Environmental Plans for Drug and Food Testing Laboratories

1. Background

1.1. Introduction

The Government of India is strongly committed to improving the quality and safety of food and drugs in the country. The long term strategy includes creating common standards and approaches in the country and policy reforms related to existing government regulations, licensing, transparency and enforcement. A number of initiatives have been taken in last few years to improve the capacity of testing laboratories and to upgrade systems and procedures. To further support this exercise and to disseminate it uniformly across all states in the country, the Ministry of Health and Family Welfare (MOHFW) of the Government of India has proposed the Food and Drug Capacity Building Project, to the World Bank.

One of the keys areas proposed within the Food and Drug Capacity Building project relates to the upgradation of capacity and competency of the Central and State Food and Drugs testing laboratories. At the policy level, the project will allow the enhancement of the existing set of laws and regulatory provisions to clearly and specifically address the handling and management of hazardous chemicals and biohazardous wastes used and generated in such Drug and Food Testing Laboratories. An environmental management action plan will be implemented to minimize negative environmental impacts of current and future operations and to increase the overall safety at these laboratories. The project will allow for the enhancement of the existing national Good Laboratory Practices (GLP) Guidelines with an environmental management health and safety component and standard Codes of Practice.

The food and drug-testing laboratory undertake analytical work involving use of various chemicals though the quantities used are small. The chemical waste generated is minimal and the only risk may be created by occasional spillage, splashes or broken glassware.

1.2. Objectives

The main objective is the development and implementation of a generic Environmental Management Action Plan which will enable review and mitigation of environmental risks related to the up-gradation, construction and operation of laboratories, in a manner to ensure compliance with environmental requirements in India and compatibility with the international environmental practices.

1.3. Methodology

1. The MOHFW did a preliminary desk review of laboratories to be covered under this project. Site visits to following 4 food and drug control laboratories were undertaken:
   - Food Research & Standardisation laboratory , Gaziabad (UP)
   - Central Indian Pharmacopuer laboratory, Rajnagar (UP)

- National Institute of Biologicals , Noida (UP)
- Central drug research institute, Kasauli (HP)

2. Consultations were held with the key stakeholders including MOHFW and laboratory staff, food and drug regulatory personnel, environmental NGOs and the affected communities.

3. The MOHFW did a desk review of the existing policy framework for environmental protection and occupational safety and health in food and drug laboratories, which included the following:
   - existing legislations in India including (a) Biomedical Waste (Management and Handling) Rules-1998; (b) Environment Protection Act – 1986; (c) The Factories Act – 1948; and (d) Drugs and Cosmetics Act, (e) The Manufacture, Storage, and Import of Hazardous Chemical Rules (1989) and (f) Hazardous Wastes (Management and Handling) Rules (1989)
   - international legislations and guidelines including WHO documents
   - Good Laboratory Practices (GLP) guidelines for Drug Quality Testing Laboratories developed by MOHFW
   - Criteria for Laboratory Accreditation, National Accreditations Board for Testing and Calibration of laboratories, Department of Science and Technology.

2. Situation Analysis

2.1 The site visits and stakeholder consultations revealed the following:

- Most of the laboratories are small, with few workers with minimal amount of materials usage and waste generation
- The volume of waste generated is small, but varied due to the different types of chemicals used. Combined waste water parameters vary from laboratory to laboratory.
- There is lack of awareness regarding waste management and in most laboratories, there is no proper segregation of waste.
- Laboratories do not keep records of quantity and quality of waste generated
- Wastewater audit and monitoring systems are lacking
- There are some basic standards for safe management of hazardous chemical materials and wastes
- Better operational practices and segregation at source can reduce waste generation.
- There is need to enhance the skills and capacity of most laboratory staff in environmental health and safety management
- There is need for updating, standardizing and enforcing existing laws and improved coordination with regulatory agencies

2.2 Review of National legal and regulatory frameworks:

2.2.1 The Environmental (Protection) Act, 1986

This Act is designed to protect environment from air and water pollution. The Act has provisions to prevent contamination of soil from improper hazardous waste disposal and from leakage, spills or leaching of chemicals. This Act categorically mentions effluent discharge standards for different categories of industries.

While there are general standards for discharge of environmental pollutants in Inland surface water, public sewer, land and marine in Schedule-1of the Act, there are no separate standards mentioned for food and drug control laboratories.

2.2.2 The Biomedical Waste (Management and Handling) Rules (1998)

These rules, which were partly amended in 2000, apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle biomedical waste in any form. Bio-medical waste is defined as any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biological, and including categories mentioned in Schedule I. Schedule I describes the different categories of biomedical waste as detailed below:-

SCHEDULE I
CATEGORIES OF BIOMEDICAL WASTES

Option	Waste Category	Treatment & Disposal
Category No. 1 (Not Applicable)	**Human Anatomical Waste** (human tissues, organs, body parts)	Incineration[1]/deep burial[2]
Category No. 2	**Animal Wastes** (animal tissues, organs, body parts carcasses, bleeding parts, fluid, blood and experimental animals used in research, waste generated by veterinary hospitals, discharge from hospitals, animal houses)	Incineration[1]/deep burial[2]
Category No. 3	**Microbiology and Biotechnology Waste** (wastes from laboratory cultures, stocks or specimens of micro-organisms, live or attenuated vaccines, human and animal cell culture used in research and infectious agents from research and industrial laboratories, wastes from the production of biologicals, toxins, dishes and devices used for the transfer of cultures)	local autoclaving/ microwaving/incineration[1]
Category No. 4	**Waste Sharps** (needles, syringes, scalpels, blades, glass, etc, that may cause puncture or cuts. This includes both used and unused sharps)	disinfections (chemical treatment[3])/autoclaving/ microwave/& mutilation/ shredding [4]
Category No. 5	**Discarded Medicines and Cytotoxic Drugs** (wastes comprising outdated, contaminated and discarded medicines)	incineration[1]/destruction and drugs disposed in secured landfills
Category No. 6	Soiled Waste (items contaminated with blood and body fluids including cotton dressings, soiled plaster casts, lines, beddings, other material contaminated with blood)	incineration[1]/autoclaving/m icrowaving
Category No. 7	Solid Waste (wastes generated from disposable items, other than waste sharps, such as tubings, catheters, intravenous sets, etc)	disinfections (chemical treatment[3])/autoclaving/ microwave/& mutilation/ shredding[4]
Category No. 8	**Liquid Waste** (waste generated from laboratory and washing, cleaning, housekeeping and disinfecting activities)	disinfections (chemical treatment[3]) and discharge into drains
Category No. 9 (Not applicable)	**Incineration Ash** (ash from incineration of any biomedical waste)	disposal in municipal landfill
Category No.10	**Chemical Waste** (chemicals used in production of biologicals, chemicals used in disinfection, as insecticides, etc)	disinfections (chemical treatment[3])and discharge into drains for liquids and secured landfill for solids

