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**Requirements for plant biotechnology
facilities at biosafety level 2 (BSL-2)**

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Requests for permission to reproduce this document should be addressed to:

Rwanda Standards Board

P.O Box 7099 Kigali-Rwanda

KK 15 Rd, 49

Tel. +250 788303492

Toll Free: 3250

E-mail: info@rsb.gov.rw

Website: www.rsb.gov.rw

ePortal: www.portal.rsb.gov.rw

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Foreword

Rwanda Standards are prepared by Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the WTO/TBT agreement on the preparation, adoption and application of standards.

The main task of technical committees is to prepare national standards. Final Draft Rwanda Standards adopted by Technical committees are ratified by members of RSB Board of Directors for publication and gazettment as Rwanda Standards.

DRS 642 was prepared jointly by Technical Committees: RSB/TC 18, *Farming*; RSB/TC 41, *Environmental Management* and RSB/TC 74, *Healthcare Organization Management*.

Committee membership

The following organizations were represented on the Technical Committee on *Farming* (RSB/TC 18); *Environmental Management* (RSB/TC 41) and *Healthcare Organization Management*. (RSB/TC 74) in the preparation of this standard.

Rwanda Agriculture and Animal Resources Development Board (RAB)

International Potato Centre (CIP)

Rwanda Forensic Institute (RFI)

University of Rwanda/College of Agriculture, Forestry and Food Science (UR/CAFF)

Rwanda Polytechnic/KITABI College

Rwanda Environment Management Authority (REMA)

African Agriculture Technology Foundation (AATF)

Ministry of Agriculture and Animal Resources (MINAGRI)

University of Rwanda/College of Sciences and Technology (UR/CST)

Rwanda Standards Board (RSB) – Secretariat

Introduction

Plant biotechnology activities involving genetically modified plants, plant-associated microorganisms, plant pests, or recombinant nucleic acids require appropriate containment measures to protect personnel, plants and environment. Biosafety Level 2 (BSL-2) plant biotechnology facilities are designed to support laboratory, greenhouse, and related operations involving biological agents and materials that present moderate potential risk and require enhanced containment and operational controls beyond basic laboratory practices.

This standard specifies the minimum requirements for the design, construction, operation, maintenance, and management of plant biotechnology facilities operating at Biosafety Level 2. It provides requirements for physical containment, equipment, waste management, access control, personnel competence, decontamination procedures, emergency preparedness, and biosafety management practices necessary to minimize accidental release, cross-contamination, or exposure.

The standard is intended for use by research institutions, universities, regulatory authorities, testing laboratories, agricultural biotechnology facilities, and other organizations engaged in plant biotechnology activities. Its implementation supports safe research and innovation, compliance with national biosafety regulations, protection of human and environmental health, and harmonization with regional and internationally recognized biosafety principles and practices.

Requirements for plant biotechnology facilities at biosafety level 2 (BSL-2)

1 Scope

This Draft Rwanda Standard provides requirements for the design, construction, operation, maintenance, management, and biosafety practices for plant biotechnology facilities operating at Biosafety Level 2 (BSL-2). It applies to all research and development activities that may pose moderate risk to human and environment.

It covers laboratories, growth rooms, greenhouses, containment rooms, and associated support areas used for plant biotechnology activities involving biological agents and materials that require BSL-2 containment. Specifically, it focuses on:

- a) facility design and containment requirements;
- b) biosafety and biosecurity management;
- c) personnel competence and training;
- d) operational and work practices;
- e) equipment requirements;
- f) waste management and decontamination;
- g) emergency preparedness and response; and
- h) environmental and occupational safety measures.

It does not apply to:

- Biosafety Level 1 (BSL-1), Biosafety Level 3 (BSL-3), or Biosafety Level 4 (BSL-4) facilities;
- open field trials or environmental release activities; or
- facilities intended exclusively for medical or animal diagnostic activities.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

3.1

biosafety level-2 (BSL-2)

level of biological containment applicable to laboratories and related facilities where work is conducted with biological agents and materials that pose moderate potential risk to personnel, plants, animal health or environment, and for which specific containment measures, controlled access, trained personnel, and enhanced operational practices are required to prevent exposure, contamination, or unintentional release.

