety	6	No change		Reduced environmental impact	0	6	b	
Past activities	Evident/ requires action —		Possible damage/difficult to evaluate		_		No damage • No change	0	0	С	
Planned activities			Increased environmental impact		No change	3	Reduced environmental impact • Planned inspection	0	0	d	
Other Operati	ing Conditions Tot	al So	core = (a + b + c + d) Total B	•			•		9		

	C: Cost Factor Ranking of Environmental Effects											
Elements	Very High	4	High	3	Medium	2	Low	1	None	0	Total	Remarks
Cost	<1,000,000 US\$		<1,00.000 US\$		<50,000 US\$		<10,000 US\$				0	
Estimated	N/A		N/A		N/A		Applicable <10,000 US\$	1	N/A		1	
Cost Factor	Cost Factor Total C											
FINAL SCOR	$E: = A + B + C \qquad I_0$	lentifi	cation Level of Signi	ficano	e						25	

Reviewed by:	
Remarks: Action program required for safety and environmental awareness of employees and resourcing of more safety equip.	nen
Remarks: Action program required for safety and environmental awareness of employees and resourcing of more safety equip-	nen

Attachment no. 4.3.1 (2) A

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

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Product Aspects/Environmental Impacts Analysis (Questionnaire)

Product/Process	Impacts
Tablets	
1. Addition of raw materialsActiveExcipients	Generation of waste: Polybags, steel drums, paper sacks, and aluminum seals Generation of dust: Human health
Preblending High-speed mixer granulator	Close operation: No impact
3. GranulatingHigh-speed mixer granulator	Close operation: No impact
4. DryingFluid-bed dryer/Tray dryer	Close system: No impact
5. SizingMill/Sieve	Dust generation: Human health
6. Addition of raw materialsLubricantsDisintegrants	Dust generation: Human health
7. BlendingCone blender/drum mixer	Close system: No impact
8. TabletingHigh-speed rotary machine	Dust generation: Human health
9. Blistering	Waste generation: Al, PVC foil, and papers
10. Boxing	Waste generation: Boxes
11. Cartoning	Waste generation: None
12. Shipping	Resource consumption: See separate review
Comments: Waste generation is controlled a generated is collected through a municipality. No major impact	extraction system and disposed by local
Reviewed by: (EMS Coordinator) Signa	ture Date

Attachment no. 4.3.1 (2) B

Product/Process	Impa	Impacts					
Capsules							
1. Addition of raw materialsActiveExcipients	Waste generation: Polyba	gs, boxes, and SS drums					
2. Aqueous granulatingHigh-speed mixer granulate	Close operation: No impa or	ct					
3. DryingFluid-bed dryer/Tray dryer	Close operation: No impa	ct					
4. SizingMill/Sieve	Dust generation: Human	health					
5. Addition of raw materialsLubricantsDisintegrants	Dust generation: Human Waste generation: Polyba						
6. BlendingCone blender/drum mixer	Close operation: No impa	ct					
7. CapsulatingHigh-speed capsulationMachine	Close operation: No impa	act					
8. Blistering/container filling	Waste generation: Rejecte P. containers, PVC foil, A	0 1					
9. Boxing	Waste generation: Rejecte	d boxes					
10. Cartoning	Waste generation: None						
11. Shipping	Refer shipping review						
, .	environment or security under cor	trol.					
Reviewed by: (EMS Coordinator)	Signature	Date					

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (2) C

Product/Process	Impacts
Powders Suspension	
 Addition of raw materials Active 	Waste generation: Polybags, plastic, and steel drums
 Excipients 	Dust generation: Human health
2. SizingMill/Sieve	Dust generation: Human health
3. BlendingCone blender/Drum mixer	Close operation: No impact
4. FillingAutomatic powder-filling machine	Close operation: No impact
5. Capping	Waste generation: Rejected aluminum caps, rejected dosing cup plastic, and rejected glass bottles
6. Boxing	Waste generation: Boxes and cartons
7. Cartoning	Waste generation: boxes and cartons
8. Shipping	Refer shipping review
Comments: No major impact or secur	rity under control.
Reviewed by: (EMS Coordinator)	signature Date

Attachment no. 4.3.1 (2) D

111	npacts
Waste generation: Polyba Dust generation: Human	gs, plastic, and Steel drums health
Closed operation: No imp	pact
Closed operation: No imp	pact: Only accidental spillage
Close operation: No imp	act
Rejected caps and dosing	cups (Plastic)
Rejected boxes	
Rejected cartons	
Refer shipping review	
Signature	 Date
	Waste generation: Polyba Dust generation: Human Closed operation: No imp Closed operation: No imp Close operation: No imp Rejected caps and dosing Rejected boxes Rejected cartons Refer shipping review

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (2) E

Product / Process	Impacts
Cream, Ointment, and Suppositories	
1. Addition of raw materials	
• Active	Waste generation: Polybags, plastic, and
 Nonactives 	steel drums
	Dust generation: Human health
2. Mixing	
 Jacketed vessel with a variable speed mixer 	Closed operation: No impact
3. Filling	
 Automatic filling machine 	Closed operation: No impact
4. Boxing	Rejected boxes
5. Cartoning	Rejected cartons
6. Shipping	Refer shipping review
Comments: No major impact.	
Reviewed by:	
(EMS Coordinator) Signature	Date

Attachment no. 4.3.1 (2) F

Product/Process	Impacts
Aseptic Fill Products	
1. Issuance of raw and packaging material	No impact
2. Addition of raw materials	-
• Active	Closed system: No impact
 Nonactives 	·
3. Medium	
 Water for injection 	No impact
4. Steam sterilization	
 Pressure vessel/filling and filtration assembly/stopper and seals/gowning 	No impact. Only accidental vessel pressure failure, human health
5. Mixing	
 Pressure vessel 	No impact
6. Ampoules/vials	
 Washing 	Broken glass ampoules/vials
7. Ampoules/vials	
 Hot air sterilization 	Broken vials and ampoules (glass)
8. Filtration	
 Filtration assembly and a 0.22 μm filter 	No impact
9. Aseptic filling	
 Automatic filling and sealing machine In-line filtration 	No impact. Only rejected aluminum seals
• Gassing	D: (1 1 /:1/1)
10. Leak test	Rejected ampoules/vials (glass)
11. Inspection of filled	D: . 1 1 / : 1
• Ampoules/vials	Rejected ampoules/vials
12. Labeling/Packing	Rejected boxes and leaflets
13. Shipping	Refer shipping review
Comments: No major impact.	
Reviewed by:	
(EMS Coordinator) Signate	ire Date

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (2) G

Product/Process	Impacts
Terminally Sterilized Products	
1. Issuance of raw and packaging material	No impact
2. Addition of raw material	Closed system: No impact
• Active	· · · · · · · · · · · · · · · · · · ·
 Nonactive 	
3. Medium	
Water for injection	No impact
4. Steam sterilization	-
 Pressure vessel 	No impact. Only accidental vessel
 Filling and filtration assembly 	pressure failure, human health
Gowning	_
5. Mixing	
Pressure vessel	No impact
6. Ampoules/vials	-
Washing	Broken glass ampoules/vials
7. Ampoules/vials	Broken vials and ampoules (glass)
Sterilization	
8. Filtration	No impact
 Filtration assembly and a 0.22 µm filter 	
9. Filling/Sealing	No impact. Only rejected aluminum seals
 Automatic filling/sealing machine 	
 In-line filtration 	
 Gassing 	
10. Steam sterilization of filled ampoules/vials	Rejected ampoules/vials (glass)
11. Leak test	Rejected ampoules (glass)
12. Inspection of filled ampoules/vials	Rejected ampoules/vials
13. Labeling/Packing	Rejected boxes and leaflets
14. Shipping	Refer shipping review
Comments: No major impact.	
Reviewed by:	
(EMS Coordinator) Signature	e Date
(Livio Coolumator) Signaturi	Date

Attachment no. 4.3.1 (2) H

2. Addition of raw material Clo • Active • Nonactive 3. Medium No	impact sed system impact
2. Addition of raw material Clo • Active • Nonactive 3. Medium No	sed system
2. Addition of raw material Clo • Active • Nonactive 3. Medium No	sed system
ActiveNonactiveMediumNo	•
3. Medium No	impact
110	impact
	1
Water for injection	
4. Steam sterilization No	impact
Pressure vessel	1
 Filling and filtration assembly 	
Gowning	
5. Mixing No	impact
Pressure vessel	1
6. Ampoules/vials Bro	ken vials and ampoules
	ew)
7. Vials/Sterilization/Depyrogenation through dry heat	,
sterilizer Bro	ken vials and ampoules
	ew)
sterilizer No	impact
9. Filtration No	impact
 Filtration assembly and a 0.22 μm filter 	•
10. Aseptic filling No	impact: Only rejected
Automatic filling alu	uminum seals
In-line filtration	
Gassing	
Partial stoppering	
Shelf loading	
11. Lyophilization	
• Freezing No	impact
• Sublimation	1
Freeze drying	
Full stoppering	

Product/Process		Impacts
12. Vial sealing		No impact
13. Inspection of filled vials		No impact
14. Labeling/Packing		Rejected boxes and labels
15. Shipping		No impact
Comments: No impact.		
Reviewed by: (FMS Coordinator)	Signature	Date