[1] *There will no chemical pretreatment before incineration. Chlorinated plastics shall not be incinerated*
[2] *Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas*
[3] *Chemicals treatment using at least 1% hypo chlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfections*
[4] *Mutilation/shredding must be such so as to prevent unauthorized reuse.*

Food and Drug Testing Laboratories are likely to produce wastes in many of the 10 categories listed above. The correct classification and proper segregation of biomedical wastes (hazardous and non-hazardous general wastes) is essential and should be the responsibility of the staff of the laboratory.

The Biomedical Waste Rules do not cover safety, training and occupational health aspects of the food and drug laboratories.

2.2.3 The Hazardous Wastes (Management and Handling) Rules (1989)

These regulations include requirements governing waste classification, accumulation, disposal, record-keeping and emergency preparedness. Hazardous waste management requirements are dependent upon the type and quantity of wastes generated by the laboratories. Most laboratories generate hazardous waste and, therefore, are subject to these rules. The Rules specify hazardous waste in 10 categories and regulatory quantities are indicated for each category.

These Rules do not specifically mention the hazardous waste generated in food and drug testing laboratories.

2.2.4 The Manufacture, Storage, and Import of Hazardous Chemical Rules (1989)

The rules address storage and handling of flammable liquids and of compressed gases and communicating chemical hazards in the laboratories. The rules require the communication of all chemical hazards to employees in the laboratories.

These rules do not address the handling of hazardous chemicals with reference to their transportation and movement.

2.2.5 The Factories Act, 1948

This law specifically focuses on occupational health and safety and identifies the need for Material Safety Data Sheets (MSDS).

The basic provisions for safe workplace provided for under this Act can be applied as a baseline, but needs to be updated to reflect current understanding of health and safety issues and the myriad of new chemicals in use in manufacturing and the food and drug industry.

2.2.6 Drugs and Cosmetics Act & Rules

The provisions under this Act are applicable to drug manufacturing units and provide guidelines on ‘good manufacturing practices’.

But this Act does not mention environmental plans or have any significant reference on health and safety in the laboratories. There is a passing reference to first aid, but with no details.

2.2.7 Good Laboratory Practices (GLP), MOHFW

The GLP Guidelines for Drug Testing Laboratories focuses on procedures, practices, techniques of drug testing. The GLP guidelines do not cover the food labs.

The National Accreditation Board for Testing and Calibration Laboratories (NABL) establishes criteria for laboratory accreditation. The focus is on maintaining good environmental conditions related to standards for accuracy of testing

The GLP and accreditation standards for laboratories do not contain guidelines for environmental management of Food and Drug Testing Laboratories.

2.2.8 Conclusion

Though the existing laws in India have established standards on occupational health, safety, waste management and general environmental protection for manufacturing units, they do not provide specifically for environmental health and safety in Drug and Food quality testing laboratories. Laboratories present unique working conditions, even though the quantities of chemicals used and amount of wastes generated are relatively small. The disposal of hazardous chemicals, empty containers and bottles and wastewater are issues which need to be addressed since indiscriminate use, storage, handling and disposal can have serious implications for the health of the public and of the environment.

2.3. Review of International Guidelines

2.3.1 Safe Management of wastes from health-care activities (1999), WHO

While the focus of this guideline is on establishments providing direct health care services, much of the material on chemical wastes and bio-hazardous waste management would be applicable or could be adapted to address similar wastes in laboratories.

In particular this would be useful in Sharps Management Guidelines, General guidelines for large and small facility waste planning and Chemical waste / laboratory waste sections.

2.3.2 Environmental Management Guide for Small Laboratories, May 2000 - United States Environmental Protection Agency:

This guide provides a specific approach to environmental management systems, and is designed for laboratories in the U.S. and elsewhere that typically do not have a person employed as an environmental manager. These laboratories include research laboratories for healthcare, and those that do commercial testing for healthcare, food, industrial hygiene, waste.

This guide, with its emphasis on designing systems and supporting pollution prevention, make it an ideal resource to establish a national guide for GEMPL (Good Environmental Management Practices in Laboratories).

2.3.3. Manuals on health and safety guidelines for laboratories: National Institute of Environmental Health Sciences (NIEHS), USA

While these manuals focus on larger laboratories, elements of some of the guidelines may be appropriate to extract for reference in the Food and Drug laboratories.

2.3.4. Laboratory Procedures Manual, U.S. Food and Drug Administration (FDA)

This manual is designed for field laboratories and may be an appropriate reference tool. It focuses on worker safeguards against laboratory hazards (biological and chemical). Such worker safety practices are also generally appropriate and aligned with environmental safeguards.

2.3.5. Conclusion:

Some of the international standards may not be appropriate to conditions in Indian laboratories. However, some of the manuals, in particular those from FDA and EPA, are directed to smaller laboratories, which could probably be replicated in many of the state laboratories under the framework of this program. The MOHFW considers that such international guides provide good reference materials and a basis for developing specific manuals and protocols for the food and drug laboratories.