3.2

facility

building, laboratory, greenhouse, contained area, or a combination of associated rooms, systems, equipment, and infrastructure designed, constructed, and operated to support activities involving biological agents and materials under specified biosafety containment conditions.

3.3

plant biotechnology

application of scientific and technological techniques to plants, plant cells, tissues, or plant-associated organisms to develop, modify, propagate, analyse, or improve plant characteristics, products, or processes for research, agricultural, industrial, environmental, or commercial purposes.

3.4

biological safety cabinet (BSC)

ventilated enclosure intended to protect personnel, products, and the environment from exposure to hazardous biological materials and aerosols.

3.5

decontamination

procedure that eliminates or reduces biological contamination to an acceptable safe level.

3.6

genetically modified organism (GMO)

organism in which the genetic material has been altered using modern biotechnology techniques.

3.7

risk assessment

systematic process of identifying hazards, evaluating risks, and determining appropriate control measures.

3.8

containment

application of physical barriers, operational procedures, and management practices intended to prevent exposure to or release of biological materials.

3.9**personal protective equipment (PPE)**

protective clothing or equipment designed to reduce exposure to biological, chemical, or physical hazards.

3.10**biosafety**

safe working practices associated with handling of biological materials, particularly infectious agents. It addresses containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release. Responsible laboratory practices, including protection, control and accountability for valuable biological materials will help prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

3.11**biosecurity**

institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.

3.12**volunteers**

individual plant species that grows spontaneously in a field from seeds, tubers, or other vegetative propagules, without being intentionally sown or planted during the current growing season.

3.13**biosafety management system policy**

formal institutional framework designed to identify, assess, and mitigate risks associated with handling biological agents. It outlines mandatory procedures, containment levels 2 (BSL-2), and responsibilities to protect personnel, the community, and the environment

3.14**biological agent**

any microorganism (3.15), including those which have been genetically modified, cell cultures and human endo-parasites, which can provoke any infection, allergy or toxicity

3.15

microorganism

microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material

4 Principles of BSL-2 containment for plant biotechnology facilities

4.1 BSL-2 plant biotechnology facilities shall apply a combination of:

- a) good microbiological and plant containment practices;
- b) appropriate safety equipment;
- c) engineering controls;
- d) administrative controls; and
- e) facility design measures.

4.2 Containment measures shall be based on documented risk assessment and shall consider:

- f) the nature of the biological agent and material;
- g) methods of manipulation;
- h) potential for aerosol generation;
- i) potential environmental exposure;
- j) survival and dissemination of plant materials;
- k) escape of pollen, seeds, propagules, insects, or vectors; and
- l) potential impacts on human health, plants and environment.

4.3 The organization shall apply the hierarchy of risk control measures by:

- a) elimination of hazards where practicable;
- b) substitution with lower-risk materials or procedures;

- c) engineering controls and containment;
- d) administrative controls and safe work procedures; and
- e) personal protective equipment.

5 Facility design and containment requirements

5.1 General

5.1.1 The facility shall be designed, constructed, and maintained to ensure safe handling and containment of biological agents and materials used in plant biotechnology activities.

5.1.2 The facility design shall minimize risks to personnel, the environment and surrounding communities.

5.2 Location and access

The facility shall:

- a) be located in an area suitable for containment activities;
- b) have restricted access limited to authorized personnel;
- c) have automated closing and lockable entry doors;
- d) have door with a viewing window;
- e) display biosafety signage (e.g.: see annex A) at all entrances; and
- f) maintain records of personnel access where applicable.

5.3 Structural requirements

The facility shall:

- a) have cleanable, non-absorbent, and chemical-resistant surfaces;
- b) provide sufficient space for safe operations;
- c) ensure separation between contaminated and clean areas;
- d) provide hand-free handwashing facilities near exits;
- e) have adequate lighting and ventilation; and

- f) prevent pest entry and escape of biological agents and materials.