Attachment no. 4.3.1 (2) I

Product/Process	Impacts
Ready-to-Use Disposable Syringes	
1. Issuance of raw and packaging material	No impact
2. Addition of raw material	Closed system
Active	
 Nonactive 	
3. Medium	No impact
 Water for injection 	
4. Steam sterilization	No impact
 Pressure vessel 	
 Filling and filtration assembly 	
 Gowning 	
5. Mixing	No impact
 Pressure vessel 	
6. Sterile syringes	No impact
7. Filtration	No impact
 Filtration assembly and a 0.22 μm filter 	
8. Aseptic filling	No impact; Only rejected syringes
 Automatic syringe filling 	
 Stoppering machine 	
 In-line filtration 	
Gassing	
9. Leak test	No impact
10. Inspection of filled syringes	No impact
11. Plunger rod assembly	No impact
Blister packing	
12. Boxing	Rejected boxes and leaflets
13. Shipping	No impact
Comments: No impact.	
Reviewed by:	
(EMS Coordinator) Signature	Date

> SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (3) A

	Impacts
Administration Operations	
1. Kitchen	Disposable glasses and boxes
2. Paper work	Paper waste
3. Cartons	Empty boxes
4. Empty boxes	Waste
5. Printing cartridges	Plastic waste, recycling opportunity

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.1 (3) B

Activities	Impacts
Quality Control Laboratory	
1. Physical laboratory	
Analyzed raw materialsAnalyzed finished products	Waste generation: Land pollution, human health, paper waste, aluminum, PVC, and glass waste
2. Chemical laboratory	
Analyzed raw materialsAnalyzed finished products	Waste generation: Land pollution, human health, and sea pollution
SolventsChemicals	Ozone depletion: Chlorinated solvents only
3. Microbiological laboratory	
Biological wasteAnalyzed raw materialsAnalyzed finished products	Biological waste: Human health, paper waste, aluminum, PVC and glass, and microbiological media
4. General	
Paper/boxes/filesGlass apparatus washingsRejected materials	Waste generation: Land pollution
Comments: No major impact. The l	biological waste is controlled.
Reviewed by:	
(EMS Coordinator)	Signature Date
Rejected materials Comments: No major impact. The l Reviewed by:	

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (3) C

Activities		Impacts
Product Development Laboratory		
1. Papers	Waste generation: N	Vature
2. Rejected raw materials	Land pollution and	sea pollution: Human health
3. Rejected stability samples	Land and sea pollu	tion: Human health
4. Rejected finished products	Land and sea pollu	tion: Human health
5. Washings from the lab	Land and sea pollu	tion: Human health
6. PVC foil	Material assets: Res	ources
7. Aluminum foil	Material assets: Res	ources
8. Glass bottles	Material assets	
9. Solvents	Chlorinated—ozon	e depletion
	Nonchlorinated—la	and and sea
10. Chemicals	Land and sea	
Chlorinated solvents and	ty for disposal. The wast	e water should be recycled. bottles, PVC foil, and alumi-
Reviewed by: (EMS Coordinator)	Signature	Date

Attachment no. 4.3.1 (3) D

Activities	Impacts
Maintenance Workshop	
 Mechanical/fabrication 	Natural resources: human health
 Rejected steel bars 	Natural resources: human health
 Rejected steel plates 	Natural resources
Electrical	
Damage cables	Natural resources
• Used oil	Land and sea
 Used batteries 	Land and sea, and air
Air-Conditioning	
Rejected isolation	Human
Rejected filters	Resources
Damage ductings	Resources
Water Treatment Plant	
 Empty plastic drums 	Resources
should be sold fo	be sent for recycling. General waste or recycling where possible. The items mans should be disposed off by local
ed by:	
Coordinator) Sign	nature Date

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (3) E

Activities Aspects/Environmental Impacts Analysis

Activities	Impacts
Kitchen	
1. Gases	Air pollution, human health
2. Used oil	Land and sea
3. Junk food	Human health
4. Disposable kitchen items	Natural resources

Comments: The above impacts are dependent on consumption quantities. SOP will be written to adopt good practices and optimal utilization of resources. Oil should be disposed in a container to local municipality or the drums should be buried in an isolated land away from natural resources of potable water.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.1 (3) F

Activities	Impacts
Kitchen	
1. Cartons	Natural resources
2. Plastic bags	Ozone depletion, sea pollution
3. Rejected wooden pallets	Natural resources, fire hazard
4. Disposable head and shoe covers	Ozone depletion, sea and land pollution
· ·	ld be minimized. Plastic bags should be assible. Ozone depletion items should be

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (3) G

Activities	Impacts		
Civil Department			
1. Carpentry			
Wooden scrap	Resources utilization, fire hazard		
Empty cans of solvents	Resources utilization		
 Empty cans of thinners and paint 	Ozone depletion		
Empty boxes	Resources utilization		
2. Fabrication			
 Rejected steel bars 	Resources utilization		
Rejected steel drums	Resources utilization		
Metallic dust	Human health		
3. Construction site			
 Empty cans of thinner & paint 	Ozone depletion		
Wooden scrap	Fire hazard, natural resources		
 Metallic scrap 	Resource utilization		
4. Cement mixing plant			
 Broken blocks 	Landscape		
 Damage concrete 	Landscape		
 Disposable gloves 	Waste generation		
 Empty boxes 	Natural resources utilization		
Comments: Waste generation should be minimized where possible. Environmental-friendly solvents should be preferred. Waste should be adequate to arrange recycling.			
Reviewed by: (EMS Coordinator) S	nature Date		

Attachment no. 4.3.1 (3) H

Activities	Impacts	
Plastic Dosing Cups Plant		
1. Plastic raw material from supplier (injection molding grade)	Storage: Accidental fire hazard only	
2. Raw material mixing	Closed operation: No impact	
3. Raw material loading	Closed operation: No impact	
4. Injection molding	Closed operation: No impact	
5. Scrap grinding	Dust generation: Human health, air pollution	
6. Inspection	No impact (rejected waste)	
7. Packing into polybag lined carton	No impact	
Comments: No major impact. Human adequate extraction system	n health is protected through good practices and n.	
Reviewed by: (EMS Coordinator) Si	gnature Date	

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (3) I

Activities Aspects/Environmental Impacts Analysis

Activities	Impacts
Aluminum Caps Plant	
1. Aluminum sheet from supplier	No impact
2. Guillotine shear	No impact
3. Gang slitter	Metal dust
4. Power press	No impact
5. Separator	No impact
6. Inspection conveyor	Rejected aluminum caps
7. Knurling and scoring	No impact
8. Wadding	No impact
9. PE liner from supplier	No impact
10. Packaging into polybag-lined cartons	No impact

Comments: No major impact. Operators are controlled.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.1 (3) J

Activities Aspects/Environmental Impacts Analysis

Activities	Impacts
Stores	
1. Wooden pallets	Waste generation
2. Steel drums	Waste generation
3. Polybags	Waste generation
4. Plastic drums	Waste generation
5. Plastic ropes	Waste generation
6. Metal clips	Waste generation

Comments: No major impact.

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (3) K

Activities	Impacts		
Electricity Generator			
1. Transformer	Human health: (CO2, CO, nitrog	en, and carbon compounds)	
2. Oil disposal	Health, land, and sea		
3. Circuit breaker	Human health		
4. Fuel tank (diesel)	Land and human health (emergency only)		
5. Oil disposal	Human health and land		
6. Batteries	Human health		
Comments: Very minimal in	npact. No major impact. Energy cons	servation is more desirable.	
Reviewed by: (EMS Coordinator)	 Signature	 Date	

Attachment no. 4.3.1 (4) A

Services Aspects/Environmental Impacts Analysis

Activities	Impacts
Shipping	
1. Land	Accidental land pollution
2. Sea	Accidental sea pollution
3. Air	Accidental land or sea pollution or air pollution

Comments: No major impact. Local regulatory bodies are responsible for handling the pollution.