3. Environmental Impacts

The proper identification of the environmental impacts related to laboratory operation and construction activities is important so as to define effective mitigation and management practices. This has a beneficial effect not only on overall environmental performance but also on the safety and health of the laboratory personnel and related community.

Laboratories present unique working conditions and environment even though the quantity of chemicals used is small. Even chemicals that are generally considered to be benign have the potential to be hazardous under specific circumstances.

1.1 Environmental Impacts related to Laboratory Construction

Some of the environmental impacts associated with laboratory construction are listed below:

1.1.1 Water Pollution

Construction activities generate waste water from wash-pits, wheel washing, equipment cleaning, etc which can be a source of water pollution if the drainage system is

ineffective. Additionally the large number of temporary construction workers will generate sanitary waste, which if not properly managed, can Also if there is no arrangement to handle the sanitary waste, it could pollute the surface/under-ground water. There is the added risk of mosquito breeding, if water around the construction site is allowed to stagnate.

3.1.2 Air Pollution

Dust generated during the process of cutting and filling earth and improper burning causes air pollution. Fly ash is also generated during cement mixing.

3.1.3 Noise Pollution

Noise pollution due to operation of different types of equipment and machinery during construction activities may disturb the surrounding premises, including residential dwellings, schools, hospitals etc.

3.1.4 Construction design issues

Some of the environmental risks associated with poor design of laboratories are:

- Improper design of flooring may lead to falls, slippage, retention of infectious material etc.
- Absence of separate waste movement corridor may cause occupational health hazard.
- Inadequate and poor quality of drinking water could be a health hazard
- Insufficient ventilation and absence of natural lighting may adversely affect health and energy efficiency.
- Improper design of fire safety system could result in leakage of hazardous materials.

3.2 Environmental Impacts related to Laboratory Operation

Some of the environmental impacts associated with regular laboratory operations are listed below:

3.2.1 Water Pollution

The food and drug laboratories use a wide range of chemicals, disinfectants and sample drugs. Direct release, without treatment and segregation of any of these chemicals and hazardous wastes to the drain without treatment can contaminate and corrode the waste water system and create health risks for the general public, directly or indirectly. Such pollution is also detrimental to aquatic life and the marine environment.

3.2.1 Air Pollution

The operation of laboratories may result in a number of hazardous emissions to the air from fume hoods and vents, sterilization / disinfection technologies; plant operations (boilers and generators), refrigerants (Ozone depleting substances) and

treatment technologies (incinerators, if any). Open and incomplete burning of wastes can create hazardous air emissions such as dioxins.

3.2.2 Soil Contamination

The disposal of untreated and un-segregated solid waste (containing organic, degradable mixed with hazardous chemicals) can result in contamination of the soil and the solid waste system.

3.2.3 Handling & Disposal of Chemicals and hazardous wastes

Improper handling of hazardous chemicals is a health hazard for the laboratory workers and its indiscriminate disposal can have environmental risks as detailed above. The same applies for other substances, such as untreated and expired drugs, treated samples of food and drugs and sharps (needles, syringes, broken laboratory glassware etc).

Rag-pickers, whose livelihood is dependent on the facility are also at risk though infection and injury. Indiscriminate dumping of wastes can also result in illegal and dangerous recycling of chemicals, sharps and other substances, which can become a public health hazard.

Poor drainage and infrequent collection resulting in decomposition of wastes around the facility can encourage breeding of mosquitoes, flies, rats and other scavengers.

4. Environmental Impact Management and Mitigation

Precautionary measures to ensure high environmental and health safety standards would be ensured while planning, designing, and constructing laboratories. Emphasis would be given to pollution prevention and control rather than clean-up.

4.1 Mitigation of environmental impacts during Laboratory Construction

4.1.1 National code of practices:

The design and construction of the laboratories will comply with the existing set of codes, regulatory guidelines and manuals, as listed below:

- National Building Code of India
- IS 1172-1983: Code of basic requirements for Water Supply, drainage and Sanitation
- IS 2065-1983: Code of practice for water supply in buildings
- IS 1742-1983: Code of practice for building drainage
- IS 1200: Code of practice for water supply and drains
- Central Public Health and Environmental Engineering Organization (CPHEEO)

manual on Water Supply & Water Treatment
- CPHEEO manual on Sewerage & Waste Treatment
- CPHEEO manual on Solid Waste Management.
- Tariff Advisory Committee (TAC) manual on Fire Protection System

The construction practices shall also comply with the national standards and code of practices established by the Ministry of Environment and Forests and other environmental agencies, some aspects of which are highlighted below:

- Site clearing before construction and work place, all trash, debris and other weeds will be removed.
- Metal or heavy-duty plastic refuse containers with tight fitting lids for disposal of all garbage or trash will be used. Refuse containers shall be kept upright with their lids shut tight. These containers shall be emptied daily to maintain site sanitation.
- Temporary fencing around the project site will be provided to regulate the entry and exit of material, personnel and equipment.
- All existing stream courses and drains within, and adjacent to the site will be kept safe and free from any debris and any excavated materials arising from the works.
- It will be ensured that chemicals and concrete agitator washings are not deposited in the watercourses.
- All water and waste products arising on the site shall be collected and removed from the site via a suitable and properly designed temporary drainage system and disposed off at a location and in a manner that will cause neither pollution nor nuisance.
- Temporary drainage works will be constructed, maintained, removed and reinstated for the avoidance of damage by flooding and silt washed down from the works.
- In the event of any spoil or debris from construction works being deposited on adjacent land or silt washed down to any area, all such spoil, debris or material and silt shall be immediately removed and the affected land and areas restored to their natural state by the contractor to the satisfaction of the employer's representative.

Additionally a team of experts in environmental planning and designing from the internal Environment wing of the construction management consulting firm will review and approve the design before construction.