5.4 Ventilation

5.4.1 The facility shall have a ventilation system designed to maintain controlled inward airflow without recirculation.

5.4.2 Airflow shall minimize contamination and aerosol dissemination.

5.4.3 Where necessary, exhaust air shall be filtered or treated prior to release.

5.5 Containment equipment

5.5.1 General

The facility shall provide appropriate containment equipment, including but not limited to:

- a) biological safety cabinets;
- b) autoclaves or equivalent decontamination systems; and
- c) emergency eyewash stations.

5.5.2 Maintenance and calibration

5.5.2.1 Equipment shall be maintained, inspected, and calibrated where applicable.

5.5.2.2 Records shall be retained.

5.5.3 Biological safety cabinets

Biological safety cabinets shall:

- a) be certified upon installation;
- b) be periodically inspected and maintained; and
- c) be used according to manufacturer instructions.

5.6 Greenhouse and growth room requirements

5.6.1 The facility shall:

- a) maintain physical barriers sufficient to prevent escape of viable plant materials and associated organisms;

- b) use self-closing doors and lockable access systems;
- c) provide insect-proof screens or equivalent containment barriers where vectors or pollinators may be present;
- d) implement procedures for handling and disposal of soil, plant residues, irrigation water, and growth media;
- e) establish procedures for control of volunteers, pests, insects, and rodents;
- f) prevent unintended transfer of plant reproductive materials through personnel, clothing, equipment, or airflow;
- g) maintain drainage systems designed to minimize environmental contamination; and
- h) ensure that contaminated or regulated materials are decontaminated before removal from containment areas.
- i) provide handwashing facilities that are hand-free near exits;
- j) have cleanable and impervious greenhouse floor;
- k) have restricted access limited to authorized personnel; and
- l) display biosafety signage (e.g.: see annex A) at all entrances.

5.6.2 Environmental conditions including temperature, humidity, airflow, and lighting shall be monitored to ensure safe operation and containment integrity.

5.6.3 The organization shall establish procedures for inspection and maintenance of greenhouse containment systems.

6 Biosafety management system

6.1 General

The organization shall establish, implement, maintain and continually improve a biosafety management system.

6.2 Biosafety management system policy

The organization shall establish a documented biosafety management system policy appropriate to the nature of activities performed.

6.3 Roles and responsibilities

6.3.1 Management shall define responsibilities and authorities related to biosafety.

6.3.2 A qualified biosafety officer or designated responsible person shall be appointed.

6.4 Risk assessment

6.4.1 The organization shall conduct documented risk assessments before commencement of activities involving biological materials.

6.4.2 Risk assessments shall consider:

- a) biological hazards;
- b) likelihood of exposure or release;
- c) environmental impact;
- d) personnel competence; and
- e) effectiveness of control measures.

6.4.3 Risk assessments shall be reviewed periodically and updated when changes occur.

6.4.4 The assessment report shall be approved by competent authority

6.5 Documentation and records

The organization shall maintain documented procedures and records related to:

- a) risk assessments;
- b) training;
- c) equipment maintenance;
- d) incidents and corrective actions;
- e) waste pre-treatment and disposal; and
- f) facility inspections.

7 Personnel competence and training

7.1 Competence

Personnel shall be competent on the basis of education, training, skills and experience; acquired, or any combination thereof, that are appropriate to their responsibilities and activities.

7.2 Training

7.2.1 The organization shall ensure that specific and appropriate biosafety training programmes are developed and implemented for all personnel. The training programme may include, but not limited (see annex B) to:

- a) biosafety principles;
- b) facility procedures;
- c) emergency response;
- d) waste management;
- e) use of PPE; and
- f) decontamination procedures.

7.2.2 The management shall ensure that all new employees are oriented/trained in BSL-2 facilities' general and role specific safety requirements, regardless of how much experience they can have from their previous employment.

7.2.3 Training programme shall be documented and periodically refreshed.

7.3 Medical surveillance

The organization shall implement appropriate occupational health measures and medical surveillance.