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.1 (4) B

Services Aspects/Environmental Impacts Analysis

Activities	Impacts
Sewage Treatment Plant	
Collection Tank	
1. Plant I	
2. Plant II	
3. Plant III	
4. Hosing	Bad odor, human health, accidental overflow,
5. PP cap	ground and land pollution, air pollution
6. Aluminum cup	
7. Administration	
8. Maintenance	
Continuous Aeration Tank (2)	
1. Settling tank (decontaminate)	Accidental overflow, bad odors, human health
2. Filtration cartridge	Accidental overflow, bad odors, human health
3. Buffer tank	Accidental overflow, land pollution
4. Sand filter	Accidental overflow, land pollution
5. Contamination	Accidental overflow, land pollution
6. Storage	Distribution for irrigation
7. Irrigation	Gardening and plantation
Comments: No major impact, uno	der control.
Reviewed by:	
(EMS Coordinator)	Signature Date

Attachment no. 4.3.1 (5) A

Environmental Aspects/Impacts Analysis of Products/ Activities/Services (Rating)

Activity		Impacts
1. Air conditioning)	
2. Electricity generation		
3. Sewerage treatment plant		
4. Stores		The average overall ranking is 116, indicating the
5. Aluminum caps plant	}	highest priority; however, the highest rank is attributed due to the biological waste from the
6. Plastic dosing caps plant		QC lab. Operations are under the control
7. Catering services		
8. Maintenance		
9. Civil works)	
Comments: No major impact.		
Reviewed by: (EMS Coordinator)	Sic	gnature Date
(Livio Coordinator)	JIE	5 Date

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials:

Attachment no. 4.3.1 (5) B

Environmental Aspects/Impacts Analysis of Products/ Activities/Services (Rating)

Services		Remarks	
1. Shipping	Rank is 72. Very much t	Rank is 72. Very much under the control operation	
2. Sewage treatment plant	0 , 1	ollution of land and sea will and human beings and sea life	
Comments: However, the sew recycling of waste		g at its optimum, that is, 100%	
Reviewed by: (EMS Coordinator)	Signature	 Date	

SOP no.: EMS-4.3.1 Issue date: mm/dd/yyyy Revision no.: New Initials:

Attachment no. 4.3.1 (5) C

Environmental Aspects/Impacts Analysis of Products/ Activities/Services (Rating)

Products	Remarks
1. Tablets)
2. Capsules	
3. Powders suspension	
4. Syrups, suspension, and drops	
5. Cream, ointment, and suppositories	Dei seiter von bin seis 55
6. Aseptic fill products	Priority ranking is 55
7. Terminally sterilized products	
8. Lyophilized products	
9. Tablets	
10. Ready-to-use disposable syringes	J
Comments: No major impact.	
Reviewed by:	
(EMS Coordinator) Signatur	re Date

SOP no.: EMS-4.3.2 Issue date: mm/dd/yyyy

Revision no.: New Initials: ____

Attachment no. 4.3.2 (1)

Aspects/Regulatory Requirement Review/Priority

Activity/ Products/ Services and Aspects	Types of Impacts	How Disposed	RAK Legislation	Federal Legislation	Dubai Municipality Legislation	Remarks	Priority Marking
Attachment no. 4.3.1 (3) A to 4.3.1 (3) K Attachment no. 4.3.2 (2) A to 4.3.1 (2) I	Waste 1. Cafeteria junk food 2. Broken bottles 3. Disposable shoe and head covers 4. Disposable kitchen items 5. Rejected raw materials 6. Rejected finished products 7. Damage PVC roll 8. Metallic dust 9. Gardening waste 10. Biological waste	Local municipality	Not available	Not available	Available and adopted as best practice where possible	EMS compliance	1

Activity/ Products/ Services and Aspects	Types of Impacts	How Disposed	RAK Legislation	Federal Legislation	Dubai Municipality Legislation	Remarks	Priority Marking
	Energy Conservation 11. Electric 12. Water	Optimization recycling	Not available	Not available	Best practice adopted	EMS compliance	2
Attachment no. 4.3.1 (4) A to 4.3.1 (4) B Attachment no. 4.3.1 (5) A to 4.3.1 (5) C	Other Wastes 13. Kitchen oil (used) 14. Transformer oil (used) 15. Chemical dust 16. Ozone-depleting solvents 17. Total liquid waste 18. Batteries (used) 19. Smoke detector sensors (used) 20. Sewage sludge 21. Accidental fire 22. Human health	Local municipality Sewage treatment plant Local municipality Emergency preparedness personal safety equipment provided	Not available	Not available	Available and adopted as best practice where possible	EMS compliance	3

Attachment no. 4.3.1 (3) A to 4.3.1 (3) K	Scrap Not for Sale 23. Plastic waste 24. Cartons 25. Empty boxes	Local contractor	Not available	Not available	Available and adopted as best practice where possible	EMS compliance	4
Attachment no. 4.3.2 (2) A to 4.3.1 (2) I	Scrap for Sale 26. Empty plastic drums 27. Empty steel drums 28. Rejected wooden pallets 29. Aluminum scrap	Local buyers	Not available	Not available	Available and adopted as best practice where possible	EMS compliance	5
Attachment no. 4.3.1 (4) A to 4.3.1 (4) B	Scrap for Destruction 30. Broken blocks 31. Damage concrete 32. Wooden scraps	Local dumping sites, land fills	Not available	Not available	Available and adopted as best practice where possible	EMS compliance	6
Attachment no. 4.3.1 (5) A to 4.3.1 (5) C	Reusable Scrap 33. Steel bars 34. Steel plates 35. Electrical cables 36. Ducting 37. Pipes	Company scrap area	Not available	Not available	Available and adopted as best practice where possible	EMS compliance	7

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.3.2 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.3.2 (2)

Objectives Established and Reviewed

Copy to: Concerned Responsible

Significant Aspect Identified	Impact Rating	Objective	Impact	Target	Indicator	Limit	Policy	Prepared by Concerned Manager
Activities • Air conditioning • Electric generator • Water treatment Plant • Manufacturing • Packaging • Storage								

Reviewed by:			
-	(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.3.2 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.3.2 (3)

Other Examples of Significance Assessment Model By: Concerned Manager

Criteria	3 Points	2 Points	1 Point
Regulation	Consistent regulatory noncompliance	Stricter regulatory requirements have been announced Temporary regulatory noncompliance	Used according to regulatory requirements No tightening of requirements is foreseen
Public opinion (internal and external)	The substance is subject to continual criticism by media and the public (despite regulatory compliance)	Independent experts call for stricter regulatory requirements	The substance is not subject to criticism
Economic criteria (material, waste, and scrap)	Use of the substance generates significant losses of material	Use of the substance generates medium- size losses of material	Hardly any material losses
Quantity	Significant quantity or level	Medium quantity or level	Small or very small quantity or level
Ecological criteria	Use of the substance generates environmental impact throughout the production	Use of the substance generates environmental impact in some steps of the production process	No significant environmental impact during production

Signature

Date

(EMS Coordinator)

Reviewed by:

SOP no.: EMS-4.3.2 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.3.2 (4)

Example of an Environmental Flow Chart for a Construction Site

Demolition of ferr	menter		Quantitie (to be filled	es/Levels I in by the c	oncerne	d manager	•)	
Inputs/Aspects	Manufacturing Process	Output / Aspects	Normal Operation	Abnormal operation	Costs	Require- ments	Moni- toring	Emergency risks
Fermenter	Demolition activities	Noise Scrap Waste Dust Visual impact						
Fermenter	Transport	Mud on road Noise Spills Increased traffic						

Remarks:			
Reviewed by:			
,	(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.3.2 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.3.2 (5)

Example of an Environmental Flow Chart

Inputs/Aspects	Manufacturing	Output / Aspects	Normal	Abnormal	Costs	Require- ments		Emergenc
r may a series	Process	- I my my see	Operation	operation		ments	toring	risks
Sheet iron fittings acetylene gas Nitrogen gas water	Cutting	Water/sludge Emissions (smoke) Scrap Dust Noise						
Cutting oil Machine oil	Machining - Grinding - Milling - Drilling -Bending	Water Scrap Lubricants Noise						
	- Drilling							

Remarks:			
Reviewed by:			
,	(EMS Coordinator)	Signature	Date

Attachment no. 4.3.2 (6)

Example of Discharges from a Manufacturing Facility

A			Annual quantity	Monitoring weekly
		A Discharge to sewer	2000 m ³	
	D	B Cooling water to watercourse	160 kg	
F		C Oil from oil separator	-	
	C	D Emission to air (welding smoke)	100 kg	
В		E Emission to watercourse	-	
Е		F Emission of VOC from paint booth	13 t	
		G Solid waste	2000 t	
		H Liquid hazardous waste	50 t	
G	Н			

Attachment no. 4.3.3 (1) A

	Ob ³	jectives	and	Targets
--	-----------------	----------	-----	----------------

Product/Activity/Services: Waste water treatment plant

Policy (P)

P1: Virtual Pharmaceutical Industries will conserve the natural resources of water through recycling and optimization of consumption where technically and practically possible.

Objectives and Targets (OT)

- **OT1A:** Complete the installation and operation of the waste water treatment plant by mm/dd/yyyy to achieve 100% recycling of waste water.
- **OT1B:** The quality of recycled water should meet the specification of irrigation water in accordance with local legislation.
- **OT1C:** The recycled water should be 100% utilized for gardening by mm/dd/yyyy.
- **OT1D:** 100% utilization of recycled water for irrigation from plant JI, JII, and JIII by mm/dd/yyyy through installation of an automatic sprinkler system to achieve optimization.
- **OT1E:** 100% recycling of waste water discharged from new administration building subject to its start-up, expected by mm/dd/yyyy.
- **OT1F:** Use of irrigation water in decoration fountains if in compliance with the USP potable water specification by mm/dd/yyyy.

Action program (AP)

Refer, program AP1.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (1) B

	Ob ³	jectives	and	Targets
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Product/Activity/Services: Steam generator (boilers)

Policy (P)

P2: To comply with the legislation of local environmental requirements for the discharge of controlled and uncontrolled emission to the atmosphere due to the company's operations, activities, and services.

Objectives and Targets (OT)

- OT2A: Replace two old boilers to comply with local and EU environmental requirements for the emission of CO₂ and CO due to the burning of diesel by mm/dd/yyyy.
- **OT2B:** Control and monitor the discharge of carbon dioxide (CO₂), should be within a range of 10–15% by mm/dd/yyyy due to the burning of diesel for the generation of steam.
- **OT2C:** Control and monitor the discharge of carbon monoxide (CO), should be within a range of NMT 2% by mm/dd/yyyy.