4.1.2 Design improvements

Following environmental factors will be taken care while designing laboratory facilities for safer storage, handling, treatment and disposal of waste:

- Chemical/infection resistant flooring/plastering
- Proper waste movement separate corridor planning/ exist gate etc.
- Natural lighting and well ventilated system

- Adequate and good quality water supply system.
- Sanitary and drainage system for waste water flow
- Storage bins and collection equipment for different categories of waste.
- On-site/off-site waste treatment facilities
- Secured landfill site
- Ducts, fume hoods for proper air circulation/ exhaust of toxic and other gases
- Fire safety

4.2 Mitigation of environmental impacts during Laboratory operations

Many of the pollution problems associated with laboratory wastes stem from the types of materials and chemicals used. Establishing good purchasing and procurement practices is the first step in effective pollution control. Ensuring the selection and implementation of environmentally sound and cost-effective treatment technologies is an important element in the process. The option for final disposal of infectious and hazardous will be decided in consultation with the State Pollution Board. Identification of landfills (on-site or off-site) and evaluation of the condition of those landfills to accept wastes from these treatment technologies should be done. For off-site facilities, contractual arrangements with specialized independent transportation companies can be considered. If such facilities exist within a feasible neighbourhood, construction of leachate proof deep burial pit will need to be considered for disposal of hazardous waste.

Planning of a waste management system will take into consideration pollution prevention, waste minimization and recycling activities. (This will usually entail several different systems to manage the multiple waste streams identified for treatment. The planned waste management system has been shown in flow chart, attached as **Annex I**.

4.2.1 Identification of material/waste

All type of solid, liquid and gaseous waste generated from different sources will be identified and segregated for storage, collection, treatment, transportation and eventual disposal.

4.2.2 Storage

All chemicals will be stored in proper identified place as per manufacturer's instructions and if required, separate from other chemicals or environmental conditions which can cause reactions. Closed containers will be used for storage of hazardous chemicals. Separate storage areas will be identified for incompatible chemicals.

4.2.3 Segregation & collection

Most of the waste is a combination of hazardous and non-hazardous wastes. By establishing good segregation practices at source, effective waste management (including treatment and disposal) can be implemented with less effort and minimal resources. The different categories of waste will be quantified and analysed for handling and disposal.

The waste will be segregated at source and collected in proper identified color coded storage bins/ containers. Labeling and coding of hazardous waste will be done, so that emergency services will be able to deal with accidental spillages. The waste will be collected in wheel barrows from the storage bin/containers and transported to identified storage areas inside or outside the facility. Personnel safety measure will be ensured while segregating and collecting different categories of waste.

4.2.4 Transportation

The hazardous solid and liquid waste collected in containers will be taken to off-site treatment /disposal facilities in specially designed vehicles. Contractual arrangements can be made with specialized private agencies in the area of waste management. If no such facilities exist within a feasible neighbourhood, construction of leachate proof deep burial pit will need to be considered for disposal of hazardous waste.

4.2.5 Treatment and Disposal

There is no standard treatment process that adequately treats all the hazards identified in health care wastes.

- **Liquid waste**

To safeguard against water pollution, precautionary measures will be taken at source to reduce the quantity and strength of pollutants in the waste water flow. Waste water will be segregated at source, using the separate drainage system for laboratory waste. Liquid waste generated from different sources will be treated and disposed as detailed below:

(a) **Domestic waste:** The waste generated from toilet, kitchen, plain hand washing are non-infectious and can be disposed in the public sewage system, which is finally connected to terminal STP. In absence of public sewer, this waste can be disposed in a septic tank or biological filter.

(b) **Chemical Waste:** The infectious liquid waste will be disinfected by treatment with different disinfectant reagents such as hypochloride solution, savlon etc. The waste generated from food and drug sample analyses, solvents, disinfecting reagents, glassware and apparatus cleaning solutions and other accessories in the laboratories will be given chemical pretreatment viz. neutralization before final disposal in sewage system. If there is presence of heavy metals or other hazardous contamination, the waste will be given onsite treatment, if available, before disposal. If on-site treatment is not feasible, the waste will be stored in container and taken to nearby treatment facilities.

- **Solid waste**

(a) **Municipal Solid waste :** The non-hazardous solid waste generated from the kitchen, toilet, packaging, facility cleaning and sweeping etc, will be disposed at nearby municipal landfill sites, in accordance with Municipal Solid Waste disposal guidelines.

(b) **Hazardous Waste:** This category of waste is critical and needs careful handling and disposal. Disposal methods for the various types of hazardous wastes are detailed below:

- Sharps : Needles, syringes and other sharp instruments will be placed in puncture-resistant plastic/metal containers. They can be boiled/autoclaved or chemically disinfected, mutilated in shredder and then buried in secure land fill site. Glassware and other solid material can be disinfected by autoclaving, sterlisation or by other methods.
- Samples: Drug samples for analysis will be disposed of in secured landfills. For food samples which are bio-degradable the option of composting will be explored.
- Pharmaceutical Waste: Expired or unwanted drugs or other chemicals will be returned to distributing companies for proper disposal or buried in secured landfill site
- Pressurized Containers: Containers can be depressurised by cutting holes or disposed in secured landfill site or they can recycled after chemical disinfections.
- Batteries: Will be disposed in secured landfill.
- Generator Oil: Will be soaked in cotton and disposed in secured landfill.

If on-site deep burial is not possible, the waste can be stored in different container/ bags and transported to appropriate off-site facilities. Contracting local private entrepreneurs in the field of waste management can be an option to save capital as well as operation & maintenance cost of waste treatment equipments.

5. Environmental Management Action Plan

5.1. Scope and Outcome:

To strengthen the system for management of environmental health and safety in the food and drug testing laboratories, the Environmental management action plan will detail (a) procedures for handling equipment and materials; (b) use of personal protective equipment including adoption of safe work practices; and (c) management of bio-medical wastes.