8 Operational practices

8.1 General work practices

8.1.1 Work involving plant biotechnology materials shall be planned and conducted in a manner that prevent formation of aerosols, splashes, contamination and accidental release.

8.1.2 Access to active work areas shall be restricted during ongoing operations.

8.1.3 Written standard operating procedures (SOPs) shall be established and implemented for all activities.

8.1.4 Personnel shall wash hands:

- a) after handling biological materials;
- b) after removing gloves;

- c) before leaving work areas; and
- d) after contact with potentially contaminated surfaces.

8.1.5 Mouth pipetting shall be prohibited.

8.1.6 Work surfaces shall be decontaminated:

- a) after completion of work;
- b) after spills;
- c) after contamination incidents; and
- d) at defined routine intervals.

8.1.7 Work practices shall minimize exposure, contamination and accidental release.

8.1.8 Eating, drinking, smoking and storage of food shall be prohibited in work areas.

8.2 Personal protective equipment

PPE shall be used in appropriate manner and may include but not limited to:

- a) laboratory coats;
- b) gloves;
- c) eye protection (goggles);
- d) closed footwear or shoe covers and
- e) respiratory protection.

8.3 Biological agent and material handling

8.3.1 Biological agents and materials shall be handled in a manner that minimizes aerosol generation and contamination.

8.3.2 Procedures likely to generate aerosols shall be conducted in a biological safety cabinet.

8.4 Transport and storage

8.4.1 The facility shall have separate storage spaces for general store, chemical store and consumable store.

8.4.2 Biological agents and materials shall be appropriately labelled, packaged, transported and stored.

8.4.3 Biological agents and materials prepared for transport shall be placed in a secondary leak-proof, unbreakable carrier.

8.5 Housekeeping

8.5.1 The facility shall be maintained in a clean and orderly condition.

8.5.2 Routine cleaning and disinfection schedules shall be implemented.

9 Decontamination and waste management

9.1 Decontamination

9.1.1 The organization shall establish validated procedures for cleaning, disinfection, sterilization, and decontamination.

9.1.2 Selection of decontamination methods shall consider:

- a) the biological material involved;
- b) concentration and quantity of material;
- c) contact time requirements;
- d) compatibility with surfaces and equipment;
- e) personnel health and safety; and
- f) environmental and occupational safety considerations.

9.1.3 Autoclaves and other sterilization equipment shall be periodically verified for effectiveness using appropriate indicators.

9.1.4 Decontamination procedures shall also apply but not limited to:

- a) reusable equipment;
- b) work surfaces;
- c) transport containers;
- d) greenhouse tools and equipment; and

- e) contaminated PPEs.

9.2 Waste management

9.2.1 Waste generated in BSL-2 facilities shall be categorized, handled and treated in accordance Annex C.

9.2.2 Waste collection, storage, transportation and disposal shall be done in accordance with applicable standards.

10 Emergency preparedness and response

10.1 General

The organization shall establish emergency preparedness and response procedures.

10.2 Emergency procedures

10.2.1 Emergency response procedures shall be documented, communicated, and periodically tested. Emergency information to be communicated is given in Annex D.

10.2.2 The organization shall ensure immediate availability of emergency response materials including but not limited to:

- a) spill kits;
- b) disinfectants;
- c) first aid supplies (see annex E); and
- d) fire extinguishers.

10.2.3 Spill response procedures shall include:

- a) isolation of affected areas;
- b) use of appropriate PPE;
- c) containment of spills;
- d) decontamination of affected materials and surfaces; and
- e) reporting and investigation of incidents.

10.2.4 Personnel shall receive training on emergency response procedures relevant to their duties.

10.2.5 Procedures shall address:

- a) spills;
- b) exposure incidents;
- c) fire emergencies;
- d) equipment failure;
- e) accidental release of biological materials; and
- f) natural disasters where applicable.