Action Program (AP)

Refer, program AP2.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (1) C

\sim 1		1	
()h	jectives	and	Largets
-	J C C C I V C B	ullu	Iuigeto

Product/Activity/Services: Burning of diesel (electricity generation)

Policy (P)

P3: Virtual Pharmaceutical Industries will seek measures to reduce 20% of its electrical energy consumption by mm/dd/yyyy.

Objectives and Targets (OT)

- **OT3A:** Achieve 20% electrical energy saving for plant I by mm/dd/yyyy through correction of the phase angle to $380 \text{ V} \pm 10$.
- **OT3B:** Achieve 20% electrical energy saving for plant I, II, III, and workshops through correction of the phase angle to $380 \text{ V} \pm 10 \text{ by mm/dd/yyyy}$.
- OT3C: Achieve 20% electrical energy saving through correction of the phase angle to $380 \text{ V} \pm 10$ for Digdaga substation and housing by mm/dd/yyyy.
- **OT3D:** Monitoring and control of CO₂, CO, and nitrogen compounds in accordance with local legislation by mm/dd/yyyy.

Action Program (AP)

Refer, program AP3.

Reviewed by:	(EMS Coordinator)	 Signature	——————————————————————————————————————

Attachment no. 4.3.3 (1) D

Ob	jectives	and	Targets
\sim	CCCIVCO	ullu	IUISCU

Product/Activity/Services: HVAC system

Policy (P)

P4: Virtual Pharmaceutical Industries will seek measures to reduce the consumption of ozone-depleting substances (ODSs) through replacement, recycling, and effective maintenance of its HVAC system.

Objectives and Targets (OT)

- **OT4A:** Eliminate the use of ozone-depleting substances, CFCs, to 100% by mm/dd/yyyy from the existing HVAC system.
- **OT4B:** Minimize the emission of CFCs to 95% from the existing HVAC equipments through recycling at the time of maintenance by mm/dd/yyyy.
- **OT4C:** Quantifying possible leakages due to R22 at the time of maintenance by mm/dd/yyyy.
- **OT4D:** Reduce the existing consumption of R22 by 25% by mm/dd/yyyy as compared to mm/dd/yyyy through prevention of possible leakages during the maintenance.

Action Program (AP)

Refer, program AP4.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (1) E

Objectives and Targets

Product/Activity/Services: Plastic caps and dosing cups manufacturing plant

Policy (P)

P5: Virtual Pharmaceutical Industries will encourage the recycling of plastic waste through continuous awareness programs for the staff and the customers.

Objectives and Targets (OT)

OT5A: Quantify the dosing cups produced in 1998, 1999, and 2000 to see the impact by mm/dd/yyyy.

OT5B: Evaluate the countries of significance importance by mm/dd/ yyyy.

OT5C: Prepare a public awareness program on yearly basis for safe disposal of dosing cups and encourage recycling.

Action Program (AP)

Refer, program AP5.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (1) F

Objectives and rangets	Ob.	jectives	and	Targets
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Product/Activity/Services: Aluminum caps manufacturing plant

Policy (P)

P6: Virtual Pharmaceutical Industries will reduce and encourage the safe disposal and recycling of aluminum waste through continuous customer awareness program.

Objectives and Targets (OT)

OT6A: Quantification of annual consumption of aluminum in 2004, 2005, and 2006 by mm/dd/yyyy.

OT6B: Preparation of priority countries listing the distribution by mm/dd/yyyy.

OT6C: Staff and customers awareness program for safe disposal of aluminum caps and encourage recycling on continuous basis.

Action Program (AP)

Refer, program AP6.

Reviewed by:			
Reviewed by	(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (1) G

Objectives and Targets

Product/Activity/Services: Transportation (administration)

Policy (P)

P7: Virtual Pharmaceutical Industries will reduce the impact of its transport operations by maximizing the efficiency of routes and optimization of vehicles maintenance and awareness programs for the drivers.

Objectives and Targets (OT)

- **OT7A:** Provide training to the drivers on good driving skills and techniques to reduce nitrogen oxide emission by 20%, while reducing fuel consumption by an average of 15% by mm/dd/yyyy.
- **OT7B:** Achieve 2% reduction in fuel consumption through managing routine services and check-up by mm/dd/yyyy.
- **OT7C:** 10% reduction in consumption of petrol with lead by mm/dd/yyyy.

Action Program (AP)

Refer, program AP7.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (1) H

	<u></u>		
Objec	tives and Targets		
Produc	ct/Activity/Services: Laundr	y	
Policy	(P)		
P8:	Virtual Pharmaceutical Indu manage the disposal of hazar consumption where possible	dous substances and	
Object	ives and Targets (OT)		
OT8A:	Reduce the consumption of laundry) by 5% by mm/dd/y	9	
Action	Program (AP)		
Refer, p	orogram AP8.		
D:	11		
Keviev	ved by: (EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (1) I

Object	tives and Targets
Produc	t/Activity/Services: Kitchen
n.P.	va.
Policy	(P)
P9:	Virtual Pharmaceutical Industries will educate, train, and motivate employees to carry out their tasks in an environmentally responsible manner.
Object	ives and Targets (OT)
OT9A:	100% training of kitchen staff to be in compliance with health & safety requirement of local legislation health & safety in food preparation areas by mm/dd/yyyy.
Action	Program (AP)
Refer, p	orogram AP9.
Review	
	(EMS Coordinator) Signature Date

Attachment no. 4.3.3 (1) J

Objectives and Targets

Product/Activity/Services: Processing/Tablets/Capsules/Powders/Semisolids/Liquids and sterile products

Policy (P)

P9: Virtual Pharmaceutical Industries will educate, train, and motivate employees to carry out their tasks in an environmentally responsible manner and prevent pollution.

Objectives and Targets (OT)

OT10A: Conduct training for all staff members by mm/dd/yyyy.

- Health & safety
- Pollution prevention

Action Program (AP)

Refer, action program AP10.

n · 11			
Reviewed by:	(EMS Coordinator)	Signature	— Date
	UEIVIS Coordinatori	Signature	Date

Attachment no. 4.3.3 (1) K

Objectives and Targets

Product/Activity/Services: QC and PDL

Policy (P)

P10: Virtual Pharmaceutical Industries will reduce the amount of waste resulted from its operations. We will minimize the use of materials, design, and modify operations to minimize waste generation where possible.

Objectives and Targets (OT)

- **OT11A:** 5% reduction in the use of chlorinated solvents (ODs) in year (yyyy) as compared with year (yyyy) in QC and PDL laboratory.
- **OT11B:** 10% reduction in the use of volatile organic solvents in year (yyyy) as compared to year (yyyy) in QC and PDL laboratory.
- **OT11C:** Construction of a new QC laboratory and Product Development Laboratory in compliance with the International Safety Rules and environmental requirements of United Arab Emirates by year (yyyy).
- **OT11D:** 5% reduction in QC and PDL laboratory waste generation in year (yyyy) as compared to year (yyyy).

Action Program (AP)

Refer, program AP1.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (1) L

Objectives and rangets	Ob.	jectives	and	Targets
------------------------	-----	----------	-----	----------------

Product/Activity/Services: Administration/Plant

Policy (P)

P10: Virtual Pharmaceutical Industries will reduce the amount of waste resulted from its operations. We will minimize the use of materials, design, and modify operations to minimize waste generation where possible.

Objectives and Targets (OT)

OT13A: Monthly quantification of total waste for the year (yyyy).

OT13B: Review of products and activities to reduce waste by 5% by mm/dd/yyyy.

Action Program (AP)

Refer, program AP13.

Reviewed by:			
110 · 10 · · · · · · · · · · · · · · · ·	(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (1) M

Objectives and rangets	Ob.	jectives	and	Targets
------------------------	-----	----------	-----	----------------

Product/Activity/Services: Stores

Policy (P)

P11: Virtual Pharmaceutical Industries will periodically conduct envi-

ronmental system audits based on ISO 14001 to continually

improve our environmental performance.

Objectives and Targets (OT)

OT12A: Prepare store inspection program by mm/dd/yyyy.

OT12B: Establish a list of safety equipment and their procurement by

mm/dd/yyyy.

OT12C: Review of 100% materials safety data sheets (MSDS) by mm/dd/yyyy.

OT12D: 100% availability of MSDS in stores, weighing area, production, and QC laboratory by mm/dd/yyyy.

Action Program (AP)

Refer, program AP12.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (2)

Targets Established and Reviewed

Copy to: Concerned Responsible

Significant Aspect Identified	Impact Rating	Objective	Impact	Target	Indicator	Limit	Policy	Prepared by Concerned Manager
Product/ Process tablets ^a	Air pollution (powder dust)	Prevent dust dispersion in air	-Employees health -Air pollution	Dust dispersion in the air	Swabs from the plant exhaust show negative results for the chemicals processed inside the plant	0	Prevent generation of dust due to powder operations inside the plant	Production manager

^a For details, refer enclosed report.