The action plan will specifically address:

- How to ensure a safe laboratory environment to protect the health of the staff working at the food and drug testing laboratories

- How to ensure safe disposal of infectious and chemically toxic wastes produced from food and drug testing laboratories
- Who will be accountable to implement the plan for promoting environmental safety and disposal of toxic material as per the National guidelines
- How to integrate these concerns in a sustained manner with the proposed National Program of building capacities of the food and drug administration

One outcome of the action plan is the development of a set of standards and an operating manual for Food and Drug Laboratories. These elements will be incorporated into the existing national GLP manual to expand its scope to cover environmental management practices.

The Plan will be implemented in 50% of the project laboratories by mid term and will be extended in a phased manner in other laboratories.

5. 2. Process:

The preparation of the action plan will be done sequentially in the following six phases:

i) Assessment
ii) National Workshop
iii) Training plans and material
iv) Implementation of Training and Procurement
v) Implementation and documentation
vi) Monitoring of implementation

MOHFW would appoint an agency or consultant to facilitate development of the proposed action plan. The Project Management Unit headed by the Joint Secretary, MOHFW would provide overall coordination, administrative assistance and managerial oversight .

5. 3. Action Plan

3.3.1 Assessment

An assessment will be undertaken to review the health and safety and environmental practices in a representative sample of food and drug testing laboratories. To ensure adequate representation, the laboratories would be stratified by size (medium, small and very small based on number of staff and samples handled) and a survey sample will be taken from each group. It is proposed to cover at least 10% of laboratories from each group for the assessment. Prior to the assessments, a detailed checklist will be prepared and pre-tested to guide the survey team in accurate and consistent data collection.

Output:

i) A "background" document will be prepared, which will set the stage for the national workshop. The document will include the survey findings on the following issues:
   - Prevailing health, safety and environmental practices;
   - Types and quantities of hazardous materials used and waste generated;
   - Management practices with regard to labeling, handling, storage and disposal of wastes;
   - Commitment of management towards worker safety and environment;
   - Existing health surveillance protocols for the persons at risk from exposures to chemicals;
   - Preparedness to deal with emergencies; and
   - Training needs for good waste management of drug and toxic wastes.

5.3.2 National Workshop:

A national workshop will be organized to discuss the findings of the assessment. To facilitate focused discussion, the participation at the workshop will be limited to a select group, identified on the basis of established criteria (qualification, experience, type of laboratory). In addition to representatives from MOHFW and state authorities, the group could include experts from universities, representatives from WHO, NGOs and industry. Based on the findings of the assessment and the discussions, draft guidelines of environmental health and safety practices for the laboratories will be formulated.

Outputs:

i) An environmental management health and safety component will be added to the existing national GLP. This component will establish a general set of Codes of practices for all laboratories, with specific provisions to address the environmental impacts and worker safety issues.

ii) Detailed specific operating manuals for individual laboratories will be formulated, including a set of environmental standards to guide construction/upgrading of food and drug testing laboratories

iii) An Environmental Health and Safety Plan (EHS) will be developed, which will include guidelines for worker safety in use of chemicals, general safety, proper disposal of waste, medical surveillance and emergency preparedness. It will also delineate the responsibilities of the laboratory staff, recommend actions to deal with the identified problems, establish a reporting system and safety committees.

5.3.3. Training plans:

Based on the assessment and the guidelines, training modules will be developed along with checklists for monitoring separately for food and drug laboratories. A detailed training schedule will be prepared in consultation with MOHFW and state authorities.

Employee training programs will include, at a minimum, the following subjects:

- Methods of detecting the presence of hazardous chemicals (sight, odor, real-time monitoring, air sampling, etc.)
- Basic toxicological principles, including toxicity, hazard, exposure, routes of entry, acute and chronic effects, dose-response relationship, LD50, threshold limit values and permissible exposure limits, exposure time, and health hazards related to classes of chemicals;
- Good laboratory practice, including general techniques designed to reduce personal exposure and to control physical hazards, as well as specific protective mechanisms and warning systems used in individual laboratories. Appropriate use of fume hoods is to be specifically addressed;
- Description of information available, including Material Safety Data Sheets;
- Emergency response actions appropriate to individuals laboratories;
- Applicable details of the Plan, including general and laboratory-specific Standard Operation Procedures;

Outputs:

- Training modules and checklists for improving environmental safety in food and drug laboratories
- Training plans

5.3.4. Implementation of Training and Procurement of equipment

Each laboratory will identify two officers as trainers in environmental safety. The MOHFW with help of the consultant will organize training of trainers who in turn would organize training of all staff at their respective laboratories. The training will include good laboratory practices, including substance handling, pollution prevention, waste segregation, disposal processes and emergency management. Specific indicators will be used to measure the progress and quality of the decentralized training. It is proposed that few national resource persons will be identified to undertake independent assessment of decentralized training and provide feedback to safety committee. implementation of environmental action plan would be included in the scope of the quality audit of laboratories. this would provide periodic feedback based on which refresher training would be provided.

Outputs:

- Two Trainers trained in each laboratory
- Decentralized Training Programs organized
- Resource persons identified to monitor and improve quality of decentralized training

5.3.5. Implementation:

The MOHFW will be the lead agency coordinating the implementation, supported by the PMU. Two senior officers from MOHFW, one from the DGCI and one from PFA, will be responsible to oversee the implementation of the plan and facilitating the adaptation of good practices at the laboratories (if required, organizing reorientation training). Each laboratory will have an officer designated as Environmental Health and Safety Officer (EHSO) who will be accountable for implementation of the plan. During this phase, a detailed inventory of hazardous materials and material safety data sheets would be prepared.

Outputs:

i) Environmental action plan implemented
ii) Inventory of hazardous materials prepared
iii) Material Safety Data Sheets prepared

5.3.6. Monitoring of Implementation

Every laboratory must have an environmental health and safety officer (EHSO) to organize different activities and monitor the implementation of the environmental plan. Routine monitoring would be done by EHSO at laboratory level. He/she will be responsible for maintaining records as per the agreed protocols. In addition, two health, safety and environmental surveys would be undertaken (once during mid term another before project closure) by a competent independent agency. Environmental audit will be taken up along with technical audit of the food and drug laboratories.