10.3 Handling of emergencies and incidents

10.3.1 The organization shall respond to actual emergency situations and incidents by:

- a) ensuring applicable statutory and regulatory requirements are identified;
- b) communicating internally;
- c) communicating externally;

10.3.2 The organization shall take action to reduce the consequences of the emergency situation, appropriate to the magnitude of the emergency or incident;

10.3.3 Incidents and near misses shall be documented, investigated, and corrective actions implemented.

11 Environmental safety measures

11.1 The organization shall implement measures to minimize adverse environmental impacts.

11.2 Special attention shall be given to preventing escape of genetically modified plants, pollen, seeds, plant tissues, insects, or associated microorganisms.

12 Audits and continual improvement

12.1 The organization shall conduct periodic inspections and audits to evaluate compliance with this standard. An example of inspection checklist is proposed in annex E.

12.2 Corrective actions shall be implemented where nonconformities are identified.

12.3 Management shall periodically review the effectiveness of the biosafety management system.

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Annex A
(informative)

Examples of biosafety signage

A.1 General

BSL-2 plant biotechnology facilities may display biosafety signs containing:

- a) biosafety level designation
- b) emergency contact information
- c) access restrictions
- d) applicable hazard warnings.

A.2 Example of signage

The international biohazard warning symbol can be displayed on the doors of the rooms as it is shown in figure A1.



ADMITTANCE TO AUTHORISED PERSONNEL ONLY
Biosafety Level.....
Responsible Investigator.....
In case of emergency call.....
Daytime phone..... Another phone.....
**Authorization for entrance must be obtained from
the Responsible Investigator named above.**

Figure A1. Biohazard warning symbol for laboratory doors

Annex B
(informative)

Minimum elements of a biosafety training programme

The biosafety training programme should include, but not limited to:

- a) principles of biosafety and biosecurity;
- b) containment practices;
- c) emergency response procedures;
- d) waste management;
- e) use and maintenance of PPE;
- f) decontamination procedures;
- g) safe handling of genetically modified plant materials;
- h) prevention of environmental release; and
- i) incident reporting.

Annex C
(informative)

Classification, handling and treatment of waste generated in BSL-2 facilities

Waste Category	Description	Examples	Minimum Handling Requirements	Recommended Treatment/Disposal
General Non-Hazardous Waste	Waste not containing biological, chemical, radioactive or sharps hazards	Office paper, uncontaminated packaging materials, food waste from designated areas	Collect in designated containers, segregate from hazardous waste	Municipal disposal in accordance with applicable standards and regulations
Biological Waste	Waste containing viable biological materials capable of contamination or environmental release	Genetically modified plant tissues, microbial cultures, recombinant DNA materials, contaminated pipette tips, contaminated PPE	Use biohazard-labeled containers, prevent aerosol generation, segregate at source	Autoclaving, chemical disinfection, incineration or validated biological inactivation
Plant Waste Requiring Containment	Plant-derived waste capable of propagation or dissemination	Seeds, pollen, whole transgenic plants, roots, contaminated soil	Maintain containment during handling and transport, prevent pest access	Autoclaving, incineration, thermal treatment or authorized deep burial
Sharps Waste	Items capable of puncturing or cutting skin and contaminated with biological material	Needles, scalpels, broken glass, razor blades, glass pipettes	Dispose immediately after use in puncture-resistant sharps containers	Decontamination where necessary followed by approved hazardous waste disposal
Chemical Waste	Waste containing hazardous laboratory chemicals	Solvents, acids, alkalis, stains, disinfectants, pesticides	Segregate according to compatibility, label containers appropriately	Disposal according to hazardous chemical waste regulations
Mixed Waste	Waste containing both biological and chemical hazards	Biological cultures mixed with solvents or hazardous chemicals	Assess primary hazard and apply compatible containment measures	Treatment methods addressing both biological and chemical hazards
Liquid Waste	Liquid waste generated from laboratory or greenhouse activities	Culture media, wash water, nutrient solutions, disinfectant solutions	Collect in designated containers, prevent uncontrolled discharge	Chemical disinfection, heat treatment or effluent treatment before disposal

Contaminated Reusable Equipment	Reusable laboratory items contaminated with biological materials	Glassware, tools, trays, reusable containers	Handle using PPE, segregate before cleaning	Cleaning followed by decontamination or sterilization
Animal or Vector Waste (where applicable)	Waste associated with insects or biological vectors used in plant biotechnology	Dead insects, vector cages, contaminated feed materials	Prevent escape or environmental release	Autoclaving, incineration or validated decontamination methods

Annex D
(informative)

Emergency information

D.1 Laboratory Manager:

Office Phone.....

Cell Phone.....

Email address.....

National Emergency Number 112

Fire and Rescue 111

Ambulance / Referral Hospital 912 or

Biological Spill / Exposure Response

Institutional Security

D.2 Staff Health and Exposure Management

Working Hours - Occupational Health / Designated Clinician

After Hours / Weekends / Holidays - Exposure Response

Biosafety Officer / Infection Prevention and Control Focal Person

Laboratory Supervisor / Section Head

Healthcare Waste / Decontamination Focal Person

Evacuation Assembly Point for BSL-2 Laboratory Staff: (Insert designated location)

**Refer to your institution's biosafety, infection prevention and control, and emergency evacuation procedures for BSL-2 laboratories.*

Annex E (informative)

First Aid

E.1 General

First aid is the skilled application of accepted principles of medical treatment at the time and place of an accident. It is an approved method of treating a casualty until he or she is placed in the care of a doctor for definitive treatment of the injury. The minimum first-aid equipment consists of a first-aid box, protective clothing and safety equipment for the person rendering first aid, and eye irrigation equipment.

E.2 The first-aid box

The first-aid box shall be constructed from materials that will keep the contents dust- and damp-free. It shall be kept in a prominent position and be easily recognized. By international convention, the first-aid box is identified by a white cross on a green background. The first-aid box may contain:

- a) Instruction sheet giving general guidance
- b) Individually wrapped sterile adhesive dressings in a variety of sizes
- c) Sterile eye-pads with attachment bandages
- d) Triangular bandages
- e) Sterile wound coverings
- f) Safety pins
- g) A selection of sterile but un-medicated wound dressings
- h) An authoritative first-aid manual, e.g. one issued by the International Red Cross.
- i) Protective equipment for the person rendering first aid includes:
 - 1) Mouthpiece for mouth-to-mouth resuscitation
 - 2) Gloves and other barrier protections against blood exposures, and
 - 3) Clean-up kit for blood spills.
- j) Eye irrigation equipment should also be readily available, and staff trained in its correct use.

Annex F
(informative)

Example of inspection checklist

1. GENERAL INFORMATION			
<ul style="list-style-type: none"> • Name of organization: • Facility name: • Facility location: • Type of facility: • Date of assessment: • Assessor (s): • Scope of assessment: 			
2. ASSESSMENT RATING GUIDE			
Rating	Description		
C	Compliant		
PC	Partially compliant		
NC	Non-compliant		
NA	Not applicable		
3. FACILITY DESIGN AND CONTAINMENT			
S/N	Requirement	Rating	Evidence/Comment
1.	Facility access is restricted to authorized personnel		
2.	Biosafety signage is displayed at entrances		
3.	Doors are lockable and self-closing where required		
4.	Work surfaces are cleanable and non-absorbent		
5.	Floors and walls are easy to clean and resistant to moisture		
6.	Hand-free washing sinks are available near exits		
7.	Adequate lighting is provided		
8.	Ventilation systems are functional and maintained		
9.	Airflow minimizes contamination and aerosol spread		
10.	Adequate space is available for safe work practices		
11.	Clean and contaminated areas are separated		
12.	Pest prevention measures are implemented		
13.	Drainage systems minimize environmental contamination		
14.	Emergency exits are clearly marked and unobstructed		
15.	Emergency eyewash facilities are available where required		
4. GREENHOUSE AND GROWTH-ROOM CONTAINMENT			
S/N	Requirement	Rating	Evidence/Comment
16.	Greenhouses prevent escape of plant materials		