Reviewed by:		
(EMS Coordinator)	Signature	Date

Attachment no. 4.3.3 (3)

Aspects/Impacts/Objectives and Targets Review Copy to: Concerned Responsible

Significant Aspect Identified	Impact Rating	Objective	Impact	Target	Indicator	Limit	Policy	Prepared by Concerned Manager
Services	10	Yes	-Ozone	Yes	Yes	Yes	Yes	Transportation
 Transportation^a 			depletion	Yes	Yes	Yes	Yes	manager
			-Air					Transportation
			pollution					manager

^a For details, refer enclosed report.

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.3.4 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.3.4 (1)

Environmental Management Program

Copy to: Concerned Responsible

Policy no.

1	1.	Policy statement, e.g., Minimize water use whenever technically and commercially feasible.								
2	2.	Description of objective, e.g., Reduce water consumption at selected sites by 50,000 m³ from present level within one year.								
3	3.	Description of target, e.g., Carry out a program if investigations to measure the use of water at different parts of process are needed. Install the necessary equipment to tackle the worst three users by October next year.								
4	4.	Summary : As ab	ove							
		Aspect	Environmental impact	Legal nonconform	Internal standard nonconform	Severity	Priority	Location	Refer to site plan	
		Natural sweet water	Wastage of natural resources	None	None	Medium	Medium	Process assembly	Drawing No. 1	

	iewed by: S Coordinator)	Signature	Date		
2	Cours d have				
	Comments:	Satisfaction, policy in com	pliance		- -
	Corrective action:		Date :	mm/dd/yyyy	_
	Time frame respected		Date :	mm/dd/yyyy	_
3.			Date :	mm/dd/yyyy	_
	October 2000	US\$50,000	US\$200,000	US\$50,000	25% / year
	Target	Internal cost	External cost	Savings	Return
7.	Cost and investment				
	April 2000	Water consumption	Weekly	Production	Production File
	Target	Indicator	Frequency	Responsibility	Refer Record
5.	Monitoring:				
	March 2000	Process review	Production	February 2000	
	Target	How (Means)	Responsibility	When	Achieved on
o. 	out by the production ma		er for process "A" for reus	e in process "B" by (Object	tive) October next year to be carrie
5.	Program e g install equit	ament to recycle rinse wat	er for process "A" for rous	e in process "B" by (Object	tive) October next year to be carrie

SOP no.: EMS-4.4 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4 (1)

Personnel and Responsibilities Copy to: Concerned Responsible

Sample Environmental Responsibilities	Typical Person(s) Responsible			
Establish overall direction	General manager, chief executive officer (CEO), and board of directors			
Develop environmental policy	President and chief environmental management system controller			
Develop environmental objectives, targets, and programs	Relevant managers			
Monitor overall EMS performance	Environmental system coordinator			
Assure regulatory compliance	Senior operating manager			
Ensure continual improvement	All managers			
Identify customers expectations	Sales and marketing staff			
Identify suppliers expectations	Purchasers and buyers			
Develop and maintain accounting procedures	Finance/account managers			
Comply with defined procedures	All staff			
<i>Note:</i> In the case of SMEs, the person responsible can be the owner.				

Reviewed by: _____ Date

SOP no.: EMS-4.4

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4 (2)

Structure and Responsibility Example

To: Person Concerned From: Concerned Manager

Job Title: EMS coordinator	$\underline{\hspace{1cm}}$ Reporting to: \underline{G}	General manager
Department: Engineering	Qualification: B	S.Sc. Environmental Science
Summary (Job Title):	Maintain, monitor, and c	control the elements of EMS
Responsibilities		
 Maintain a list of environmenvironmental aspects. Maintain a list of environmental aspects. Maintain a list of environmental aspects. Follow-up the progress tower to environmental objectives. Maintain contacts with gover as a prepare the documentations. Report on environmental new to coordinate EMS audits. Consolidate environmental. Prepare the environmental. Prepare the environmental. Report on regulatory compensations. 	nental training records. for new environmental objective he process for regular identities and targets. Formmental authorities. In necessary for the management at the management at the management at the management at the statement if the facility is research.	ctives. ves. ification and updating nent reviews. ment review meetings. thorities.
13. Prepare documents needed	I for the management review	v meetings.
Authorization		
Authorized to stop any activity environmental protection.	y, product, or services not ir	n compliance with the
Approved by:	Accepted by	7:
Reviewed by:		
EMS Coordinator)	Signature	Date

SOP no.: EMS-4.4

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4 (3)

Resources Allocation	on	
To: Concerned Manag	From: Personnel Manager	
Policy No.: P1		
1. Personnel Resources		
 Job title: Utilities man Personnel qualification		
Practical experience: Training received: Yes		
Computer awareness:Personnel character: 0		
2. Financial Resources (Pr	ovide details):	
 Equipment cost: 100,00 Personnel cost: 26,000		
3. Redirection of Existing	Personnel	
Yes		
4. Training Requirements No		
5. Benefits for the Compar	ny	
No training expensesNo new recruitment		
6. Personnel Motivation		
Yes		
Reviewed by:		
(EMS Coordinator)	Signature	Date
Approved by:		
(General Manager)	Signature	Date

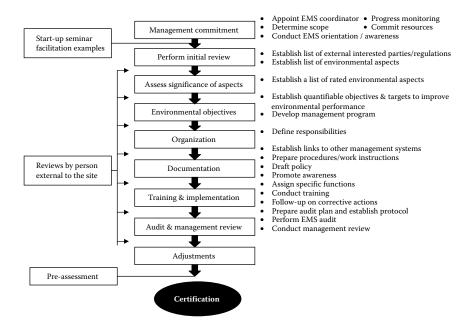
SOP no.: EMS-4.4

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4 (4)

General Implementation Process



SOP no.: EMS-4.4
Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4 (5)

Example Job Description of EMS Coordinator

The list contains examples of the ISO 14001 elements that usually the EMS coordinator (or any other person who has been given the responsibility to document the EMS) is responsible for.

Issue	Activity/Responsibility
Policy	 Coordinate the establishment of a site-specific environmental policy that is relevant to the facility's size and activities. Ensure that the local environmental policy is in line with the company policy for environmental protection. Ensure that the local environmental policy fulfills the requirements of ISO 14001, e.g., it shall contain commitments to continual improvement and compliance with relevant environmental legislation. Document the procedure for the environmental policy.
Environmental aspects	 Coordinate and document the initial review. This process can be more or less comprehensive depending on how well the processes are documented. Develop a site-specific model for how to assess the significance of the environmental aspects. Document the procedure for identifying environmental aspects.
Legal requirements	 Ensure that the organization has procedures for regular updating of relevant regulatory requirements. Establish a list of how the legal requirements are applied to the organization, i.e., a list containing the laws and the environmental aspects, e.g., emissions, where laws are applicable to the organization.
Environmental objectives	 Establish a list of environmental objectives and programs that have recently been completed. Establish procedures for how to identify environmental objectives and programs within all relevant functions of the organization. Establish a list of ongoing environmental objectives and programs. Document the procedure for setting environmental objectives.
Environmental programs	 Confirm that all environmental objectives have programs setting out how the objective and targets are to be achieved. Document the procedure for environmental programs.

Issue	Activity/Responsibility
Environmental organization	 Identify activities and functions that may have a significant impact on the organization's environmental performance. Delegate responsibilities.
Education & training	 Ensure that functions needing special education and training are identified. Identify training requirement for functions that may have a significant environmental impact. Coordinate EMS general training. Coordinate function specific training. Establish procedure for retaining of training records.
Communication	 Ensure that the environmental policy and the significant environmental objectives are communicated to the whole organization. Coordinate formal delegation of environmental responsibilities and authorities. Establish the procedure for external and internal communication
EMS documentation	 Describe the elements of the EMS, e.g., types of documents. Describe the organization and its environmental aspects. Maintain the EMS documentation, i.e., regular updating.
Document control	 Establish a procedure for document control, e.g., refer to the corresponding procedure within the quality system. Establish a list of environmental documents and the recipients of documents.
Processes	 Implement procedures for regular updating of environmental aspects, e.g., environmental aspects of new or significantly modified manufacturing processes and new product lines. Identify and list all processes that need to have documented procedures in order to control their environmental impacts. Coordinate the documentation of procedures and instructions.
Emergency	 Coordinate an inventory of potential emergency situations. Establish procedures for how to train emergency situations. Document the procedure for emergency control.
Monitoring	 Identify those environmental aspects that are necessary to monitor in order to verify legal compliance. Establish procedures for how to monitor environmental aspects. Establish procedures for reporting regulatory compliance.
Nonconformance	 Establish procedures for how to handle nonconformance. Verify that the nonconformance procedure is working.

Issue	Activity/Responsibility
Records	Establish procedures for how and where to retain environmental records.
Internal EMS audits	 Establish a plan for when, and by whom, the internal system audits shall be conducted. Establish procedures for how to document EMS audits. Document the EMS audit procedure.
Management review	 Establish a list of issues to be addressed and documented at the management review meetings. Establish a schedule for when the management review meetings are to be conducted. Document the management review procedure.

