Research Journal of Pharmaceutical Sciences ISSN 2319 – 555X
Vol. **2(3),** 12-16, March **(2013)** *Res. J. Pharmaceutical Sci.*

Study on the Development of Environment Management System in an Indian Pharmaceutical Industry through Implementation of ISO 14001:2004 Guidelines

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Available online at: www.isca.in
Received 26th March 2013, revised 28th March 2013, accepted 30th March 2013

Abstract

Many pharmaceutical industries in India are concern of *environment management through waste treatment only, some* are concern of *environment management through waste treatment and minimization only, very few are* concern of *environment management through implementation of international standard ISO14001:2004*[1]. *This paper presents an analysis on implementation of environment management system following the requirements of ISO14001:2004 international standard and its impacts on a pharmaceutical industry of Kolkata, India. The main focus of this paper is the evaluation of achievement in waste management through implementation of ISO14001:2004, Environment management system (EMS) in a pharmaceutical formulation industry.*

Keywords: ISO 14001:2004, Significant environmental aspects, Significant environmental impacts, operational control, EMS internal audit, Management review.

Introduction

ISO 14001: 2004, international standard is Environmental management systems – Requirements with guidance for use. As per ISO 14001:2004, international standard, Environment means: Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans and their interrelation. Surroundings in this context extend from within an organization to the global system[1]. This standard has six main clauses as Clause 4.1 to 4.2.

Clause 4.2 is 'Environmental policy' top management has to ensure to continual improvement and commitment for prevention of pollution.

Clause 4.3.1: Environmental aspects: Organization has to identify Environmental aspects of its activities, products and services and to determine those significant aspects that have significant impacts on the environment.

Clause 4.3.2: legal and other requirements: Organization has to identify applicable legal requirements and other requirements to which the Organization subscribes.

Clause 4.3.3: Objective, targets and programmes: Organization has to establish, implement and maintain documented environmental objective and targets and has to establish, implement and maintain programmes for achieving its objective and targets with designated responsibility and time frame.

Clause 4.4.3: Communucation: Organization has to establish, implement and maintain environmental aspects internal Communication with all levels of the organization including external interested parties of the factory.

Clause 4.4.6: Operational control: Organization shall identify and plan for those operations associated with identified significant environmental aspects consistent with its environmental policy, objectives and targets. Establishing, implementing and maintaining procedures related to identified significant environmental aspects of goods and services used by the factory and communicating applicable procedures and requirements to the suppliers, including contractors.

Clause 4.4.7: Emergency preparedness and response: Organization has to establish, implement and maintain procedures to identify and respond to emergency situations and mitigate adverse significant impacts on the environment.

Clause 4.5.1: Monitoring and measurement: Organization has to establish, implement and maintain procedures to monitor and measure, on a regular basis, the key characteristics of its operations that can have a significant environment impact. Measurement of effluent parameters like pH, Oil and Grease, TSS, BOD, COD are measured and monitored here.

Clause 4.5.2: Evaluation of compliance: Consistent with its commitment, the Organization has to establish, implement and maintain procedures for periodically evaluating compliance with legal requirements and other requirements to which it subscribes.

Clause 4.5.1: Monitoring and measurement: Organization has to establish, implement and maintain procedures to monitor and measure, on a regular basis, the key characteristics of its operations that can have a significant environment impact.

Clause 4.5.3: Nonconformity, corrective action and preventive action: Organization has to establish, implement and maintain procedures for dealing with actual and potential non-conformity and taking corrective and preventive action.

Clause 4.5.5 'Internal audit' states that organization shall ensure that internal audits to environmental Management system are conducted at planned intervals to determine that environmental Management system conforms to the requirements to the international standard and properly implemented. Selection of auditors and conduct of audits shall ensure objectively and the impartiality of the audit process.

Clause 4.6 'Management review' states that top management shall review organizations Environmental Management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, opportunities for improvement, environmental policy, objectives and targets, environmental internal audit, evaluation of compliance with legal requirements, communications from external interested parties including complaints. Other agenda must be discussed in Management review meeting(MRM) are Environmental performance of the organization, the extent to which objectives and targets have been met, changing circumstances, including developments in legal and other requirements related to environmental aspects, recommendations for improvement.