Outputs:

i) Compliance reports/records
ii) Inventory of hazardous material and Material safety data sheets
iii) Audit reports

7 Summary Matrix of the Environment Plan

The environment component seeks to upgrade laboratories in terms of their operational procedures for storage and handling of chemicals as well as the storage and disposal of the waste generated. The project would provide for the preparation of a Laboratory Guidance Manual that will contain standard operating procedures (SOPs) and specific implementation plans for selected laboratories. During project implementation, laboratory staff would be trained on the use of the Laboratory Guidance Manual in selected laboratories. Laboratories would report on their efforts on waste management and an audit would be conducted to assess the environmental impacts.

7.1. Budget For Addressing Environmental Issues

ACTIVITY	Budget	By Whom
Assessment to review the health and safety and environmental practices in sample of food and drug testing laboratories.	Rs. 15 Lakhs	Environmental Consultant in the PCU
National workshop to discuss the findings of the assessment and review proposed actions (Rs. 5 lakhs)	Rs.15 lakhs	Environmental Consultant in the PCU
Development of an EHS Plan, and operating manuals for individual laboratories, including environmental standards to guide construction/upgrading of food and drug testing laboratories (Rs. 3 lakhs)		
Preparation of training module, schedule, manual and checklists (for those involved in implementing the plans and program) (Rs.2 lakhs)		
Training of trainers and laboratory staff (Rs. 5lakhs)		
Implementation and monitoring of the plan.	Rs. 50 Lakhs	Environmental Consultant in the PCU
External Audit On going Rs.5.0 lakhs External Rs. 20.0 lakhs	Rs. 25 Lakhs	MOHFW (Environmental Auditor)

7.2 Time-Schedule of Activities

Steps	Timeframe	Responsibility	Reporting
Engagement of Environmental Consultant	Immediately after negotiations of credit	MOHFW	PCU
Assessment to review the current health and safety and environmental practices in sample of food and drug testing laboratories and preparation of checklist	Upon engagement of consultant (for completion by Nov.2003)	Environmental Consultant	MOHFW / PCU
First draft of Standard operating procedures	Dec 2003	Environmental Consultant	MOHFW / PCU
Development of draft EHS Plan, and operating manuals for food and drug testing laboratories	Dec 2003	Environmental Consultant	MOHFW / PCU
Preparation of all background documents for national workshop.	Year 1 – 1st quarter	Environmental Consultant	MOHFW / PCU
National workshop to discuss the findings of the assessment and discuss proposed implementation	Year 1 – 2nd quarter	Environmental Consultant	MOHFW / PCU
Finalization of Standard operating procedures and EHS	Year 1 -- 2nd quarter		MOHFW / PCU
Dissemination of Standard operating procedures and EHS	Year 1 -- 3rd quarter	Environmental Consultant	MOHFW / PCU
Preparation of training module, schedule, manual and checklists (for those involved in implementing the plans and program)	Year 1 3rd quarter	Environmental Consultant	MOHFW / PCU
Preparation of monitoring framework	Year 1 3rd quarter		
Training of trainers	Year 1 4th quarter	Environmental Consultant	MOHFW / PCU
Training of laboratory staff	To commence by beginning of Year 2	Trainer under supervision of Environmental Consultant	MOHFW / PCU
Monitoring and evaluation as per monitoring framework	Year 2 – 5	Environmental Consultant	MOHFW / PCU
External Audit	Mid-term review	External auditor	MOHFW / PCU

7.3. Environmental Management Framework for Food and Drug Laboratories in India

Possible Environmental Issues	Process Already Applied / Current Practices	Mitigation Measures	Monitoring Strategy and Contingency measures
1. Air Emissions	♦ Lack of information on sources of air pollution. ♦ Inadequate knowledge of equipment containing ODS. ♦ Lack of good practices to prevent emissions	♦ Lab staff will be provided with information and training on methods to minimize air emissions, such as – ensuring lids are tightly closed on volatile solvents. – sending containers back for refilling to supplier. ♦ Procurement of equipment which is ODS free (refrigerator, A/C, fire extinguisher etc.) and proper servicing of ODS containing equipment. ♦ List of hazardous air pollutant sources and emissions and category will be provided to the laboratory. ♦ A list of actual and potential emissions in the lab (fumes foods, stacks vents etc.) will be prepared.	♦ Periodic exposure assessment of air pollutants will be developed. ♦ Periodic verification of control systems will be undertaken. ♦ Records of emissions will be kept and reviewed periodically. It will be responsibility of EMS Incharge for annual certification. ♦ Regular inspection and maintenance of ventilation system.
2. Waste Water Discharges	♦ Inadequate waste minimization procedures in laboratories. ♦ Limited information and awareness of sources and flow of waste water. ♦ Indiscriminate disposal method for wastewater.	♦ A comprehensive listing of sources and location of wastewater discharge will be prepared and maintained. ♦ Appropriate operating procedure will be undertaken for minimization of wastewater (such as neutralizing predisposal treatment etc). ♦ Safe and secure waste water discharge	♦ Spot check will be carried out. ♦ Periodic maintenance will be undertaken of the sewer system. ♦ Periodic testing of lab procedures will be carried

