

MINISTRY OF HEALTH



REPUBLIC OF KENYA

NATIONAL QUALITY CONTROL LABORATORY



P. O. Box 29726 – 00202 Nairobi Kenya

Website: www.nqcl.go.ke

Email: info@nqcl.go.ke

PHARMACEUTICAL AND BIOLOGICAL WASTE MANAGEMENT PLAN

	Prepared by:	Reviewed by:	Approved by:
Name:	Ms. Ruth Ndanyo	Dr. Rebecca Manani	Dr. Sultani Matendechemo
Signature:			
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ABBREVIATIONS AND ACRONYMS

BSL	Biosafety Level
ESCP	Environmental and Social Commitment Plan
ESF	Environment and Social Framework
ESMF	Environmental and Social Management Framework
ESMP	Environment and Social Management Plan
ESSs	Environmental and Social Standards
E&S	Environmental and Social
HEPRRP	Health Emergency Preparedness Response and Resilience Program
ICWMP	Infection Control and Waste Management Plan
IPC	Infection Prevention and Control
IUD	Intra-uterine Device
KBI	Kenya Biovax Institute
LMP	Labour Management Procedures
NEMA	National Environment Management Authority
NPHI	National Public Health Institute
NQCL	National Quality Control Laboratory
OSHA	Occupational Safety and Health
OSHA	Occupational Safety and Health Act
PCT	Project Coordinating Committee

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PPB	Pharmacy and Poisons Board
PPE	Personal Protective Equipment
SOP	Standard Operating Procedures
WBG	World Bank Group
WHO	World Health Organization

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DEFINITION OF TERMS

Biological waste - any waste containing or contaminated by biological materials, such as bacteria, viruses, microbiological cultures, or other substances that may pose a risk of infection or environmental harm.

Chemical waste - waste containing chemical substances (e.g. laboratory reagents; film developer; disinfectants that are expired or no longer needed; solvents; waste with high content of heavy metals, e.g. batteries; broken thermometers and blood pressure gauges).

Disposal site - any area of land on which pharmaceutical waste disposal facilities are physically located or final discharge point without the intention of retrieval but does not mean a re-use or re-cycling plant or site.

Hazardous waste - Any solid material, chemical, fuel, or compressed gas that is dangerous to human health or the environment and is no longer useful, so it is intended to be discarded.

Incineration - A dry oxidation process at a minimum temperature of 850°C that reduces organic and combustible waste to inorganic, incombustible matter and results in a significant reduction of waste volume and weight.

National Environment Management Authority - principal instrument of the Government of Kenya for the implementation of all policies relating to the environment and established under the Environmental Management and Co-ordination Act Number 8 of 1999.

Pharmaceutical waste - waste containing pharmaceuticals e.g. pharmaceuticals that are expired or no longer needed; items contaminated by or containing pharmaceuticals (bottles, boxes).

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Pharmaceutical waste generator – any person whose activities or activities under his or her direction produces pharmaceutical waste or if that person is not known, the person who is in possession or control of that pharmaceutical waste.

P-listed chemical – a discarded chemical product that is considered acutely hazardous and is dangerous even in small quantities.

Segregation – any activity that separates waste materials for processing.

Sharps waste – used or unused sharps (e.g. hypodermic, intravenous or other needles; auto-disable syringes; syringes with attached needles; infusion sets; scalpels; pipettes; knives; blades; broken glass).

Storage – the temporary placement of pharmaceutical waste in a suitable location or facility where isolation, environmental and health protection and human control are provided in order to ensure that the pharmaceutical waste is subsequently retrieved for disposal.

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PREFACE

Kenya generates an approximate 22,000 tons of waste daily, with healthcare waste being approximately 220 tons/day (1% of total waste produced/day). These healthcare wastes, generated in healthcare services among other human undertakings, are a potential risk to public and environmental health. Potentially infectious waste such as sharps, cultures from medical and biological laboratories carry a higher risk of infection and injury than any other type of waste. The absence of proper healthcare waste management measures to prevent exposure from infectious healthcare waste results in adverse health risks to the public, as well as the personnel in the healthcare settings.

Articles 42, 43 and 69 of the Constitution of Kenya form a strong constitutional basis for policies aimed at environmental protection, health service provision and public health protection. Every person is therefore duty bound to cooperate with the state in environmental protection and public health measures enhancement.

Effective management of healthcare waste requires appropriate identification, segregation, collection, storage, treatment, transportation, and disposal, as well as importance associated with standard precautions including hand hygiene, cleaning and disinfection, personal protection, and training.

Improper disposal of the infectious healthcare waste may result in pharmaceuticals, masks, gloves, syringes, and needles being scavenged and reused thus leading to spread of diseases. Furthermore, improper treatment or disposal of healthcare waste such as open-air burning constitute a significant source of pollution to the environment through the release of chemical substances such as dioxins, furans or mercury.

Safe management of pharmaceutical and biological waste is a key pillar to achieving the goal of environmental and public health protection. In both the short and long term, effective implementation of safe waste management programs requires cooperation and collaboration across multiple sectors at all levels. Developing guidelines and plans for

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safe waste management, training personnel, and increasing public awareness are crucial components of managing pharmaceutical and biological waste safely.

This ICWMP has therefore been prepared to provide guidance to NQCL in the sound management of pharmaceutical, medical devices and biological waste generated during routine operations.

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1.0 INTRODUCTION

1.1 Project Overview

The Government of Kenya, through the State Department for Medical Services, is implementing the Health Emergency Preparedness, Response and Resilience project (HEPRR) as part of a regional multiphase HEPRR Program aimed at strengthening health system resilience and response to health emergencies in Eastern and Southern Africa. Implementation of the project will be carried out by four (4) agencies within the Ministry of Health. These include the Pharmacy and Poisons Board (PPB), National Quality Control Laboratory (NQCL), the National Public Health Institute (NPHI) and the Kenya Biovax Institute (KBI).