Small and medium sized (SME) enterprises play a vital role in our socioeconomic systems. Collectively they are responsible for considerable environmental impacts[2]. Implementing ISO:14001has helped Rockwell's automation plant reduce its hazardous waste by 18%, Ford's Lima engine plant reduced in water usage by 2.4 million gallons annually, Lockheed Martin's Syracuse plant was able to reduce its wastewater by 86%, solid wate by 78% and process waste by 34%, recycling at the plant improved by 22%[3,4]. The focus of the standard is to bring environmental issues into the mainstream of the corporate decision making process, and therefore the ISO:14001 standard may well be an indicator of a company's commitment to environmental responsibility[5,6]. In India, around 1500 organization have been ISO:14001 certified, which is around 1.7% of world share- quite negligible compared to Japan, China and Spain[7]. Encap Drug Delivery is a pharmaceutical company in Livingstone, filling two piece hard capsules with liquid medications, employs 70 people with 6 million dollar turn over. After implementing ISO:14001, EMS, the company reduced the waste sent for landfill for disposal by 25%, by adopting recycling process by segregating glass, paper, cardboard, plastics and metal[8]. One company reported that it was able not only to recycle 94% of its waste, but also to create a profit centre[9]. In Lebanon Cosmaline produces cosmetics and Pharmaline produces pharmaceuticals and para-pharmaceuticals after implementing EMS ISO14001 demonstrate sound environment performance in waste management by recycling waste into primary materials, like carton, nylon, oil waste are sold or given free to waste contractor for recycling. At Cosmaline's polyethylene waste is recycled upto three times for production of bottles, caps jars, when these polyethylene waste can no longer recycle internally then sold to contractor for manufacture of cistern, floate etc.[10].

The present study is aimed to mitigate environment aspect-impact in a drug formulation unit producing tablets, oral liquids, capsules by adopting and implementing Environment Management System (EMS), following ISO:14001:2004 international standard.

Material and Methods

The present study was conducted in a pharmaceutical formulation industry having producing drugs formulations of tablets, capsules and oral liquids. The work done in this drug plant in three subsequent years (2010, 2011 and 2012). In the first visit, extensive studies of the in-plant processes were made. Samples were collected from the final effluent stream and analyzed for the parameters pH, TSS, TDS, COD and BOD. Those are failing with higher values and does not complying environment norms. Then an environment audit are conducted to found out the root causes, and a very in systematic environment management approach are found. Then present investigator suggested to the management for implementing ISO:14001 environmental management systems (EMS) to resolve the problem. The suggestions were accepted by the management.

Seven step action plan has been prepared. Selection of an EMS manager, formation of an EMS team from multivarious activity staff, as shown in table-1, Formation of environment policy, a commitment to develop EMS, signing by the top management, displaying to all strategic places of the factory for communicating to all concerned and outside the gate for public also, awareness and internal auditor training are given by the investigator to all EMS team members, to make them qualified Inter auditor of EMS, as shown in table-2,

Identification of environmental aspects and significant environmental aspects as shown in 1st column of Table-3, environmental aspects (clause 4.3.1.a), Identification of environmental impacts and significant environmental impacts as shown in 2nd column of table-3, environmental impacts (clause 4.3.1.b), Establish Operational control to tackle identified environmental aspects and significant environmental aspects and identified environmental impacts and significant environmental impacts, as shown in column 3rd of table-3, operational control (clause 4.4.6), formulation of objective, targets and programmes to mitigate identified environmental aspects and impacts, as shown in column 4th of table-3., Closing

of Nonconformity (NC) for significant environmental aspects and impacts and NC raised during internal audit and corresponding corrective action - preventive action taken to close them as shown in 5th column of table-3.

Before starting of ISO:14001:2004 implementation effluent parameters are high, after implementation of environmental Management system following ISO:14001:2004, the characteristics of effluent are changed as shown table-4.

Results and Discussion

Table-1
Environmental management systems (EMS) team of the pharmaceutical formulation industry

Name	Functional Designation	Qualification	Experience	Gap analysis
Jayanta Basu	EMS manager	Environmental engineer	10 years	ISO:14001:2004 training required
Ajay Biswas	Q.C.Manager	PhD in Pharmacy	20 years	ISO:14001:2004 training required
Bhuban Bakshi	Production manager	B.Pharm	25 years	ISO:14001:2004 training required
Tapan Tapadar	Store Incharge	B.Com.	6 years	ISO:14001:2004 training required
Pallab Ghosh	Purchase Incharge	B.Sc.	7 years	ISO:14001:2004 training required
Panchu Sarkar	Safety Officer	Diploma in safety	10 years	ISO:14001:2004 training required
Bhagabati Sharma	Plant Manager	M.Tech. (pharmaceutical technology)	20 years	ISO:14001:2004 training required
Bishnu Jain	Maintenance Incharge	AMIE Engineer	20 years	ISO:14001:2004 training required

Table-2
Training record for Environmental management systems (EMS) team to develop as internal auditor of the pharmaceutical formulation industry

Name	Awareness Training given on August 2011	Internal auditor Training given on September 2011	Internal auditor examination taken on October 2011 for 100 marks	Qualification (pass marks 50)
Jayanta Basu	Awareness for EMS of ISO:14001:2004	Internal auditor of EMS	80 marks	Qualified as Internal auditor of EMS
Ajay Biswas	Awareness for EMS of ISO:14001:2004	Internal auditor for EMS	70 marks	Qualified as Internal auditor of EMS
Bhuban Bakshi	Awareness for EMS of ISO:14001:2004	Internal auditor for EMS	65 marks	Qualified as Internal auditor of EMS
Tapan Tapadar	Awareness for EMS of ISO:14001:2004	Internal auditor for EMS	40 marks	Non qualified as Internal auditor of EMS
Pallab Ghosh	Awareness for EMS of ISO:14001:2004	Internal auditor for EMS	35 marks	Qualified as Internal auditor of EMS
Panchu Sarkar	Awareness for EMS of ISO:14001:2004	Internal auditor for EMS	65 marks	Qualified as Internal auditor of EMS
Bhagabati Sharma	Awareness for EMS of ISO:14001:2004	Internal auditor for EMS	80 marks	Qualified as Internal auditor of EMS
Bishnu Jain	Awareness for EMS of ISO:14001:2004	Internal auditor for EMS	75 marks	Qualified as Internal auditor of EMS

Summary results: Six Qualified Inter auditor of EMS are developed.

Table-3
Waste Minimization in a pharmaceutical formulation industry following ISO 14001:2004

Environmental aspects (Clause 4.3.1.a)	Environmental impacts (Clause 4.3.1.b)	Operational control (Clause 4.4.6)	Objectives, targets and programme (Clause 4.3.3)	Nonconformity, corrective action and preventive action (Clause 4.5.3)
Powder spillage during sampling and weighing of Raw materials (RM)	i)Contamination of air and land ii)Effect on human lungs	i) Work to be done under laminar in sampling booth ii) Operator has to wear masks	i)Sampling booth with laminar to be purchased within 10/02/12 ii) Operator has to wear masks within two days Responsibility : CEO	i) Sampling booth with laminar purchased and installed on 08/02/12 ii) Operator are wearing masks within one day
Heavy sound generating during RM movement in store	Effect on human ear of sound pollution	RM movement are to be done in trolley fitted with wheel with rubber lining	trolley fitted with wheel with rubber lining are to be purchased within 25.02.2012. Responsibility: Plant manager	trolley fitted with wheel with rubber lining are purchased and installed on 20.02.2012.
Powder, broken pieces of tablets, torn strips, torn labels, torn papers on production floors	i) Contamination of land ii) Increase load on ETP and BOD and COD in wastewater	i) Each material should be segregated and kept in separate labeled bins ii) No materials should be allowed to go to drain	i) Each material are segregated and kept in separate labeled bins within 10.02.2012 ii) No materials are allowed to go to drain, 100% are to be implemented within 10.02.2012 Responsibility : EMS manager	i) Each material are segregated and kept in separate labeled bins within 08.02.2012 ii) No materials are allowed to go to drain, 100% are implemented on 08.02.2012
Flying dust generates in tablet compression machine Mixed waste generates after sweeping floor in oral liquid depart.	i) Effect on human lungs ii) Ultimate load on ETP i) Contamination of land ii) Increase load on ETP and BOD and COD in wastewater	Foolproof dust catcher are to be installed in the compression machine i) Each material should be segregated and kept in separate labeled bins ii) No materials should be allowed to go to drain	Foolproof dust catcher machine are to be installed in the compression machine within 20.02.2012 Resp.: CEO i) Each material are segregated and kept in separate labeled bins within 15.02.2012 ii) No materials are allowed to go to drain, 100% are to be implemented within 15.02.2012 Responsibility : EMS manager	Foolproof dust catcher machine are installed in the compression machine on 16.02.2012 i) Each material are segregated and kept in separate labeled bins within 12.02.2012 ii) No materials are allowed to go to drain, 100% are implemented on 08.02.2012
Oil leakage found from trucks during transferring HDO to boiler tank	i) Contamination of land ii) Increase load on ETP and BOD and COD in wastewater	i) New hose pipe are to fitted to stop oil leakage ii) Oil tray must be used to catch hold any type of oil drips	i) New hose pipe are to used within 01.03.2012 ii) Oil tray must be used within three days Responsibility : Maintenance manager	i) New hose pipe are used from 28.02.2012 ii) Oil tray must be used within three days
Canteen waste materials are going to drain	i) Contamination of land ii) Increase load on ETP and BOD and COD in wastewater	Canteen waste materials are to be transferred to compost chamber in the garden	The system has to be implemented within three days Responsibility : EMS manager	The system has to be implemented within two days
Expired control samples	i) Contamination of land ii) Increase load on ETP and BOD and COD in wastewater	i) Each material should be segregated and kept in separate labeled bins ii) No materials should be allowed to go to drain	i) Each material are segregated and kept in separate labeled bins within 25.02.2012 ii) No materials are allowed to go to drain, 100% are to be implemented within 25.02.2012 Responsibility : EMS manager	i) Each material are segregated and kept in separate labeled bins within 21.02.2012 ii) No materials are allowed to go to drain, 100% are implemented within 18.02.2012
Daily road sweeping waste materials, parts from trees, leafs, broken branch, wood sticks	i) Contamination of land ii) Increase load on ETP and BOD and COD in wastewater	To be collected and disposed in compost chamber in the garden	To be collected and disposed in compost chamber in the garden, the operation should start within three days. Responsibility : Estate manager	collected and disposed in compost chamber in the garden, the operation should started within two days.

Table-4
Characteristic Change in Effluent Generated from pharmaceutical Industry before Implementation of ISO:14001:2004 and after Implementation of ISO:14001:2004

Parameters	Effluent Characteristics	
	Before Implementation of EMS, ISO:14001:2004	**After Implementation of EMS, ISO:14001:2004**
Volume (m^3/h)	05 – 8	03 - 06
pH	5 – 9	6.5 – 7.5
TSS (mg/l)	500-600	< 150
TDS (mg/l)	600-700	< 100
COD (mg/l)	500 – 600	< 100
BOD (mg/l)	200 – 300	< 30

Conclusion

Adoption of ISO:14001:2004 environment management system standards, with regular self assessment and internal audit can develop waste management and cleaner production in pharmaceutical industry, as basic drug plants are red category industry as per CPCB norms. ISO:14001:2004 is a scientific tool by which small and medium size (SME) pharmaceutical industry, will be benefitted. We have to develop a EMS team as shown in table-1, then we have to train them as shown in table-2, then we have to minimize and treat the waste as shown in table-3, and finally we achieved to reduce effluent characteristics as shown in table-4.

Implementation of ISO:14001:2004 environment management system is necessary rather than certification of ISO:14001:2004 for the organization.

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