Possible Environmental Issues	Process Already Applied / Current Practices	Mitigation Measures	Monitoring Strategy and Contingency measures
	♦ Insufficient on site waste treatment methods.	methods will be formulated in accordance with chemical properties of the waste material e.g. flammability Corrosively polymerizing, volatility and bio- degradability etc. ♦ On-site septic tank systems or appropriate waste water treatment system depending on the waste water characteristics will be encouraged for implementation. After proper treatment waste water will be discharged in to existing municipal sewer line. ♦ Lab personnel will be trained in minimization and management of wastewater discharges.	out to ensure compliance with regulatory measures. ♦ Regular training will be provided to ensure waste minimization. ♦ Operation and maintenance procedure will be prepared for wastewater discharge system.
3. Hazardous and Radio active waste	♦ Inadequate waste management practices including segregation and disposal of different types of hazardous waste. ♦ Lab personnel not trained for handling and disposal of waste.	♦ Different types of hazardous waste stream such as unused chemicals, spent solvents etc. will be identified for appropriate collection, transportation and disposal system. ♦ Special segregation and disposal method will be adopted for used lead acid batteries and alkaline batteries ♦ Appropriate procurement plan will be prepared for substitution of hazardous chemicals where possible. ♦ Appropriate segregation, collection treatment storage and disposal methods will be developed. ♦ Training and awareness program will be imparted to laboratory staff for safe handling of Hazardous waste. ♦ Waste minimization procedure will be	♦ Periodic audit will be undertaken for hazardous and radioactive waste. ♦ Monitoring strategy for radioactive hazard will be implemented. ♦ Periodic medical surveillance will be conducted for all employees. ♦ Records of waste generation and disposal will be kept and reviewed on regular basis. ♦ Monitoring of handling and disposal waste practices.

Possible Environmental Issues	Process Already Applied / Current Practices	Mitigation Measures	Monitoring Strategy and Contingency measures
		developed.	
4. Glassware and Equipment	♦ Insufficient first aid for cuts and injury caused by broken glassware and sharp equipment. ♦ Insufficient inspection system for broken glassware. ♦ Ineffective cleaning and disinfection methods. ♦ Lack of proper housekeeping for storage and maintenance of glassware and equipment.	♦ Proper disinfection and decontamination procedures will be implemented before reusing glassware and used laboratory equipment ♦ Safe operating procedures will be developed for vacuum equipment. ♦ Good practices will be instituted for handling broken glassware. ♦ Broken glassware will be appropriately disposed off after proper disinfection in properly marked receptacles. The broken glass will be disposed on municipal landfill site or it can be sold to authorized agencies for recycling.	♦ Records of all major/ minor accidents will be maintained and preventive measures will be taken to avoid recurrence. ♦ Regular maintenance of laboratory equipment or parts will be undertaken ♦ Inventory management for purchasing glassware and equipment will be prepared and followed.
5. Handling of hazardous chemicals	♦ Limited precautionary measures to minimize chemical exposures. ♦ Lack of Work-place Hazardous material Information system (WHMIS). ♦ Lack of color-coding system for hazardous chemicals and in adequate labeling system. ♦ Little information on Material Safety Data Sheet (MSDS) is given by manufacturers. ♦ No provision available for hazardous material substitution.	♦ Required precautionary measures (such as hand gloves, masks and apron) as per manufacturer requirements / recommendations for handling different types of chemicals to minimize potential chemical exposure when working with hazardous chemicals. ♦ Appropriate labels for all hazardous chemicals, e.g. flammable and combustible material, oxidizing material, poisonous material, radioactive material, toxic material, and corrosive material, for clear identification of risks and precautionary measures to be taken. ♦ Proper color-coding system (ANSI) for different hazardous chemicals will be developed and implemented.	♦ Periodic personal exposure assessment will be undertaken for chemicals. Simultaneously, Periodic medical surveillance program will be undertaken for all employees. ♦ Periodic visual inspection of all labels, symbols and signs will be designed and followed. A strategy will be made to replace deformed labels, symbols or signs immediately.

Possible Environmental Issues	Process Already Applied / Current Practices	Mitigation Measures	Monitoring Strategy and Contingency measures
	♦ Lack of training in safe handling and in health effect assessment associated with chemical exposure. ♦ Inadequate first-aid, fire prevention and protection measures. ♦ No measures in place for radiation protection ♦ Limited inventory management.	♦ Labels (Cover Slips) will be provided with information like with hazardous property, first aid measures and preventive measures. ♦ Labeling methods for daily-use chemicals and stock chemicals will be adopted. ♦ Provisions will be made for substitution of hazardous chemical with non-hazardous chemicals. Good procurement practices where possible through evaluation will be carried out on feasibility of using instruments that require less reagent or smaller or fewer samples. ♦ An inventory of all hazardous Chemicals will be prepared and updated periodically. ♦ Material Safety Data Sheet (MSDS) of chemicals for employees will be made available in all locations. ♦ Selection use and maintenance matrix for personal protective equipment will be developed for preventing direct contact with corrosives, carcinogens and irritants. ♦ During construction proper ventilation / exhaust system will be designed to avoid exposure to vapors and fumes of Hazardous Chemical. ♦ Appropriate fire prevention procedures will be instituted while working with flammable organic solvents and fire drills will be conducted periodically. ♦ Appropriate radiation protection devices will be procured and used to work with radioactive chemicals.	♦ Training will be conducted regularly to educate all the employees about the meaning of symbols and signs. ♦ Compliance with regulatory measures will be undertaken by the Laboratory Incharge. ♦ Periodic safety audit will be carried out at the laboratory workstation. ♦ Periodic maintenance and validation schedule will be prepared for checking effectiveness of the engineering control devices mitigation measures. ♦ Records of all incidents/ events related to handling of hazardous chemicals will be kept and reviewed periodically. ♦ Periodic upgradation of training module will be established.