The project comprises the following four components:

Component 1: Strengthening the preparedness and resilience of Kenya's health system to manage health emergencies. This component focuses on multisectoral and cross-border planning, financing, and governance for improved resilience to health emergencies, workforce development, strengthening of local pharmaceutical and vaccine manufacturing capacity and digitization of the health sector. It comprises the following sub-components:

Subcomponent 1.1: Multisectoral and cross-border planning, financing, and governance for improved resilience to health emergencies.

Subcomponent 1.2: Health workforce development.

Subcomponent 1.3: Strengthening of local pharmaceutical and vaccine manufacturing capacity, which further focuses on the four (4) key activities listed below:

- a. Strengthening the regulatory capacity of the Pharmacy and Poisons Board

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- b. Strengthening the quality control and quality assurance of health products and technologies by strengthening the capacity of the National Quality Control Laboratory and the Kenya Biovax Institute
- c. Investments in human resources capacity, learning, and development to effect knowledge and technology transfer
- d. Establishing capacity for fill and finish of human vaccines.

Subcomponent 1.4: Information systems for health emergencies and the digitalization of the health sector.

Component 2: Improving the detection of and response to health emergencies. This component focuses on strengthening multisectoral disease surveillance and laboratory diagnostics, investment in strategic stockpiles for emergency preparedness and response, financing supply chain planning and supporting the Ministry of Health to implement climate adaptation activities.

Component 3: Project Management that supports implementation of the project through coordination of activities and monitoring to strengthen management capacity.

Component 4: contingent emergency response component which will be activated as needed based on established World Bank operational procedures in case of eligible emergencies.

1.2 Project Purpose

The purpose of the HEPRR is to strengthen health system resilience and response to health emergencies in Eastern and Southern Africa. The project development objective for the Kenya project is to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Kenya.

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1.3 Project Activities

The project activities that will be carried out by NQCL within the HEPRR project relate to the quality control of pharmaceuticals and biopharmaceuticals in support of the local manufacturing and commercialization of vaccines by the KBI as well as operations of the NQCL in bioequivalence testing of pharmaceutical products. In the life of the project, NQCL will also play a key role in strengthening the internal quality control laboratories of local and regional pharmaceutical manufacturers. These activities are envisaged to generate hazardous waste that necessitates proper handling and disposal in order to protect public health and the environment.

1.4 Scope and Objectives of the Infection Control and Waste Management Plan (ICWMP)

This ICWMP shall apply to pharmaceutical, medical devices and biological waste generated at NQCL during routine operations and during implementation of the HEPRR Project.

The main objective of the ICWMP is to prevent and/or mitigate the negative effects of pharmaceutical and biopharmaceutical waste on humans and the environment.

The specific objectives are:

- i. To implement safe and effective procedures for managing pharmaceutical and biopharmaceutical waste.
- ii. To reduce occupational and public health risks associated with exposure to hazardous materials.
- iii. To comply with national and international regulatory standards on waste management.
- iv. To support environmental sustainability through responsible waste minimization and disposal.
- v. To enhance institutional capacity through staff training, proper documentation, and continuous improvement of waste handling practices.

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2.0 CONTEXT AND APPLICATION OF THE ICWMP

2.1 Policies

The NQCL ICWMP aligns with national policies including the following:

- The National Infection Prevention and Control Policy 2021 which is designed to strengthen infection prevention and control systems across the health sector with the aim of enhancing health system resilience and safeguarding the health of healthcare workers and the public.
- Kenya Environmental Sanitation and Hygiene Policy 2016-2030 which aims to increase the proportion of the population with access to improved sanitation to 100% by 2030 and ensure a clean and healthy environment for all in Kenya.
- Sustainable Solid Waste Management Policy 2021 whose overarching aim is to reduce pollution thereby protecting public health and the environment. The policy emphasizes treating waste as a valuable resource within a circular economy framework. It emphasizes resource efficiency through the waste hierarchy—prioritizing reduction, reuse, recycling, recovery, and safe disposal of waste.

2.2 Legislations

The legal basis for the formulation and implementation of the ICWMP is provided for by

- Constitution of Kenya, 2010 under article 42 guarantees that every person has the right to a clean and healthy environment, including protection of the environment for the benefit of present and future generations. Additionally, article 43 requires that every person has the right to the highest attainable standard of health including the right to Healthcare services and reasonable standards of sanitation. The two articles form a strong constitutional basis for policies aimed at environmental protection and public health.
- Environmental Management and Coordination Act (EMCA), Cap 387. The Act, enacted in the year 1999 and revised in 2015, is Kenya's primary environmental legislation. It provides a legal and institutional framework for managing the

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environment and ensuring sustainable development. It also provides for enforcement of environmental standards through the National Environment Management Agency (NEMA).

- iii. Public Health Act, Cap 242 provides the legal framework for safeguarding and promoting public health, covering a wide range of public health issues, among them waste management.
- iv. Occupational Safety and Health Act (OSHA), 2007 which provides for the safety, health, and welfare of all persons at workplaces, and aims to protect workers from work-related injuries, illnesses, and hazards. The Act requires employers to provide a safe working environment, proper equipment, health and safety training, and mechanisms for preventing occupational injuries and diseases.
- v. Environmental Management and Co-ordination (Waste Management Regulations, Water Quality Regulations, Air Quality regulations) 2006. Together, these EMCA regulations establish Kenya's framework for managing environmental risks, enforcing pollution control and safeguarding public health and ecosystems.
- vi. Health Act No 21 of 2017 require healthcare providers and facilities to adhere to established standards for the collection, handling, segregation, transportation, treatment, and disposal of medical waste.
- vii. Pharmacy and Poisons Act (Cap. 244) governs the handling and disposal of pharmaceutical products including un-used and expired medicines, to guard against environmental conservation or drug misuse.