17.	Insect-proof screens or barriers are installed		
18.	Access to greenhouses is controlled		
19.	Procedures exist for handling soil and plant waste		
20.	Procedures exist for management of irrigation water		
21.	Pest and vector monitoring is implemented		
22.	Measures exist to prevent transfer of pollen or seeds		
23.	Environmental controls are monitored where required		
24.	Greenhouse containment systems are routinely inspected		
25.	Hand-free washing sinks are available near exits		
26.	Self-closing and lockable doors		
27.	Biosafety signage is displayed at entrances		
28.	Access is restricted to authorized personnel		
5. BIOSAFETY MANAGEMENT SYSTEM			
S/N	Requirement	Rating	Evidence/Comment
29.	A documented biosafety policy exists		
30.	Biosafety responsibilities are defined		
31.	A biosafety officer or responsible person is designated		
32.	Risk assessments are documented		
33.	Risk assessments are periodically reviewed		
34.	SOPs are available for all activities		
35.	Incident reporting procedures are established		
36.	Corrective actions are documented and implemented		
37.	Records are maintained and retrievable		
6. PERSONNEL COMPETENCE AND TRAINING			
S/N	Requirement	Rating	Evidence/Comment
38.	Personnel are trained in biosafety principles		
39.	Personnel are trained before beginning work		
40.	Refresher training is periodically conducted		
41.	Training records are maintained		
42.	Personnel are trained in emergency procedures		
43.	Personnel are trained in waste handling procedures		
44.	Personnel demonstrate competence for assigned tasks		
45.	Occupational health measures are implemented		
7. OPERATIONAL PRACTICES			
S/N	Requirement	Rating	Evidence/Comment
46.	Eating and drinking are prohibited in work areas		
47.	Hand hygiene procedures are implemented		
48.	Mouth pipetting is prohibited		
49.	Aerosol-generating procedures are controlled		
50.	Biological safety cabinets are used where required		
51.	PPE is available and properly used		

52.	Biological agents and materials are correctly labelled		
53.	Procedures exist for safe transport of materials		
54.	Work surfaces are routinely decontaminated		
55.	Housekeeping procedures are implemented		
8. DECONTAMINATION AND WASTE MANAGEMENT			
S/N	Requirement	Rating	Evidence/Comment
56.	Decontamination procedures are documented		
57.	Appropriate disinfectants are available		
58.	Autoclaves or sterilization systems are functional		
59.	Waste is segregated according to risk		
60.	Biological waste is treated before disposal		
61.	Waste disposal complies with regulations		
62.	Reusable equipment is properly decontaminated		
63.	Spill kits are available and maintained		
9. EMERGENCY PREPAREDNESS AND RESPONSE			
S/N	Requirement	Rating	Evidence/Comment
64.	Emergency procedures are documented		
65.	Personnel know emergency response procedures		
66.	Spill response procedures are implemented		
67.	First aid materials are available		
68.	Fire extinguishers are available and maintained		
69.	Emergency contacts are displayed		
70.	Incidents and near misses are investigated		
71.	Emergency drills are periodically conducted		
10. EQUIPMENT MANAGEMENT			
S/N	Requirement	Rating	Evidence/Comment
72.	Equipment is suitable for intended use		
73.	Equipment maintenance schedules exist		
74.	Calibration records are maintained where applicable		
75.	Equipment malfunctions are documented and addressed		
76.	Safety equipment is routinely inspected		
11. BIOSECURITY			
S/N	Requirement	Rating	Evidence/Comment
77.	Access control systems are implemented		
78.	Biological agent and material inventories are maintained		
79.	Storage areas are secure		
80.	Unauthorized access is prevented		
81.	Biosecurity incidents are documented and investigated		
12. ENVIRONMENTAL PROTECTION			
S/N	Requirement	Rating	Evidence/Comment
82.	Measures prevent environmental release of GMOs		
83.	Procedures prevent escape of pollen and seeds		

84.	Wastewater management measures are implemented		
85.	Pest management systems are effective		
86.	Environmental monitoring is conducted where required		

13. INSPECTION SUMMARY AND ACTION PLAN

Observation/ Nonconformity	Risk level	Corrective action	Responsible person	Target date	Status

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