SOP no.: EMS-4.4.1 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.1 (1)

Structure and Responsibility

Copy to: Concerned Responsible

Elements	Prepared by (Concerned Managers)	Frequency of Review	Remarks
1. Organization chart personnel	Departmental	Once/year	Satisfactory
qualification	managers		
2. Personnel qualifications	Human resource	Once/year	Satisfactory
0.7.1.1	manager	,	
3. Job description	Departmental managers	Once/year	Satisfactory
4. Training of staff to increase environmental awareness by	Departmental managers		
Internal means			
External means			
5. Motivation schemes	Departmental managers	Once/year	Satisfactory
Financial			
Nonfinancial			
6. Communication to employees	Departmental managers	Once/year	Satisfactory
by			
• Slogans			
Sign boards			
• Pictures			
• Memos	_		
7. Staff goals and objectives based on EMS objectives and targets	Departmental managers	Once/year	Satisfactory
Management review			
 New objectives and targets 			
Corrective actions follow-up			
Audit findings follow-up			
8. Interested parties	Departmental managers	Once/year	Satisfactory
Supplier			
Questionnaire			

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.4.1 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.1 (2)

Supplier Questionnaire		
	Yes	No
Have you registered acc. to EMAS? If yes, please send us your environmental report		
2. Are you certified to ISO 14001 of BS 7750?		
If either of the above questions have been answered with "yes," you do not have to reply to the following questions.		
3. Are you planning to implement a certified environmental management system If so, which and when?		
Date:		
4. Do you have an environmental policy? If yes, please send us your policy.		
5. Have you undertaken an external or internal environmental audit? If yes, please send us a summary of your program.		
6. Do you have an up-to-date environmental impact assessment? If yes, please send us a summary of your program.		
7. Do you have an up-to-date environmental impact assessment? If yes, please send us a copy. If no, please describe briefly below what kind of environmental impacts your operations cause.		
8. Do you need consent, authorization environmental permit to operate?		
9. Have you an environmental contact person?		
Name, title		
10. Do you educate your staff in environmental issues?		
11. Do you have any sites for surface treatment, metal plating, pickling, and so on?		

	Yes	No
12. Do you have formal procedures for handling of hazardous waste from your sites?		
13. Did you receive instruction from our company to be in compliance with our EMS program during operations by your staff at our site.		
14. Other comments and responses to questions 12 and 13, if any		
Reviewed by: Signature Da	ate	

SOP no.: EMS-4.4.2 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.2 (1)

Copy To: All Concerned

Examples of the types of environmental training that can be provided by the organization are as follows:					
Type of Training	Audience	Purpose			
Raising awareness of the strategic importance of environmental management	Senior management	To gain commitment and alignment to the organizations' environmental policy			
Raising general environmental awareness	All employees	To gain commitment to the environmental policy, objectives and targets of the organization and instill a sense of individual responsibility			
Enhancement of skills	Employees with environmental responsibilities	To improve performance in specific areas of the organization, e.g., operations, research, and development and engineering			
Compliance	Employees whose actions can affect compliance	To ensure regulatory and internal requirements for training			

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.4.2 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.2 (2)

An Example List of Operations and Competence, and Requirements

Environmental Aspect	Activity	Min. Training Level
Emission of dust	Maintenance of bag-filters	Filter training course provided by the filter manufacturer
Noise from fan test	Measurement of noise level	Training on noise detector provided to new employee

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.4.2 Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4.2 (3)

Name:	Re	esponsibility	:	Ass	t. EN	AS c	oord	inat	or_	Jo	ob ti	tle:		Seni	or mana	ger
Name: Qualification: <u>Chemical en</u>	gineer	Location	:	_Uti	lities	<u> </u>		_ D	epa	rtme	ent:		<u>En</u>	<u>gine</u>	ering/N	<u>laitenance</u>
Programs	Training Procedure	Training Tools	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.	Signature	Remarks
Environmental awareness	001	Reading/Exam													XYZ	Satisfactory
Aspects identification	002	Reading/Exam													XYZ	Satisfactory
Impact analysis	003	Reading/Exam													XYZ	Satisfactory
• ISO 14001 standard	004	Reading/Exam													XYZ	Satisfactory
Environmental regulatory requirements	005	Reading/Exam													XYZ	Satisfactory
Specific skills and techniques	006	Reading/Exam													XYZ	Satisfactory
Specific equipment operation	007	Reading/Exam													XYZ	Satisfactory
Reorientation	008	Reading/Exam													XYZ	Satisfactory
SOP reading	009	Reading/Exam													XYZ	Satisfactory
Emergency handling	010	Reading/Exam													XYZ	Satisfactory
Fire fighting	011	Reading/Exam													XYZ	Satisfactory
First aid	012	Reading/Exam													XYZ	Satisfactory
Evacuation drill	013	Reading/Exam													XYZ	Satisfactory
Others	014	Reading/Exam													XYZ	Satisfactory
Trainer:Signature	————Date	Training			-				Sig	natur	e			_	Date	

SOP no.: EMS-4.4.3 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.3 (1)

Communication

Copy to: Concerned Responsible Communication: Internal/External

Communication Source	Reference to	Reasons	Concerned Manager Remarks
Customer	• Policy✓	Awareness	Departmental
• Media	New or altered system		manager
Academic	request		
Science	Significant aspect		
Government	Objectives and targets		
Contractors and suppliers	Noncompliance report		
Regulatory body	Suggestion for		
Insurance company	improvement		
• Banks	Training request		
 Industrial federation 	• Audits		
Competitors	Management reviews		
• Employees	• Others		
Shareholders			

(EMS Coordinator)	Sig	gnature	Date	
Reviewed by:				
Implementation date:				
Program amended:	YES	NO✓		
Targets amended :	YES	NO✓		
Objectives amended:	YES	NO✓		
Policy amended:	YES	NO✓		
Communication: (Completed)	YES✓	NO		

SOP no.: EMS-4.4.4 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.4 (1)

Critical Documents Index

Key Procedures	Responsibility (Departmental Manager)
Environmental policy	Concerned manager
 Identifying environmental aspects 	Concerned manager
 Setting environmental objectives 	Concerned manager
Environmental programs	Concerned manager
Retention of training records	Concerned manager
 Internal and external communication 	Concerned manager
 Processing instructions 	Concerned manager
Emergency control	Concerned manager
Regulatory compliance	Concerned manager
Monitoring	Concerned manager
 Nonconform investigation 	Concerned manager
Change control	Concerned manager
 Corrective action and preventive measures 	Concerned manager
Calibration	Concerned manager
 Environmental monitoring records 	Concerned manager
Auditing	Concerned manager
Management review	Concerned manager
Complaints	Concerned manager
Interested parties	Concerned manager

Reviewed by:		
(EMS Coordinator)	Signature	Date

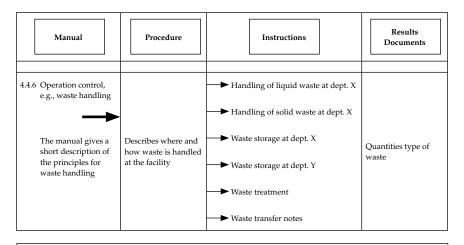
SOP no.: EMS-4.4.5

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.4.5 (1)

Example of EMS Documentation



- * Objective * Responsibility
- * Sogmatire * Date
- Procedure/Instructions Direction to the next level in the hierarchy

- * Authority

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.5 (2)

Procedures Index

Subject	Procedure no.	Issue Date

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.5 (3)

SOP Distribution Record	
SOP no.:	
Subject:	

			so	P Recei	ved	Supersed	ed SOP F	Returned
Copies to	Issued on	Supersedes	From	Ву	Date	Ву	То	Date

SOP no.: EMS-4.4.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.4.5 (4)

Document Retention Time

Document Description	Retention Time	Location	Responsibility
Emission	3 years	Utilities office	Utilities manager

SOP no.: EMS-4.4.6 Issue date: mm/dd/yyyy Revision no.: New

Initials:

Attachment no. 4.4.6 (1)

Operational Controls

To: All Concerned

Environmental Aspects	Product Activity/ Service	Negative Impact Code No.	Significance Aspect Ranking	Objective and Target	Operational Control Procedures
A1 to Q1	Waste water treatment	N1-001	27	OT1A OT1B OT1C OT1D OT1E OT1F	EMS-001 EMS-002 EMS-003 EMS-004 EMS-005 EMS-006 EMS-007 EMS-008 EMS-009 EMS-010 EMS-111
A2 to Q2	Steam generation (boilers)	N1-002 N1-003 N1-004 N1-005	45	OT2A OT2B OT2C	EMS-112 EMS-111 EMS-112 EEP-086 OCP-026 OCP-020 OCP-021 OCP-022
A3 to Q3	Burning diesel electricity generation	N1-002 N1-004 N1-006	42		OCP-023 EMS-114 EMS-115 EMS-131 EEP-090 EEP-091
A4 to Q4	HVAC system (CFCs ozone- depleting substances)	N1-006 N1-007 N1-008	42	OT4A OT4B OT4C OT4D	EMS-116 EMS-117 EMS-118 EEP-119 EES-120 EEP-121

Environmental Aspects	Product Activity/ Service	Negative Impact Code No.	Significance Aspect Ranking	Objective and Target	Operational Control Procedures
A5 to Q5	Plastic plant	NI-009	28	OT5A OT5B OT5C	EMS-122 PPC-000 PPC-001 PPC-002 PPC-003 PPC-004 PPC-005 PPC-006 PPC-007 PPC-008 PPC-009 PPC-010 PPO-001 PPO-001 PPO-003 PPO-004 PPO-005 PPO-005 PPO-006 PPO-007
A6 to Q6	Aluminum plant	NI-006 NI-010	22	OT6A OT6B OT6C	EMS-123
A7 to Q7	Transportation	NI-002 NI-005 NI-006 NI-010 NI-112 NI-113	33	OT7A OT7B OT7C	EMS-124
A8 to Q8	Laundry operations	NI-007 NI-112	33	OT8A	EMS-125 EMS-126 EMS-030 EMS-034
A10 to Q10	Civil works	NI-006 NI-007 NI-114	25	OT10A OT10B	EMS-007
A11 to Q11	Tablet processing	NI-006 NI-010 NI-013 NI-014	33	OT11A	EMS-007
A12 to Q12	Capsule processing	NI-006 NI-114	36	OT11A	EMS-007
A13 to Q13	Powder processing	NI-006 NI-010 NI-114	36	OT11A	EMS-007

Environmental Aspects	Product Activity/ Service	Negative Impact Code No.	Significance Aspect Ranking	Objective and Target	Operational Control Procedures
A14 to Q14	Semisolid processing	NI-115 NI-110	30	OT11A	EMS-007
A15 to Q15	Liquid processing	NI-115	24	OT11A	EMS-007
A16 to Q16	Sterile processing		24	OT11A	EMS-007
A17 to A17	QC/PDL	NI-006	36	OT12A OT12B	Lab. safety manual EMS-130
				OT12C OT12D	EMS-138 EMS-139
A18 to Q18	Stores	NI-115	30	OT13A OT13B OT13C	WHS-001 WHS-027
A19 to Q19	Administration	NI-116	27	OT14A OT14B	EMS-007 EMS-132 EMS-133 EMS-134 EMS-135 EMS-136 EMS-137 Safety

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.4.7 Issue date: mm/dd/yyyy Revision no.: New Initials:

Attachment no. 4.4.7 (1)

Prepared by: Concerned Manager narks ne ase of fire only	
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: Emergency-handling team	
onduct twice/year	

SOP no.: EMS-4.4.7 Issue date: mm/dd/yyyy Revision no.: New

Initials:

Attachment no. 4.4.7 (2)

Emergency Plan

To: All Concerned Managers

Emergency Type	Location	Responsibility	Reference Procedure	External Help	Key Telephone Number
ACTIVITY					
1)Boiler operation	Utilities area	Utilities manager	001	No	xxxxx
2)					
3)					
4)					
5)					
6)					
PRODUCT					
1) Tablet	Production	Production	002	No	xxxxx
2)		manager			
3)					
4)					
5)					
6)					
SERVICES					
1) Shipping	Loading bag	Shipping	003	No	xxxxx
2)		manager			
3)					
4)					
5)					
6)					

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.5

Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5 (1)

Checking and Corrective Action To: Concerned Manager From: Responsible

1. Source	Details of Noncompliance
Activities	Major Minor Critical
Product	
Services	
Operational work	
Instructions	
Service report	
Customer complaint	
2. In-process control	
3. Preventive measure	
4. Corrective action program	
5. Change control approval	
	FD 60
Concerned manager	EMS coordinator
6. Follow-up audit	By:
Planned on:	Yes No
Close out:	10
Remarks:	
Reviewed by:	
(EMS Coordinator) Signatu	re Date

SOP no.: EMS-4.5

Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.5 (2)

Го: Concei	ned Manager				
From:				Date:	
	Aspect		Proposed		
Element	Current practice	Impact	Practice	Impact	Remarks
Activity					
Products					
Services					
	olicy revision:				
Requires ta	arget revision:				
Requires cl	nanges in prograi	m:			
Reviewed	by:				

SOP no.: EMS-4.5.1 Issue date: mm/dd/yyyy Revision no.: New Initials: _____

Attachment no. 4.5.1 (1)

Monitoring and Measurement

Activity/Products/ Services and Aspects	Types of Impacts	Monitoring	Procedure no.	Indicator	Limit
	Waste				
	1. Cafeteria junk food	Daily	EMS-000	Visual insp.	N/A
Attachment no. 4.3.1 (3)	2. Broken bottles	Daily	EMS-000	Visual insp.	N/A
A to 4.3.1 (3) K	3. Disposable shoe and head	Daily		Visual insp.	N/A
	covers		EMS-000		
	4. Disposable kitchen items	Daily	EMS-000	Visual insp.	N/A
	5. Rejected raw materials	Daily	QAS-183	Documentation	N/A
	6. Rejected finished products	Daily	QAS-183	Documentation	N/A
Attachment no. 4.3.2 (2)	7. Damage PVC roll	Daily	EMS-000	Visual insp.	N/A
A to 4.3.1 (2) I.	8. Metallic dust	Daily	EMS-000	Visual insp.	N/A
	9. Gardening waste	Daily	EMS-000	Visual insp.	N/A
	10. Biological waste	Daily	QCS-014	Visual insp.	N/A
	Energy Conservation				
Attachment no. 4.3.1 (4)	11. Electric	Daily	EMS-001 to	Computer rec.	Applicable
A to 4.3.1 (4) B	12. Water	Daily/Shift	EMS-006	Compliance rec.	Applicable

Activity/Products/			Procedure		
Services and Aspects	Types of Impacts	Monitoring	no.	Indicator	Limit
	Other wastes				
Attachment no. 4.3.1 (5)	13. Kitchen oil (used)	Weekly	EMS-000	Visual insp.	N/A
A to 4.3.1 (5) C	14. Transformer oil (used)	Yearly	EMS-000	Visual insp.	N/A
	15. Chemical dust	Daily	EMS-000	Visual insp.	N/A
	16. Ozone-depleting solvents	Weekly	EMS-000	Documentation	N/A
	17. Total liquid waste	Daily	EMS-000	Sewage treatment record	Applicable
	18. Batteries (used)	Yearly	EMS-000	Visual insp.	Applicable
	19. Smoke detector sensors (used)	Yearly	EMS-000	Visual insp.	N/A
	20. Sewage sludge	Monthly	EMS-000	Documentation	N/A
	21. Accidental fire	Ongoing	EMS-000	Documentation	N/R
	22. Human health	Ongoing	EMS-000	Documentation	N/R
	Scrap not for sale				
Attachment no. 4.3.1 (3)	23. Plastic waste	Weekly	EMS-000	Visual insp.	N/A
A to 4.3.1 (3) K	24. Cartons	Weekly	EMS-000	Visual insp.	N/A
	25. Empty boxes	Weekly	EMS-000	Visual insp.	N/A
	Scrap for Sale				
Attachment no. 4.3.2 (2)	26. Empty plastic drums	Weekly	EMS-000	Documentation	N/A
A to 4.3.1 (2) I	27. Empty steel drums	Weekly	EMS-000	Documentation	N/A
, ,	28. Rejected wooden pallets	Weekly	EMS-000	Documentation	N/A
	29. Aluminum scrap	Weekly	EMS-000	Documentation	N/A

	Scrap for Destruction				
Attachment no. 4.3.1 (4)	30. Broken blocks	Monthly	EMS-000	Visual insp.	N/A
A to 4.3.1 (4) B	31. Damage concrete	Monthly	EMS-000	Visual insp.	N/A
	32. Wooden scraps	Monthly	EMS-000	Visual insp.	N/A
	Reusable Scrap				
Attachment no. 4.3.1 (5)	33. Steel bars	Continuous basis	EMS-000	NR	N/A
A to 4.3.1 (5) C	34. Steel plates	Continuous basis	EMS-000	NR	N/A
	35. Electrical cables	Continuous basis	EMS-000	NR	N/A
	36. Ducting	Continuous basis	EMS-000	NR and	N/A
	37. Pipes	Continuous basis	EMS-000	EDS-018	N/A

Note: N/A—Not applicable; NR—Not required.

EMS Coordinator:	Date:	

SOP no.: EMS-4.5.2 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.2 (1)

Го:		From:
Department:	Name:	
Audit checks:		
Policy:	Finding:	
Objective:	Finding:	
Target:	Finding:	
Action Program:	Finding:	
Indicator:	Finding:	
Follow-up:		
Date:	Na	ame:
Note: Attach detailed audit report.		
Reviewed by: (EMS Coordinator)	 Signature	Date

SOP no.: EMS-4.5.3 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.3 (1)

Nonconformance a	nd Corrective Action Report From:	
Department:	Name:	
Deviation:		
Sentto:	Date:	
Corrective action:		
Date	Name:	
Follow-up:		
Date	Name:	
Reviewed by: (FMS Coordinator)	Signature Date	

SOP no.: EMS-4.5.4
Issue date: mm/dd/yyy
Revision no.: New
Initials:

Attachment no. 4.5.4 (1)

EMS Records

Prepared by:

To: Concerned Responsible

Source	Records	Shelf-Life	Responsibility	Location
Activity/Product	Regulatory	Replace when update received	EMS coordinator	EMS coordinator officer
and Activity	Legislation	Replace when update received	EMS coordinator	EMS coordinator officer
	Permits	3 years	Maint. director	EMS coordinator officer
	Training	3 years	Concerned managers	EMS coordinator officer
	Aspects/Impact	5 years	EMS coordinator	EMS coordinator officer
	Program	5 years	EMS coordinator	EMS coordinator officer
	Monitoring data	5 years	Concerned department managers	EMS coordinator officer
	Nonconform	5 years	and functional head responsible	
	Emergencies	5 years	Safety officer	EMS coordinator officer
	Customer feed back	5 years	EMS coordinator	EMS coordinator officer
	EMS audit	Permanent	EMS coordinator	EMS coordinator officer
	Calibration	3 years	Calib. officer	EMS coordinator officer
	Maintenance	3 years	Maintenance director	EMS coordinator officer

Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.5.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.5 (1)

Environmental Management System Audit Check List (General)

4.2 Policy	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
1. Is there an environmental policy defining appropriateness; continual improvement, and public awareness on significant aspects affecting the environment?					
2. Is there a system for policy review based on Documentation Implementation Maintenance, and Communication					
3. Is the policy statement signed off by the management responsible?					
4.3.1 Aspects/Impacts/Effects	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Environmental objectives are set on the basis of aspects/impacts/effects analysis?					
Is there a procedure describing aspects/impacts/ effects analysis?					
3. The aspects/impacts/effects analysis carried out is documented.					
4. Procedures used to identify environmental aspects/ impacts are maintained updated.					

4.3.2 Legal and Other Requirements	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure describing access to the legal and other requirements applicable to the environmental aspects of the company's Activities Products Services					
4.3.3 Objectives and Targets	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Are the objectives and targets consistent with environmental policy?					
2. Are the objectives and targets consistent with commitment to prevention of pollution?					
3. The communication (both internal and external) regarding environmental policy is • Maintained • Documented					
4.3.4 Environmental Management Program	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there an established documented environmental program?					
2. Is there a manual stating environmental policy, objectives, and targets?					
3. Is the control and distribution of the environmental management program satisfactory?					
4. Are resources, responsibilities and designations stated in the environmental management program?					
5. Is there a time frame described in the environmental management program to achieve objectives and targets?					

4.4.2 Training Awareness, Competency, and Communication	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure identifying training needs applicable to the functions of significant impacts within the company?					
Are personnel adequately trained for the functions that they perform?					
3. Is there an in-house training program?					
4. Is there an external course attendance program?					
5. Are training needs effectively identified?					
6. Are records of training maintained for each employee?					
7. Are required levels of qualifications and experience defined for environmental activities?					
Are the internal and external communications regarding environmental policy maintained and documented?					
4.4.6 Operational Control	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure to identify and document the operations and procedures related to suppliers and contractors as they impact environmental policy?					
Is there a procedure to ensure that the contractors are aware of company's EMS requirement?					
Is there an established documented purchasing system?					
Are these procedures ensuring that purchased product conforms to the specified environmental standard?					

		,			
5. Is there a system for evaluation of suppliers and subcontractors?					
Is there a documented procedure for the audit of suppliers and subcontractors?					
7. Is there an approved list of suppliers effecting the environmental policy?					
8. Are purchased materials listed by some class or grade?					
9. Is there a system to check purchased products against purchase order?					
10. Does order identify number and quality of material?					
11. Is there a procedure for verification of subcontractors products for environmental compliance?					
4.4.7 Emergency Preparedness	Reference	Reference	Reference	Remarks/	Completion
and Response	SOPs	Documents	Records	Observations	Date
1 2 7 1					
and Response 1. Do the work instructions/ procedure explain safety precautions during the					
and Response 1. Do the work instructions/ procedure explain safety precautions during the specific activity? 2. Are the employees trained to follow safety precautions					
and Response 1. Do the work instructions/ procedure explain safety precautions during the specific activity? 2. Are the employees trained to follow safety precautions at work? 3. Are the emergency-handling procedures reviewed, revised,					
and Response 1. Do the work instructions/ procedure explain safety precautions during the specific activity? 2. Are the employees trained to follow safety precautions at work? 3. Are the emergency-handling procedures reviewed, revised, and updated? 4. Are the emergency procedures tested (where					
and Response 1. Do the work instructions/ procedure explain safety precautions during the specific activity? 2. Are the employees trained to follow safety precautions at work? 3. Are the emergency-handling procedures reviewed, revised, and updated? 4. Are the emergency procedures tested (where practical) by simulation? 5. Is there an emergency/					
and Response 1. Do the work instructions/ procedure explain safety precautions during the specific activity? 2. Are the employees trained to follow safety precautions at work? 3. Are the emergency-handling procedures reviewed, revised, and updated? 4. Are the emergency procedures tested (where practical) by simulation? 5. Is there an emergency/ accident reporting system? 6. Is there a procedure to identify aspects and impacts					

4.5.1 Monitoring and Measurement	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Are there the procedures to identify the key operations impacting environment?					
Are the evaluation procedures described to ensure compliance with legislation and regulations?					
3. Are the evaluation records maintained?					
4.5.2 Nonconformance, Corrective, and Preventive Actions	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure to define responsibility to handle nonconformance followed by corrective action and preventive measures?					
Does the system make provision for the identification and segregation of non conforming items pending disposition?					
Is there a procedure of raising non conformance reports and notifying relevant personnel customers in a timely manner?					
Is there a procedure for promptly implementing the agreed remedial action?					
5. Is a provision made for review and approval of documents applicable to rework on non conforming products?					
Does the system ensure retainment of records of corrective actions taken?					
7. Does the system allow notifications to legis lative authorities?					
8. Is there a procedure to describe corrective actions and preventive measures?					

4.5.2 Nonconformance, Corrective, and Preventive Actions	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
9. Does the system allow investigation and correction of noncompliance detected • Within the process • Product • Services • Within work operations/ Instructions • Customer complaints					
10. Are CA causes and resolutions recorded?					
Are findings on nonconformance prescribed for management review?					
4.5.4 EMS Audit	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Is there a procedure describing EMS audit Frequency Based on identified activities					
Does the procedure ensure determining conformity, implementation, and maintenance of the EMS?					
3. Does the procedure indicate to inform the results to the management?					
4. Does the procedure describe the appro priate experience and qualification of the external auditors?					
4.6 Management Review	Reference SOPs	Reference Documents	Reference Records	Remarks/ Observations	Completion Date
Does the procedure exist and describe periodical review of EMS?					
Does the procedure ensure to determine effectiveness and adequacy of the EMS?					
3. Does the procedure ensure changes in the existing EMS based on the changes?					

SOP no.: EMS-4.5.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.5 (2)

Revision Form

DEPARTMENT:			PROCEDURE NO.:				
FROM:		TO:					
TITLE:	TITLE:						
DATE:							
Internal	External Audit	Customer complaint	Supplier				
(1) Statement of the problem:							
(2) Root cause of	(2) Root cause of the problem:						
(3) Solution:							
(4) Solution implementation of the action plan:							
(5) Monitor dates/actions required by others:							
Date:		Signature:					

Please attach additional pages if necessary

SOP no.: EMS-4.5.5 Issue date: mm/dd/yyyy Revision no.: New

Attachment no. 4.5.5 (3)

EMS System Audit Programme

Copy to: Concerned Manager

Scope	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.	Departments	Auditor
General and policy	Х													
Aspects, legal, program		Х												
Structure, responsibility			Х											
Communication				х										
Documentation, document control					Х									
Operational control, emergencies						Х								
Monitoring							Х							
Corrective actions, records								Х						
Audit, review									Х					

Prepared by:		
	Signature	Date
Reviewed by:		
(EMS Coordinator)	Signature	Date

SOP no.: EMS-4.6
Issue date: mm/dd/yyyy

Revision no.: New

Attachment no. 4.6 (1)

Management Review	Form
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PARTICIPANTS: All concerned managers DATE: mm/dd/yyyy

- A. Inputs to the review could include the following:
 - Audit summaries
 - Changes in viewpoints and opinions of interested parties
 - Results of any performance improvement projects
 - Monitoring summaries showing compliance results
 - Summary of communications regarding performance
 - Summary of reports to regulators
 - Proposals for new or changed objectives
- B. The review should aim to answer these questions
 - Is the EMS satisfactory? If not, what needs to be done?
 - Is it meeting company needs
 - Did we meet our objectives? If not, why not?
 - Did we achieve regulatory compliance? If not, why not?
 - What changes do we need to make?
 - Do our objectives need to be broader? Narrower? More ambitious? Less ambitious?
 - What should our objectives be for the coming period?
 - Have there been any regulatory or other changes which need to be considered?
 - Is our policy still appropriate?
 - Others

Remarks by:	Participants	
Reviewed by:	-	
(EMS Coordinator)	Signature	Date

Recommended Reading

- 1. ISO 9004, Managing for the sustained success of an organization—A quality management approach.
- 2. ISO 10001:2007, Quality management—customer satisfaction—Guidelines for codes of conduct for organizations.
- 3. ISO 1000:2004, Quality management—customer satisfaction—Guidelines for complaints handling in organizations.
- 4. ISO 10003:2007, Quality management—customer satisfaction—Guidelines for dispute resolution external to organizations.
- 5. ISO 10005:2005, Quality management systems—Guidelines for quality plans.
- 6. ISO 10006:2003, Quality management systems—Guidelines for quality management in projects.
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