2.3 Guidelines

The Project has mainstreamed the World Bank's environmental and social standards (ESSs). It shall be implemented in accordance with the Project's Environmental and Social Commitment Plan (ESCP), which forms part of the Project Financing Agreement. Other E&S instruments, which shall guide the Project implementation include Environmental and Social Management Framework (ESMF), Labour Management Procedures (LMP), Stakeholder Engagement Plan and this Infection Control and Waste Management Plan

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(ICWMP) among other E&S instruments, which may be developed as will be required during the Project period.

Additionally, in this ICWMP follows best practices from the following guidances:

- i. The World Bank Environmental Health and Safety Guidelines (WB EHSG) for Pharmaceuticals and Biotechnology Manufacturing.
- ii. World Health Organization guidelines on safe management of waste from healthcare
- iii. National environment management authority (NEMA) technical guidelines
- iv. Ministry of Health Kenya Standards and Protocols for Infection Prevention and Control
- v. Ministry of Health Guidelines for Safe Management of Healthcare Waste.

2.4 Industry Standards

Relevant industry standards informing the ICWMP include:

- i. ISO 14001:2015 - Environmental Management Systems
- ii. ISO 45001:2018 - Occupational Health and Safety Management Systems
- iii. ISO 9001:2015 - Quality Management Systems
- iv. WHO Standards for Pharmaceutical Manufacturing Waste Disposal

Applicable sections of the frameworks discussed in sections 2.1 – 2.4 are tabulated in Annex 1, which also contains the applicability of the sections and clauses to this Project.

2.5 Mitigation and Management Measures

As part of good project practice, this ICWMP sets out material measures and actions that the NQCL shall carry out or cause to be carried out, including, as applicable, during planning and the timeframes of the actions and measures, institutional, staffing, training, monitoring, and reporting arrangements, and management of grievances related to hazardous waste.

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This ICWMP is intended for use by all personnel involved in handling Biologicals, Medical Devices and Pharmaceuticals at the NQCL and staff associated with pharmaceutical waste disposal facilities. The plan shall be operationalized using standard operating procedures (SOP) in the Laboratory and the provisions of the Kenya HEPRR Project's ICWMP and ESMF.

As will be guided by the Bank and the Ministry of Health through the PCT, this ICWMP maybe be revised from time to time, during Project implementation, to reflect adaptive management of Project changes and unforeseen circumstances or in response to Project performance.

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3.0 TYPES OF WASTES TO BE GENERATED FROM THE PROJECT AND THEIR POTENTIAL IMPACTS

3.1 Sources of Wastes

Activities routinely to be carried out in NQCL that are likely to lead to waste generation are detailed in Annex 2 below. These are activities associated with routine analysis of health products and technologies. They include sample receipt and storage, handling of chemicals and reagents, actual sample analysis using organic solvents and buffers as well as the projected analysis of vaccines and biopharmaceuticals.

3.2 Potential Impacts of Wastes

Healthcare waste including laboratory, pharmaceutical and biopharmaceutical waste, if improperly handled, stored, treated and disposed may pose health risks indirectly through the release of pathogens and toxic pollutants into the environment.

Some of these impacts are as highlighted here below.

3.2.1 Health Impacts

Healthcare waste may result to toxic exposure, particularly from pharmaceutical products, like, antibiotics, devices and cytotoxic drugs released into the surrounding environment and substances such as mercury or dioxins. Healthcare waste may also result to the risk of physical harm like sharp inflicted injuries. Additionally, chemical burns may arise in the context of disinfection, sterilization or waste treatment activities. Waste is also responsible for air pollution, where the release of particulate matter during medical waste incineration. Further, thermal injuries occurring in conjunction with open burning and the operation of medical waste incinerators, and spread of antimicrobial resistance through unsafe storage, treatment and disposal of pharmaceutical waste are some of other health impacts associated with Healthcare waste including pharmaceutical or biopharmaceutical wastes.

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3.2.2 Environmental Impacts

- The disposal of untreated Healthcare wastes in landfills can lead to the contamination of drinking, surface, and ground waters if those landfills are not properly constructed.
- The treatment of Healthcare wastes with chemical disinfectants can result in the release of chemical substances into the environment if those substances are not handled, stored and disposed in an environmentally sound manner.
- Incineration of waste is widely practised, but inadequate incineration or the incineration of unsuitable materials results in the release of pollutants into the air and in the generation of ash residue. Incinerated materials containing or treated with chlorine can generate dioxins and furans, which are human carcinogens and have been associated with a range of adverse health effects. Incineration of heavy metals or materials with high metal content (in particular lead, mercury and cadmium) can lead to the spread of toxic metals in the environment.

The specific impacts of wastes to be generated in NQCL during routine laboratory activities are tabulated in Annex 2 below.

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4.0 WASTE MANAGEMENT STRATEGIES

4.1 Waste Avoidance and Reduction

Minimizing pharmaceutical waste is always preferable to generating pharmaceutical, medical device and biological waste and then managing its treatment and disposal.