Possible Environmental Issues	Process Already Applied / Current Practices	Mitigation Measures	Monitoring Strategy and Contingency measures
		♦ Suitable spill containment procedure will be developed for different types of hazardous chemicals. ♦ Training on First Aid measures will be organized to all employees. ♦ Training on handling of hazardous chemicals will be provided to the laboratory staff. 'Train the trainers' program will be undertaken.	
6. Storage of hazardous chemicals	♦ Proper segregation and separation methods developed but not strictly followed. ♦ Lack of proper compartmentalization in storage area. ♦ Inadequate management system for procuring hazardous chemicals. ♦ Lack of independent, storage criteria for flammable volatile combustible highly toxic, poisonous chemicals. ♦ Inadequate spill containment procedures. ♦ Lack of compressed gas cylinder safety manual. ♦ In sufficient ventilation or no	♦ Procedure for segregation of chemicals will be developed and followed according to chemical classes and compatibility criteria. ♦ Minimum inventory storage procedure of every hazardous chemical will be prepared. ♦ Physical separation methods will be developed for reactive and corrosive chemicals such as concentrated acids, pesticide residues (micotoxins) etc. ♦ Proper storage criteria for flammable, combustible and volatile chemicals will be identified. Filled and empty chemical containers will be segregated accordingly. ♦ Lock and key storage criteria for poisons and highly toxic chemicals will be prepared with record keeping facility. ♦ Appropriate prevention procedure such as rough / chemical resistant flouring will be designed to take care of falls, spills and sliding etc. will be	♦ Rationalized purchasing policy for chemical procurement will be established to ensure full utilization of chemicals. ♦ Periodic inspection criteria and regular visual inspection schedule to be developed and implemented. ♦ Periodic review will be carried out to procure safer alternatives for highly toxic, carcinogenic, reactive or mutagenic material. If available. ♦ Periodic checks will be done of the ventilation system.

Possible Environmental Issues	Process Already Applied / Current Practices	Mitigation Measures	Monitoring Strategy and Contingency measures
	fume hood in place. ♦ No separate storage area for filled and empty containers. ♦ Lack of incompatibility checks procedure before storage of chemicals. ♦ No separate safe storage of radioactive chemicals.	developed. ♦ Safe storage procedure for different types of compressed gas cylinders will be maintained. ♦ During construction proper ventilation / exhaust system will be designed to avoid exposure to vapors and fumes of Hazardous Chemical. ♦ Appropriate storage facility will be developed and followed for radioactive chemicals. ♦ Safe and secure spill containment procedure will be implemented for both large and small spillage. ♦ Training programme will be organised on proper storage and health effect for all employees.	
7. **Disposal of hazardous Chemicals**	♦ Unsegregated waste dumped in premises ♦ Waste not treated before disposal.	♦ Hazardous chemical/ waste will be segregated at source and treated appropriately and stored in separate container. It will be disposed in properly designed underground pit ♦ Appropriate waste management system will be defined. ♦ Lab personnel will be trained in proper waste management procedures	♦ Periodic monitoring of waste treatment and disposable procedures will be done

Possible Environmental Issues	Process Already Applied / Current Practices	Mitigation Measures	Monitoring Strategy and Contingency measures
8. Fire and Explosion	♦ Limited fire prevention measures. ♦ Non functional fire fighting equipment and improper selection of type of fire extinguishers. ♦ No emergency response procedure in place. ♦ Improper selection and installation of electrical gears.	♦ Proper selection and installation of fire fighting equipment in effective locations will need to be implemented. Required new technology (smoke sensors, thermocouple, fire alarms, as required) will be installed ♦ An emergency response procedure will be designed and implemented. ♦ ` Training on safe operation of fire extinguisher', will be imparted to all laboratory staff. ♦ Provision will be made for emergency fire exits. ♦ Proper storage and transportation of compressed gas cylinder will be implemented. ♦ Fire proof electrical wiring system and flame proof electric gears will be installed during construction stage. ♦ It will be ensured that only non ODS fire extinguisher will be used. ♦ Appropriate life saving breathing apparatus will be procured. ♦ Use of fire proof construction material will be encouraged for building purposes.	♦ Periodic inspection of fire prevention equipment will be established. ♦ Emergency response plan will be upgraded periodically. ♦ Frequent inspection and scheduled maintenance will be made compulsory. ♦ Training programs and mock drills will be carried out on regular basis. ♦ Inspection schedule for electrical wiring and equipment will be developed and maintained. ♦ Earthing/ grounding of all electrical equipment will be inspected very frequently.
9. Sustainable Practices	♦ No sustainable practices exercised currently.	♦ Water conservation measures will be taken to reduce water consumption. ♦ Minimum energy utilization measures will be implemented.	♦ A baseline energy and water audit will be carried out to identify current equipment use and associated cost.

Possible Environmental Issues	Process Already Applied / Current Practices	Mitigation Measures	Monitoring Strategy and Contingency measures
		♦ Green purchasing program will be implemented to procure environmental friendly material. ♦ Laboratory employees will be educated and motivated in energy and water management practices. ♦ Safe drinking water will be provided to all employees.	♦ Water/ energy management team or green procurement team will be organized to educate and motivate employees. ♦ Realistic goals and objectives will be established to encourage energy/ water conservation program.

Note :

- The monitoring strategy and contingency measures will be undertaken by organization or centre involved in occupational health & safety appointed by the competent authority.
- External audit will be carried out by the authorized competent organization.

7.4. Sample Table of Contents

7.4.1. Standard Operating Procedures for Food and Drug Testing Laboratories

1. General housekeeping rules:
   - Routine inspection, cleaning, maintenance, testing, calibration and standardization of instruments
   - Actions to be taken in response to equipment failure
   - Analytical data methods
   - Definition of raw data
   - Sample handling and accountability
   - Data handling, storage, and retrieval
   - Receipt, identification, storage, mixing and method sampling of test and control articles
   - Record keeping, reporting, storage and retrieval of data
   - Coding of studies, handling of data, including the use of computerized data systems
   - Storage and maintenance of microbial cultures
   - Maintenance of sterility room
   - Special handling procedures and storage requirements

2. Protective Equipment for Personnel

3. Health and safety precautions

4. Waste disposal rules

5. Engineering Ventilation Controls (Fume hood use)

6. Specialized training required

8. Spill clean-up, accident procedures and emergency first-aid procedures

9. Performance acceptance criteria, recommended corrective actions, and a template for continuous entries of test results and corrective actions,

10. Operation of “quality assurance” personnel in performing and reporting study audits and inspections

11. Approvals Required

12. Other relevant comments: (including location of SOP and translated versions)

13. Responsible officer and contact details: