

## **DEVELOPMENT AND IMPLEMENTATION OF ENVIRONMENTAL MANAGEMENT SYSTEM IN PHARMACEUTICAL INDUSTRY**

**NEHA BINDAL AND A.K. DWIVEDI**

Department of Chemical Engineering, Ujjain Engineering College Ujjain Madhya Pradesh, India

**Key words :** Development, Environmental management system, Implementation, Pharmaceutical industry, Scope, responsibility, organization.

(Received 14 August, 2012; accepted 3 September, 2012)

### **ABSTRACT**

---

---

Development of Ems can be visualized as plan do check act model. Model represent planning, implementation, correction, checking and management programme. In development, planning phase represent four components which identify how can develop EMS in pharmaceutical industry. Environmental aspects and impacts, Legal and other requirements, Objectives and targets, and Environmental management programs are the component of EMS. EMS can help pharmaceutical activity, process, product, or service that interact with or impact the environment. After development of EMS, company need to implement them. In implementation five factors that can be used to control those aspects. Operational controls, employee training, communication, emergency preparedness and response, and documentation and recordkeeping. These components implements EMS in pharmaceutical industry and improve effectiveness of product. The aim of this paper is to establish a management system, who implement in pharmaceutical industry. With the help of EMS can environment make pollution free and achieve higher production with lower cost.

---

---

### **INTRODUCTION**

As a Global Pharma Innovator, we are committed to expanding and improving our efforts to safeguard the environment. We accordingly established our environmental management system, under which the senior executive as chief executive officer for environmental management. The general manager is the environmental management officer. For set up the environmental management committee to advise the chief executive officer for environmental management committee members include divisional heads, the general manager of general affairs, and the president. (fiscals,

2007).

Pharmaceuticals companies in many locations maintain environmental management system. Environmental management reflects the nature of businesses and their specific locations around the company. In order to carry out their environmental policies and achieve their objectives, responsibility for environmental management must be clearly assigned within a corporation. Some of the companies in our sample are still vague in their annual performance reports about the organizational structure of their environmental activities, but the dominant pattern in those describing their organizational arrangements

---

\* **Corresponding author's email:** n.bindal@ymail.com; anjanidwivedi108@gmail.com

is a decentralized system of responsibility for environmental management with strong guidance and review by corporate headquarters.

**Environmental management system (EMS)**

One indicator of the pharmaceutical industry's commitment to reducing the negative environmental impacts of its operations is the progress leading companies are making toward adopting environmental management systems (EMSs) that meet internationally accepted standards, such as the International Organization for Standardization's ISO 14000 series guidelines( vonZahren,1996). Pharmaceutical companies are beginning to adopt EMSs that seek not only to comply with government environmental regulations, but also to move beyond compliance by proactively managing environmental aspects of their products and operations in order to eliminate waste and prevent pollution and environmental degradation. The basic elements of an ISO 14000 EMS are :

(1) Well-defined and publicly available policies for environmental management,

(2) The clear assignment of organizational responsibilities for environmental management,

(3) Management programs that address all of the environmental aspects of a business and that are translated into implementation and operation plans,

(4) Monitoring, measurement, and auditing programs for reporting, recording, and assessing environmental performance results, and

(5) Management review procedures for continuous improvement of environmental performance.

**Development of EMS in pharmaceutical industry**

Develop a simple Environmental Management System (EMS). Normally, an EMS can be visualized as a Plan - Do - Check - Act model. Within this context, developing an EMS represents a planning phase of the model and covers the following four planning components: Environmental aspects and impacts, Legal and other requirements, Objectives and targets, and Environmental management programs.