To minimize waste, the following practices will be adopted:

- **Material Purchasing** – purchasing only what is needed, minimizing inventories, redistributing excess materials and promote purchasing from vendors with strong sense of green and sustainable purchasing practices, like buy chemical and pharmaceuticals products and devices from suppliers with strong take-back options and also those who practice reduced packaging of materials.
- **Material Substitution** – substituting non-hazardous or less toxic materials in analytical processes and maintenance operations to reduce the toxicity of the waste.
- **Process Modification** – Procedures will be modified as needed to reduce the amount of hazardous waste produced. For example, by using microscale techniques or recirculating materials within the system (closed-loop recycling) can help achieve this.
- **Inventory Control:** Effective management of chemical inventories will reduce the amount of waste generated. Best practices include chemical redistribution, reviewing shelf-life requirements, testing outdated materials, and rotating stock.
- **Chemical Redistribution:** This will involve redistributing unopened and unused chemicals to organizations such as universities.
- **Neutralization:** Simple acids and bases can be rendered non-hazardous in the laboratory by elementary neutralization as the final step in a process.
- **Waste Segregation:** Segregation of wastes simplifies the treatment, provides an alternative method for recycling and disposal, and ultimately minimizes the costs involved. Do not mix hazardous waste with non-hazardous waste and keep waste streams as simple as possible (fewer contents). Accurately label the waste containers as to their exact contents.

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4.2 Waste Handling and Storage

4.2.1 Selection and Handling of Waste Containers

Containers and lids for waste containment must be in good condition and chemically compatible with the waste inside the container. They must have securely fitting lids, preferably the original lid for the container. Filled containers of liquid must have at least 10% headspace to accommodate expansion during storage and transport. Chemicals should be allowed to react completely and/or cool to ambient temperature before accumulating as waste; once the reaction has completed and the reagents cooled, pour into a compatible container and secure the lid.

Working containers maybe used at the laboratory bench, hood, or in the high performance chromatography room to collect waste from laboratory experiments or procedure. These are small containers (eight litres or less). They may remain open until the end of the procedure at which time they shall be closed or the contents emptied into a properly labelled waste container. Liquids shall not be left in unlabeled containers. Any container that has been used for packaging or handling acutely hazardous P-listed chemicals must be collected and disposed of as hazardous waste.

Proper protective equipment (PPE) should be used when handling hazardous chemicals. The type of PPE required should be the specific and the correct one for each chemical.

4.2.2 Container Segregation and Labelling

Pharmaceutical or chemical waste shall at the point of generation and at all stages thereafter be segregated from other wastes, be in the appropriate containers with the appropriate color code of brown and labelled with the words 'Lab Hazardous Waste'. A "Lab Hazardous Waste" label must be affixed to all waste containers and include the following information:

The accumulation start date when waste was first added to the container.

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Indicate if the material is regular waste (used) or unused pure commercial product.

Any other labelling requirement(s) as may be required by the pharmaceutical/ health or environmental regulator.

4.2.3 Biological Waste

Biological waste shall be decontaminated before storage. This includes:

- Waste from analysis of vaccines, antibiotics e.g. antigens, cell lines and cultures
- Discarded live or attenuated vaccines and biological toxins
- Systems used to grow and maintain infectious agents *in vitro*, including, but not limited to nutrient agars, gels and broths
- Culture dishes and devices used to transfer, inoculate or mix cultures, including but not limited to plastic and glass plates, paper, gloves growth media, gels, filters, stoppers, plugs, flasks, inoculation loops and wires, contaminated pipette tips, tubes, stirring devices and jars.

Solid biological waste shall be placed in an autoclave bag and autoclaved before transfer and containment as described in sub-section 4.2.6. Spills containing microorganisms shall be decontaminated by pouring a freshly prepared 10% bleach solution around the spill edges and into the centre, followed by a waiting period of 20 minutes before being cleaned up as detailed in sub-section 4.2.8.

4.2.4 Medical Devices Waste

Medical device waste that falls within the scope of this ICWMP includes contraceptive male and female condoms, injectable contraceptives, copper intrauterine devices, implants, vaginal rings and diaphragms. After completion of analysis, these shall be contained in labelled sealed waste bags and subsequently disposed of as detailed in section 4.3.

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4.2.5 Sharps and Glass

Sharps shall be disposed of in puncture-proof containers to avoid potential injuries to personnel disposing of the waste. Types of sharps waste include glass, needles, razor blades, scalpels, lancets, syringes, slide covers, specimen tubes, and pipettes (glass and plastic). Intact glassware and other items can easily break during the disposal process and therefore should not be discarded in regular trash bags. Additionally, the following measures shall be adhered to:

- Separate contaminated from non-contaminated sharps items.
- Avoid overfilling containers and discard when 2/3 full or at the indicated fill-line.
- Keep container weight below 15 kg to prevent injury from lifting during disposal.
- Do not recap needles, bend, break, or otherwise manipulate sharps by hand.
- Securely tape the container closed to ensure that contents cannot spill out during disposal.

4.2.6 Solid Waste

Solid wastes, including pharmaceutical powders, will be contained in a double-lined cardboard box or lined dust bin. Liners must be 1.5 mil or greater polypropylene bags. Each bag shall be tied and sealed individually.

4.2.7 Liquid Waste

Liquid wastes will be accumulated in glass reagent bottles compatible with the waste. Large volumes of liquid waste will be contained in 20 litre containers. Filled containers of liquids will have at least ten percent headspace to accommodate thermal expansion during transport and storage.

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4.2.8 Spill Clean-ups

Many spills are of limited hazard potential and can be safely cleaned by personnel in the vicinity. Areas within the Wet Chemistry and Biological Analysis Units storing hazardous chemicals will be equipped with a chemical spill kit to handle small, low-hazard spills.

The chemical spill kit may contain the following items:

- Absorbent material to suck up the waste
- Neutralizers for corrosives or toxics
- Materials to limit the flow of a spill (absorbent sock/boom)
- PPE (gloves, safety goggles)
- Container/bags to collect the hazard spill contents
- Hazard waste tag/label to identify the contents

When cleaning up a spill, the handler shall use PPEs including gloves, shoe covers and facemasks.

4.2.9 Biowaste Handling Area

A biowaste holding area shall be designated within the Biological Analysis Unit for storage of biological waste. This area must fulfil the following criteria:

- Prevents any leakage from the waste packaging and ensures the packaging remains intact at all times.
- Restricts access to unauthorized personnel.
- Provides ventilation and discharges to the environment so as not to create nuisance odors.
- Remains clean and uncluttered.
- Controls for vermin and insects.
- Does not create a visual or odor problem.

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4.2.10 Laboratory Clean-out

The Laboratory shall review the inventory of chemicals at least once a year as part of good laboratory practices in line with ISO 9001/14001 guidelines. Chemicals that are unwanted or no longer needed will be removed from the laboratory and disposed of.

The laboratory will conduct a laboratory cleanout one time per 12-month period. If the volume of unwanted material in the lab exceeds 200 litres (or 1 kg of solid reactive acutely hazardous material), the materials must be removed from the laboratory within 30 calendar days from the start of the cleanout (adapted from the Code of Federal Regulations on hazardous waste determination and removal of unwanted material from laboratories).

Chemicals removed as part of an annual laboratory cleanout shall be documented as such to include the laboratory location, the start date and end date of the cleanout, and the volume of hazardous waste generated during the cleanout.

4.2.11 Storage of Pharmaceuticals and Chemical Waste

- Appropriate separate and enclosed area, room, or building, with adequate lighting and good ventilation to prevent the accumulation of toxic fumes, easy access to safety shower and eyewash station and liquid/chemical proof containers in case of leaks shall be made available for storing chemical and pharmaceuticals awaiting treatment or appropriately disposal.
- There shall be no mixing of chemical waste. Compliance with the manufacturers' safety data sheet (SD) and specifications shall be followed.
- Incompatible wastes shall be stored separately
- During storage, temperature of the pharmaceuticals waste shall be kept within manufacturers' requirements.
- Storage areas shall be labeled on the exterior with an appropriate sign, including, but not limited to the following:

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NO ENTRY: Hazardous waste



No smoking
or
No eating or drinking



- The storage area shall be equipped with a liquid- and chemical-proof sump. If no sump present, catch-containers to collect leaked liquids shall be placed under the storage containers.
- Spillage kits, protective equipment and first aid equipment e.g. eye showers shall be made available in the storage area.
- Keeping clear records of the wastes storage is important to ensure a good control of waste management.

4.3 Offsite Transport of Hazardous Waste

A pre-qualified company meeting regulatory requirements of MOH, PPB and NEMA shall be contracted for offsite transportation of pharmaceutical waste. Some of the basic requirements include being well maintained, bulkhead to separate driver from vehicle load, system to secure load, proper placards and markings including hazard symbol and emergency contacts, spill kit, easy to decontaminate, etc. Drivers of vehicles carrying

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hazardous health-care waste shall be required to have appropriate training about risks and handling of hazardous waste.

The transport vehicle engaged to transport hazardous waste should have appropriate consignment or manifest system.

A consignment note should be prepared before offsite transport of pharmaceutical waste. This consignment note should be carried by the driver and should have the following information in case of accidents or official inspection:

- Pharmaceutical waste source
- Pharmaceutical waste pick-up date
- Destination
- Driver's name
- Number of containers
- Total weight of the pharmaceutical waste

On completion of a journey, the consignee shall affirm receipt of the pharmaceutical waste witnessed by PPB and NQCL staff and the driver shall return the consignment note to NQCL. Currently, pharmaceutical waste at NQCL is disposed by a subcontracted company at Stoni Athi in the Athi River area of Machakos County under the supervision of officers from the PPB.

4.4 Waste Treatment and Disposal

NQCL has existing procedures for handling, treatment and disposal of pharmaceutical and biological waste (NQCL/SOP/BIOL – 012, attached herein as Annex 6). Before treatment and disposal, pharmaceutical waste will be labeled and sorted while using the PPE detailed in Annex 4 below. Hazardous waste shall undergo decontamination and containment into designated containers within 12 hours from the completion of batch analysis. Settle plates containing contaminated culture media shall be decontaminated by autoclaving, while pharmaceutical waste and medical devices shall be wrapped and contained in a labelled waste bag. Chemical and mixed solvents' liquid waste shall be

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contained in labelled corked jerricans in both Wet chemistry and Biological Analysis Units. The waste containers shall be removed from the laboratories to the disposal site within one week from the accumulation start date indicated on the container label. If this period is exceeded, the date must be noted, a root cause analysis conducted and the waste containers removed from the laboratory within the next 48 hours.

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5.0 COMPLIANCE MANAGEMENT

5.1 Roles and Responsibilities

The effectiveness of infection control and waste management at NQCL shall be ensured through clear assignment of roles and responsibilities across the Laboratory Units and personnel, as follows:

a) Laboratory Analysts/Technicians:

All technical staff shall be expected to follow established SOPs in infection control and waste management as it relates to their daily operations in the technical Units of the Laboratory including, but not limited to use of PPEs, waste segregation and labelling at source, waste/spills clean up and reporting of any incident to their Heads of Units.

b) Housekeeping Staff:

The Head of Housekeeping shall ensure the Laboratory is kept clean at all times and all waste is segregated and stored appropriately. They shall also coordinate waste disposal with contracted service providers. In their supervisory role, the Head of Housekeeping shall ensure that housekeeping staff/cleaners adhere to the following in their daily operations:

- Following SOPs in all activities including use of PPEs
- Collecting segregated waste in accordance with the established schedule
- Keeping waste storage areas clean
- Timely reporting any incidents.

c) Heads of Units:

In their supervisory roles, the Heads of Units shall develop and enforce SOPs relating to infection control and waste management, supervise waste segregation, storage and documentation, ensure regular training of personnel, conduct regular checks on compliance to waste management procedures and coordinate with the Head of Housekeeping to ensure prompt disposal of waste generated in their various Units.

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d) Biomedical Engineers:

These shall ensure proper maintenance of waste storage areas and containment systems including the adequacy of ventilation and fire safety.

e) Quality Assurance Personnel:

Led by the quality assurance manager, these shall ensure infection control and waste management procedures in the Laboratory align with established guidances, standards and national legislations. The Manager shall review and approve SOPs on waste handling and disposal. The team shall enforce corrective actions arising from deviations in waste management procedures, and ensure traceability for audits and inspections.

f) Senior Management Team:

- Allocation of budgets for infection control and waste management
- Review infection control and waste management compliance reports
- Ensure contracts with waste management firms
- Ensure Laboratory compliance to policies relating to infection control and waste management.

g) Environmental Safeguards Focal Point:

- Overseeing infection control and waste management measures and PPE adequacy in the Laboratory
- Ensuring compliance with the safeguards instruments prepared under the project
- Preparation and submission of reports on infection control and waste management to the project environmental safeguards team.

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5.2 Training and Induction

Personnel shall receive training in pharmaceutical and biological waste management procedures. Training shall be targeted at all personnel offering services at the NQCL. In addition, all contractors and temporary workers working for the Laboratory in the HEPRR Kenya Project shall be adequately trained and continuously sensitized on the ICWMP. The training areas shall be as stipulated in Annex 3.

5.3 Monitoring and Oversight

The NQCL Occupational Safety and Health (OSH) committee will review and oversee the implementation of the ICWMP. The committee will be responsible for ensuring adherence to the plan by all personnel working in the Laboratory and will ensure the personnel are adequately trained and sensitized on the ICWM requirements. In the execution of the HEPRR Kenya Project, the OSH committee will, with support of expertise from the Ministry of Health's Environmental and Social Safeguards specialists assigned to the Project, review procedures and practices for safe management of waste, and train personnel on waste management, IPC, and environmental issues, and take other steps necessary to assure compliance with WHO guidelines, and World Bank ESF and National Regulations on infection control and waste management. The Project's Safeguard specialists will regularly review the extent of compliance with the E&S guidelines through review of quarterly reports submitted by NQCL. The National Environment Management Authority (NEMA) is the oversight authority on environmental issues in Kenya. Its role will be that of regulatory oversight in monitoring environment indicators as identified in this ICWMP. The World Bank will conduct regular support implementation missions and ensure that compliance is achieved as per the requirements of the ICWMP. The support missions shall be conducted annually.

5.4 Reporting Requirements

Currently, there is no common in-country monitoring and reporting tool for infectious waste management. However, NQCL has developed its own standard operating

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procedures (SOP) on waste management and waste disposal logs for use. The SOP NQCL/SOP/BIOL – 012 is provided in Annex 6.

Monthly monitoring reports for infection control and waste management in the Laboratory will be prepared in the format to be developed by the HEPRR project's environmental safeguard teams and approved by the World Bank. These reports will be compiled by the NQCL focal officer for environmental and social safeguards and will be forwarded to the project coordinator through the project environmental safeguards expert.

During the operational phase of the project, annual environmental audits to ascertain compliance with both national legislation, international best practice as well as WBG EHS guidelines and World Bank ESF requirements will be undertaken by the project's environmental safeguard team. On the other hand, due diligence of the contracted services of waste treatment and disposal will be carried out by NQCL with support from the project's environment safeguards specialists.

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6.0 ATTACHMENTS

Annex 1: Frameworks and their applicability in the ICWMP

Framework	Relevant clause/section	Applicability to the ICWMP
National Infection Prevention and Control Policy 2021	Section 4.2: Laboratory infection prevention and control guidelines; Section 5.1: Waste segregation and disposal	Both sections provide guidance on handling infectious samples and safe waste segregation and disposal procedures
Kenya Environmental Sanitation and Hygiene Policy 2016-2030	Section 3.3: Safe management of hazardous wastes	Provides guidance on disposal of chemical and biomedical waste in line with national sanitation and hygiene requirements
Sustainable Solid Waste Management Policy 2021	Section 2.4: Hazardous and infectious waste handling	Provides standards for solid waste management – reduction, segregation and safe disposal

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Framework	Relevant clause/section	Applicability to the ICWMP
Constitution of Kenya 2010	Article 42: Right to clean and healthy environment	States the need to prevent environmental pollution through proper waste management, with a mandate to protect the public
Environmental Management and Coordination Act	Chapter 387, Part V and VI: Waste management and control of hazardous substances	Provides a legal framework for the management of biomedical, chemical, and pharmaceutical waste safely
Public Health Act	Chapter 242, Section 115: Disposal of infectious materials	Defines the obligation to comply with public health requirements for infectious waste management
Occupational Safety and Health Act 2007	Section 10 - 12: Employer responsibility, risk assessment and employee safety	Defines the requirement to implement safe working conditions for personnel that handle infectious or hazardous wastes

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Framework	Relevant clause/section	Applicability to the ICWMP
Environmental Management and Coordination (Waste Management Regulations, Water Quality Regulations, Air Quality Regulations) 2006	Waste management regulations 6 - 10	Details procedures for segregation, transport, treatment and disposal of hazardous laboratory waste
Health Act No. 21, 2017	Part III: Disease prevention and health promotion	Provides guidance on infection prevention measures and safe handling of waste that may contain pathogens
Pharmacy and Poisons Act	Chapter 244, Section 55: Handling of pharmaceutical waste	Provides guidance on disposal of expired and un-useable pharmaceutical. These are classified as pharmaceutical waste in NQCL.