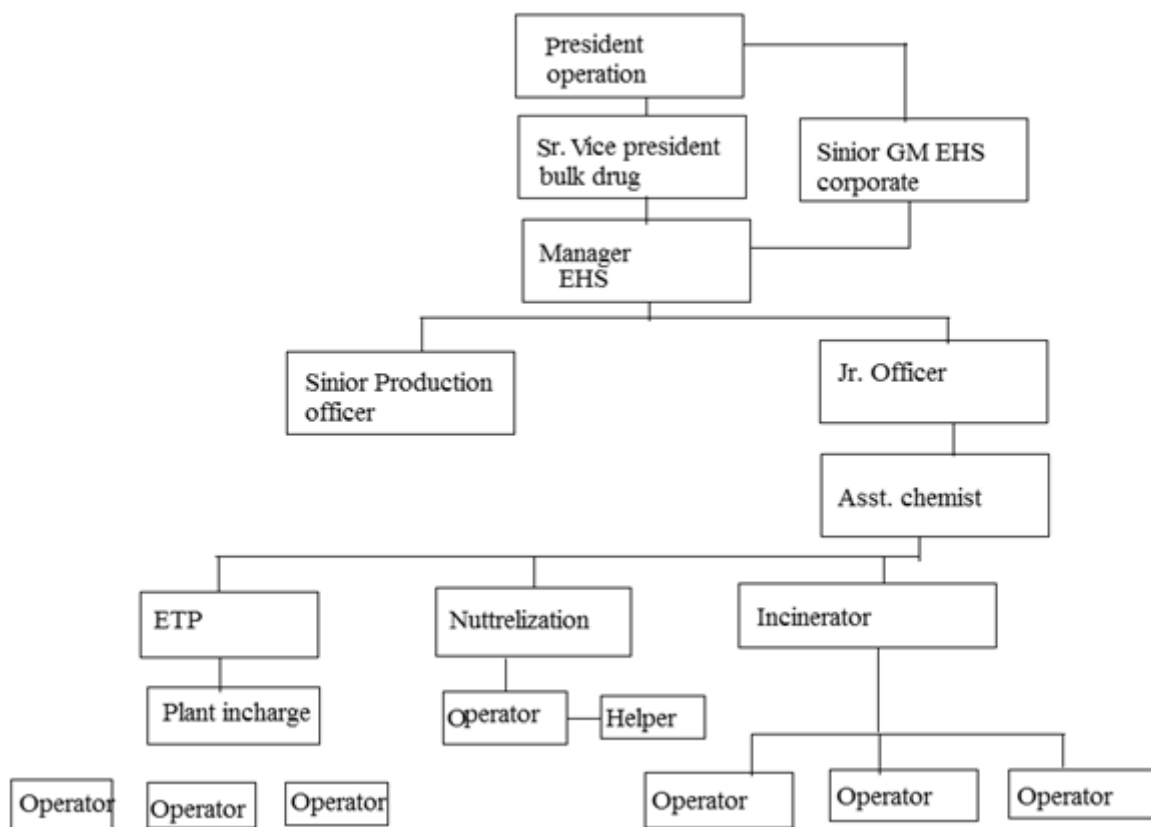


Fig.1 organization structure of pharmaceutical industry (Source IPCA, EHS manual, 2012)

Fig. 2 ISO 14001 EMS Module (Source: Hankerson 2006)

**Environmental aspect:** element of a facility's activities, processes, wastes, products, or services that can interact with the environment. An activity, process, waste, product, or service does not have to be regulated to be considered an aspect.

**Environmental impact:** any change to the environment due to a facility's activities, processes, wastes, products, or services. These changes can be positive or negative.

**Environmental objective:** an environmental goal, arising from the environmental policy, that a facility sets itself to achieve. An environmental objective is intended to reduce significant impacts, leading to improved environmental performance. Example of objective: to install a holding tank, piping, and pumping system in order to reuse treated water.

**Environmental target:** a detailed environmental goal, arising from the environmental objectives, applicable to the facility or parts thereof. An environmental target needs to be scheduled and assigned in order to meet an environmental objective. Example of target: to reduce water use by 30 percent over baseline in a 12-month period.

An EMS helps pharmaceutical company manage our activities, processes, products, or services that interact with or impact the environment. This means that in order to develop an EMS we have to do the following sequence of activities:

1. Identify activities, processes, products, or services of our facility
2. Determine aspects of these activities, processes,

products, or services that can interact with or impact the environment

3. Document which aspects have environmental regulatory requirements
4. Evaluate which aspects have significant impacts using rating criteria which company develops
5. Develop objectives and targets to manage those significant impacts

This planning stage of the EMS is the backbone of the program. It helps companies make decisions as to what to monitor and control in order to reduce impact on the environment. Objectives and targets should support companies Environmental Policy and be updated periodically as goals are reached.

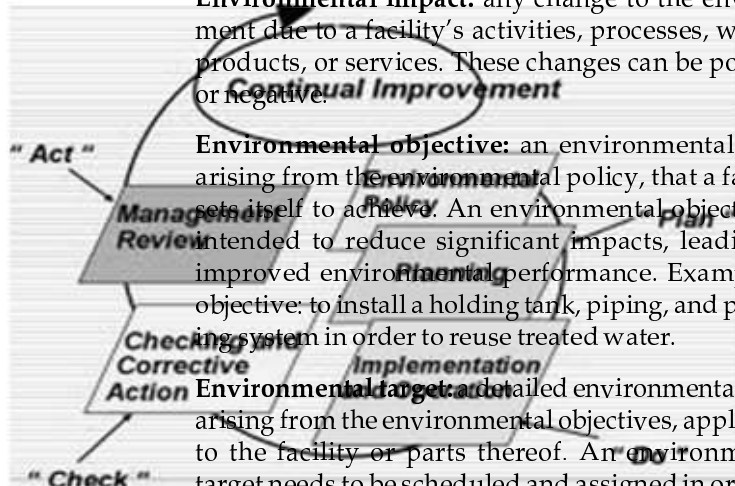
As part of developing an EMS, company need to document a procedure that use to set up the EMS. Such a procedure is necessary for consistency, particularly when company do our EMS annual review in which company reconfirm significant aspects of our operation and review progress made against our objectives and targets.

### 1. Purpose

This procedure is developed to establish the planning elements of an EMS. It involves identification of the environmental aspects of this facility's activities, processes, wastes, products, and services that have significant environmental impact, and to develop objectives and targets for reducing those impacts.

### 2. Scope

- This procedure will be used to identify activities,



processes, wastes, products, and services of the organization and to establish a methodology for determining significant impacts.

- A multifunctional team (i.e., a team consisting of representatives from many different parts of the organization) should participate in the identification of aspects and impacts. This team is the EMS team. By including representatives of the whole organization it increases the chances that all environmental impacts will be identified.

- Criteria for evaluation of significant impacts can be regulatory requirements, estimated impact on the environment, legal liability, public risk, mitigation costs, frequency, severity, ability to control the impact, and others. The EMS team will need to choose a rating methodology using these or other criteria.

- Based on the impacts determined to be significant using the rating methodology chosen, objectives and targets will be developed that promote pollution prevention, environmental compliance, and continuous improvement as stated in this facility's Environmental Policy.

- Objectives and targets will be developed by assigned personnel responsible for the program, its measurement, and progress over time. The EMS manager oversees development and progress of objectives and targets over time.

### 3. Responsibilities

**EMS manager-** Works with the EMS team and all employees to identify aspects, determine significant impacts, and develop objectives and targets.

**EMS team-** Composed of representatives of all operational areas of the facility to identify and rank environmental aspects and impacts. Ensures on going development and refinement of the EMS.

**Upper management-** Approves objectives and targets.  
**Environmental Program Managers-** Responsible for achieving objectives, targets and timeframe for achieving them.

### Implementation of environmental management system

Implementation of an effective quality assurance policy is the most important goal of pharmaceutical industry. The concept of quality assurance and quality control together develops towards assuring the quality, safety and efficacy of pharmaceutical products.

Thus, quality is critically important ingredient to

organizational success today, which can be achieved by total quality management (TQM), an organizational approach that focuses on quality as an over arching goal, aimed at the prevention of defects rather than detection of defects. It is a philosophy and practice of integrative quality management system adopted worldwide in pharmaceutical industries along with other regulatory requirements. The TQM perspective views quality as the pivotal purpose of the organization. (Bhaskar, 2011)

The operations associated with the significant aspects previously identified and discuss the ways to control them from negatively impacting the environment. five factors that can be used to control those aspects. They are: (1) operational controls, (2) employee training, (3) communication, (4) emergency preparedness and response, and (5) documentation and recordkeeping.

1. Operational controls, also known as operating procedures or work instructions represent a mechanism used by a facility to control its environmental aspects. Operational controls are basically necessary for any operation which is regulated.

2. Training of employees whose jobs or activities can impact the environment is critical for successful implementation of your EMS. The EMS team should develop and maintain procedures to identify and track environmental training needs of those employees, and implement an employee training program.

3. Communication is also vital for successful implementation of an EMS. The EMS team should establish and maintain procedures for internal communication of the EMS between all employees. Similarly, procedures for external communication with the public, including local community and environmental interest groups, should be developed.

4. Generally, most facilities have already developed some form of emergency response procedures addressing an emergency, spill or fire, and meeting OSHA, EPA, and fire department requirements. The EMS team should ensure that an appropriate emergency response plan is established and maintained to adequately prepare, respond, and mitigate accidents, spills, fires, or other emergency situations.

5. The final factor of EMS implementation is documentation and recordkeeping. The EMS team should establish documentation and record keeping procedures to ensure that the EMS program is functioning

effectively and efficiently.

### 1. Scope

- All operating procedures and work instructions shall mention the activities and processes being monitored.
- A corrective provision shall be provided in the procedure in case operating parameters are exceeded.
- The EMS and the communication techniques used for transmitting information to the appropriate audience.
- Employee training requirements for the EMS and facility operations consisting of EMS awareness training, job-related training, and environmental, health and safety (EHS) training.
- Identification of the emergency preparedness and response plans for facility operations, the types of required emergency equipment, and procedures for training, response actions and reporting.
- Requirement for keeping, indexing, storing, updating and maintaining records for the EMS.

### 2. Updates and Reviews

- Operating procedures and work instruction must be reviewed annually or when the activity described changes. The current procedure should always be available at the workplace.
- Training and tracking must be reviewed annually or when environmental or legal requirements change. Usually EMS training is given bi-yearly at a minimum.
- The communication plan will be reviewed annually and revised as necessary.
- The emergency preparedness and response plans will be reviewed annually and updated as necessary to accommodate changes in processes or legal requirements.
- Each emergency is to be reviewed for appropriate response and for prevention of reoccurrence immediately after emergency.
- The list of records will be updated as necessary. This records and recordkeeping procedure will be reviewed annually and updated as necessary

### 3. Responsibilities

- The supervisor responsible for an activity or process will be in charge for developing and implementing the operating procedure or work instruction of activities under his supervision.
- Approval of the operating procedure is usually the responsibility of the department manager.
- The procedure itself is written for the person

following it (line operator).

- The Human Resources (HR) Department is responsible for training records. Any update or change to environmental training protocol must be approved by the EMS and Operations managers.
- The EMS Manager is responsible for updating the communication plan and revising the protocol when needed.
- The EMS Manager and the Emergency Coordinator are responsible for updating the emergency preparedness and response plans.
- Each department is responsible to initiate changes in recordkeeping if deemed necessary.
- The EMS Manager is responsible for updating the list of records and the records and recordkeeping procedure

## CONCLUSION

The process of developing an EMS is described in this paper. The procedure shows that in order to develop an EMS, it requires that a facility identifying its aspects of those activities, processes, products, or services that impact the environment.

After aspects are identified, then the facility needs to determine which of those aspects have significant impacts. The determination of significance is conducted by using a rating criteria developed by the facility. The result of this process is a list of aspects that have significant impacts. From the list, objectives and targets are developed with the goal of reducing the impacts, within a specified time frame, and with an assigned EMS staff coordinating the implementation.

The assessment of the identification of aspects and impacts, and legal requirements, and the development of objectives and targets are the components of EMS planning activities. This module, following the sequences of the planning protocol, presents an example of things to do in developing the backbone of an EMS. The example is given to show the thought process, or as a guidance for any facility intending to develop an EMS of its own.

In setting up an EMS, a facility identifies aspects of its operation that impact the environment, determines which of those aspects have significant impacts, and then develops objectives and targets with the goals of reducing the impacts. In implementing an EMS, which is the subject matter of this chapter, a facility needs to address the five factors that can be used to control those aspects of its operation from negatively impacting the environment.

**REFERENCES**

- Bhaskar Mazumderet, 2011. Environment Management System included total quality management.
- Fiscals, 2007. Environment Management System, onama pharmaceutical industry.
- Hankerson, 2006. ISO 14001 EMS module. *Journal of Environment Management System*.5 (2).
- IPCA, EHS Manual, 2012. Indian pharmaceutical control association, environment health and safety department.
- Stephen, A. 2006. Arizona department of environmental quality Janet Napolitano, Publication Number TM 07-05
- Vonzahren, 1996. W.M. ISO 14000: Understanding the environmental standards, Rockville, MD: Government Institutes, Inc.