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Framework	Relevant clause/section	Applicability to the ICWMP
World Bank Environmental and Social Standards	ESS 3: Resource efficiency and pollution prevention; ESS 4: Community health and safety	ESS 3 sets out requirements to address resource efficiency and pollution prevention and management in this project; ESS 4 defines the responsibility of NQCL, in the course of project implementation, to avoid or minimize health, safety and security risks and impacts
National Environmental Management Authority Technical Guidelines	Guidelines on hazardous waste management	Provides technical procedures that aid in the safe disposal of chemical and biomedical waste
Guidelines for Safe Management of Healthcare Waste, Ministry of Health	Section 2: Segregation, transport, treatment; Section 3: Role of laboratories	Provides guidance on safe collection, handling and disposal of healthcare-related waste

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Framework	Relevant clause/section	Applicability to the ICWMP
ISO 14001:2015 - Environmental Management Systems	Clause 6.1: Environmental aspects; Clause 8.1: Operational planning	Provides guidance on integration of environmental management into laboratory operations and waste control
ISO 45001:2018 - Occupational Health and Safety Management Systems	Clause 6.1.2: Hazard identification; Clause 8.1: Operational planning	Provides guidance on occupational health and safety management for personnel handling infectious and chemical waste
ISO 9001:2015 - Quality Management Systems	Clause 8.5.1: Control of production and service provision	Provides a mechanism for ensuring laboratory processes, including waste handling, are standardized and in a state of control

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Framework	Relevant clause/section	Applicability to the ICWMP
WHO Standards for Pharmaceutical Manufacturing Waste Disposal	Section 5: Waste treatment and disposal methods	Provides guidance on best practices for neutralizing and disposing pharmaceutical residues

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Annex 2: Infection control and waste management mitigation measures

Activities	Potential health and safety risks	Proposed mitigation measures	Responsibilities	Timeline
Sample receipt, handling and storage	Infection to Laboratory personnel	- Provide appropriate PPE against exposure to infectious agents and hazardous chemicals in accordance with recognized international safety standards and guidelines. - Orientation for all staff on safe work practices and guidelines. - Continuous operationalization of the standard operating procedure (SOP) on sample receiving. - Provide relevant vaccine program for all personnel once lot release testing undertakings begin. Segregation of live vaccine samples and storage separately from other pharmaceuticals.	MOH E&S officers, Head of Client Service Unit, NQCL OSH Head, NQCL Director	Biannually
Receipt, handling and	Exposure to laboratory	Provide appropriate PPE against exposure to hazardous chemicals in accordance with	MOH E&S officers, Head,	Annually

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Activities	Potential health and safety risks	Proposed mitigation measures	Responsibilities	Timeline
storage of chemicals and organic solvents	personnel through contact or inhalation fumes; Expiry of the reagents and chemicals	recognized international safety standards and guidelines. • Orientation for all staff on safe work practices and guidelines. • Continuous operationalization of the standard operating procedure (SOP) on delivery, storage and handling of reagents and chemicals.	Procurement Unit, NQCL OSH Head, NQCL Director	
Waste handling - segregation, binning and storage	Exposure (inhalation, contact with chemical waste) and infection (arising from biological waste) to	• Adherence to bin colour codes. • Sensitization on appropriate waste handling procedures. • Operationalization of waste handling SOP. • Use of PPEs when handling waste. • Use of durable, long-lasting materials that will not allow waste spillage due to tearing.	MOH E&S officers, Heads of Units, NQCL OSH Head, NQCL Director	Quarterly

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Activities	Potential health and safety risks	Proposed mitigation measures	Responsibilities	Timeline
	waste handlers	- Contract NEMA registered waste handler to dispose of hazardous waste and have waste destruction certificate and waste transfer notes. - Use the routinely designated waste/garbage holding areas at site (in the Biological Analysis and Wet Chemistry Units)		
Routine sample analysis	Exposure and harm due to organic solvents and wastewater containing the solvents	- Purchase of appropriate containers for containment of organic wastewater / solvents. - Discharge of organic solvents into designated containers. - Adherence to SOP on handling of organic solvents. - Contract NEMA-registered waste handlers to collect and dispose of organic solvents. - Provision of first aid kits and trained first aiders. - Routinely check the kits availability for adequate restocking.	MOH E&S officers, Heads of Units, NQCL OSH Head, NQCL Director	Continuous

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Activities	Potential health and safety risks	Proposed mitigation measures	Responsibilities	Timeline
	Air emissions (fumes from concentrated acids and organic solvents); Risks by direct contact with organic solvents and corrosive chemicals	• Installation and operationalization of fume chambers. • Adherence to SOP on handling of organic solvents and hazardous chemicals during routine sample preparation and analysis. • Installation of emergency shower and eye wash bottles. • Provision of first aid kits and trained first aiders.	MOH E&S officers, Heads of Units, NQCL OSH Head, NQCL Director	Quarterly
General laboratory operation environmental health and safety issues	Physical hazards; Chemical hazards;	• All workers should be provided with appropriate PPE against exposure to hazards. • Training for all personnel on safe work practices and guidelines.	MOH E&S officers, Heads of Units, NQCL OSH Head, NQCL Director	Biannual

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Activities	Potential health and safety risks	Proposed mitigation measures	Responsibilities	Timeline
	Ergonomic hazards	- Regular maintenance of laboratory facilities and equipment. - Strategic display of the environmental health and safety policy for visibility. - Proper maintenance of PPE, including cleaning when dirty and replacement when damaged or worn out. - Adequate provision of safety systems including first aid areas, fire extinguishers and fire exits. - Provision of first aid kits and trained first aiders.		
	Electrical and explosive hazards	- All electrical repair activities should be conducted by competent electricians. - Periodic maintenance of electrical equipment. - Safe storage of supplies that have explosion potential.	MOH E&S officers, NQCL OSH Head, Biomedical engineers, NQCL Director	Annually

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Activities	Potential health and safety risks	Proposed mitigation measures	Responsibilities	Timeline
Onsite waste collection and transport	Infection to waste handlers; Corrosion and harm by direct contact with handler's skin; Non-segregation of waste; Increased generation of infectious waste due to contamination	- Ensure proper waste management practices as recommended by the World Bank EHS guidelines and NEMA guidelines. - Prompt collection of waste from point of generation to waste bin - at least once in 24 hours. - Provide appropriate waste bins for the different types of waste generated in the laboratory to allow segregation and collection at the point of generation.	MOH E&S officers, NQCL OSH Head, NQCL Director	Quarterly

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Activities	Potential health and safety risks	Proposed mitigation measures	Responsibilities	Timeline
Waste storage	Littering of waste; Contamination of surfaces	- Segregation of wastes into different categories. - Provision of color-coded waste bins with lid. - Provision of appropriate PPEs for waste handlers. - Regular decontamination of surfaces.	MOH E&S officers, NQCL OSH Head, Biomedical engineers, NQCL Director	Quarterly
Waste transportation to & disposal in offsite treatment & disposal facilities	Littering of wastes; Exposure of transport personnel to wastes; Disposal in non-permitted waste sites	- Offsite transportation of waste should comply with national regulations. - Use of NEMA licensed Waste transporters. - Keeping record of waste transfer notes as well as waste destruction certificates at the point of disposal facility. - Ensure the contracted transporter uses appropriate vehicle types for waste transportation. - Due diligence should be undertaken for all the waste treated off site to ensure waste is	MOH E&S officers, PPB Inspectorate Unit, NQCL OSH Head, Biomedical engineers, NQCL Director	Quarterly

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Activities	Potential health and safety risks	Proposed mitigation measures	Responsibilities	Timeline
Emergency events		transported through the required routes (non-busy routes) and safely treated and disposed. • Appropriate supervision of the disposal process at site.		
	Spillage, fire & others	• Emergency response plan(s) for specific emergencies; • Train all laboratory personnel on response in risk management and emergency procedures in-case of accidents and spillages.	MOH E&S officers, NQCL OSH Head, Quality Assurance Manager, NQCL Director	Annually
	Accidental releases of infectious or hazardous substances to the environment;	• Train relevant staff on response in risk management and emergency procedures in case of accidental releases of infectious or hazardous substances.	MOH E&S officers, NQCL OSH Head, Quality Assurance Manager, NQCL Director	Annually

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Activities	Potential health and safety risks	Proposed mitigation measures	Responsibilities	Timeline
	Occupational exposure to infectious agents	Ensure the provision of safe water, sanitation, and hygienic conditions, which is essential to protecting personnel at the workplace.		

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Annex 3: Trainings on environmental, health, safety and waste management for NQCL personnel

No.	Training area	Target group	Approximate cost (USD)	Responsibility
1.	Infection prevention and control measures and the roles of each actor in the Laboratory and Project	All laboratory personnel	20,000	Director, NQCL
2.	Biosafety and biosecurity	All laboratory personnel	20,000	Director, NQCL
3.	Environmental health and safety, use of safety data sheets (SDS), handling of pathogenic microorganisms and use of PPE	All laboratory personnel	20,000	Director, NQCL
4.	Implementation of the ICWMP and ESMP during NQCL operations	All laboratory personnel; contactors and stakeholders implementing the HEPRR in the Laboratory	20,000	Director, NQCL

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Annex 4: Appropriate personal protective equipment for waste categories

S. No.	Waste Category	Examples	PPE Required
1.	General Waste	Paper, paper towels, non-contaminated gloves	Gloves, lab coat, closed shoes
2.	Infectious Waste	Contaminated pipette tips, culture plates, vaccine residues	Heavy duty gloves, lab coat, face mask (N95), goggles/face shield, shoe covers
3.	Sharps Waste	Needles, broken glass, ampoules	Puncture-resistant gloves, lab coat eye protection, closed boots
4.	Heavy Metals	Broken thermometers, mercury-containing devices, reagents with lead and cadmium	Mercury-resistant gloves, face shield, respirator, chemical-resistant aprons, boots
5.	Pharmaceutical Waste (non-cytotoxic)	Expired/unused drugs, vaccine vials (non-infectious)	Lab coat, nitrile gloves, safety goggles
6.	Chemical Waste	Expired reagents, solvents, acids, bases	Nitrile gloves, lab coat, goggles, face shield, closed shoes

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S. No.	Waste Category	Examples	PPE Required
7.	Cytotoxic Waste	Chemotherapeutic agents, cytotoxic vaccine waste	Double gloving, impervious gown, respirator, eye protection, impermeable boots

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Annex 5: Colour code system for waste segregation

S. No.	Type of Waste	Examples	Colour Coding	Container
1.	Sharps	Needles, broken glass, ampoules	Yellow (marked 'Sharps')	Puncture proof
2.	Infectious	Contaminated pipette tips, culture plates, vaccine residues	Yellow	Strong leak proof bag with biohazard symbol
3.	Non-infectious (non-hazardous)	Food remains, paper	Black	Plastic bag or bin
4.	Pharmaceutical and chemical	Expired drugs, reagents and solvents	Brown	Plastic bag or bin for solids, lid fitted jerricans for liquids

Adapted from: Healthcare Waste Management Plan 2016-2021 (Ministry of Health), presenting the specific waste categories expected to be generated in NQCL.

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**Annex 6: Standard operating procedure on biological waste disposal -
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7.0 REVISION HISTORY

Version	Reason for Revision	Date
01	Initial Plan	January 2029

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PHARMACEUTICAL AND BIOLOGICAL WASTE MANAGEMENT PLAN		

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