NCRST
NATIONAL COMMISSION
ON RESEARCH SCIENCE & TECHNOLOGY

User Guide

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Title:	GUIDELINES FOR CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS UNDER THE BIOSAFETY ACT, 2006 (ACT NO.7 OF 2006) **CONTAINED USE**		
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Signature:			

DEFINITIONS/ ABBREVIATIONS/ ACRONYMS

Contained use:	means any activity involving the genetic modification of living organisms or the production, processing, culture, storage, destruction, transport, disposal of or use in any way of genetically modified organisms and for which specific physical containment measures are used to limit their contact with, and their impact on, humans and the environment.
Event:	means a genotype produced from the transformation of a single plant species using a specific genetic construct.
Facility:	means any physical structure where activities involving genetically modified organisms are carried out, including - (a) a building or part of a building; (b) a laboratory; (c) a greenhouse; (d) an animal house; (e) an aquarium or tank; (f) a fermenter; (g) any other place.
GMO:	means "Genetically Modified Organism".
Permit:	means a permit issued under section 25 of the Biosafety Act to conduct any dealings with a GMO as authorized by the permit.
Prohibited plant:	means plants of any species that are sexually compatible with the regulated plant under field conditions, including volunteers that may arise in the isolation area during the conduct of field trials.

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1. PURPOSE

The purpose of this document is to provide a guidance to researchers, the Biosafety Council and Biosafety Registrar on the conduct of biotechnology and biosafety research in a contained use facility.

2. SCOPE

These guidelines shall apply to all contained use activities of genetically modified organisms in Namibia. These guidelines must be read together with the Biosafety Regulations (Government Notice No. 210) and Biosafety Act, 2006 (Act no 7 of 2006). The information presented in these guidelines do not preclude the applicant from any other requirements within the legislative frameworks of Namibia.

3. NORMATIVE AND INFORMATIVE REFERENCES

3.1 Normative

Biosafety Act, 2006 (Act No. 7, 2006)

Biosafety Regulations: Biosafety Act, 2006 (Government Notice No. 210)

Cartagena Protocol on Biosafety

3.2 Informative

World Health Organization. 2004. Laboratory Biosafety Manual, Third Edition. Geneva, Switzerland.

Traynor, P., Adair, D. and Irwin, R. 2001. A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes. Available at: http://conacyt.gob.mx/cibiogem/images/cibiogem/comunicacion/Eventos/CIBIOGEM/Taller-Bioseguridad-Cofinamiento/Practical-guide-containment.pdf

4. GENERAL RULES

4.1 PURPOSE OF CONTAINED USE ACTIVITIES

The specific purpose of contained use is to carry out the following activities

a) development or production of a GMO;
b) processing of a GMO;
c) culturing of a GMO;
d) storage of a GMO;

e) destruction of a GMO;

f) disposal of a GMO;

g) research involving the physical presence of a GMO or any material or substance with a view to its genetic modification;

h) the contained use or handling in any other way of a GMO which, by the nature thereof, takes place in a facility.

4.2 REQUIREMENTS FOR FACILITIES FOR CONTAINED USE ACTIVITIES

4.2.1 Laboratory Containment Levels

4.2.1.1 *Laboratory Containment Level 1*

The information below serves to supplement the information in the application form.

a) A facility under containment level 1 laboratory should be separated from other areas of the building;

b) There should be adequate space provided and the laboratory should be safe, comfortable working environment that takes full account of work practices and equipment present;

c) Doors should ideally have vision panels and shall be self-closing;

d) All work can take place on the open bench, although laboratory bench surfaces should be easily cleaned, be impervious to water and resistant to acids, alkalis, solvents, disinfectants and any other decontamination agents that may be in use;

e) Hand washing facilities and a supply of soap & sanitizer should be provided.

f) The principles of good laboratory practice should be applied;

(i) Lab coats should be worn at all times when in the laboratory and removed upon exit.

(ii) Lab coats and any other protective laboratory clothing must not be worn outside the laboratory (including toilets, offices etc.);

(iii) Protective laboratory clothing that has been used in the laboratory must not be stored in the same lockers or cupboards as street clothing;

(iv) Closed shoes should be worn;

(v) The use of protective gloves is recommended, and is obligatory when working with blood, body fluids and other potentially infectious materials or infected animals. After use, gloves should be discarded and hands must be washed;

(vi) Hands must be washed before personnel leave the laboratory working area;

(vii) Safety glasses, face shields (visors) or other protective devices must be worn when it is necessary to protect the eyes and face from splashes, impacting objects and sources of artificial ultraviolet radiation;

(viii) Long hair must be tied back or restrained;

(ix) Eating, drinking, smoking, applying cosmetics and handling contact lenses is prohibited in the laboratory working areas;

(x) Storing human foods or drinks anywhere in the laboratory working areas is prohibited;

(xi) Pipetting by mouth is strictly prohibited;

(xii) No equipment or samples shall be placed in the mouth;

(xiii) Labels shall not be licked;

(xiv) All technical procedures should be performed in a way that minimizes the formation of aerosols and droplets;

(xv) All spills, accidents and overt or potential exposure to infectious materials must be reported to the laboratory supervisor. A written record of such accidents and incidents should be maintained;

(xvi) A written procedure for the clean-up of all spills must be developed and followed;

(xvii) Contaminated liquids must be decontaminated (chemically or physically) before discharge into drains or sewers. An effluent treatment system may be required, depending on the risk assessment for the agent(s) being handled;

(xviii) Written documents that are expected to be removed from the laboratory need to be protected from contamination while in the laboratory;

(xix) The laboratory should be kept clean, neat and free of materials that are not pertinent to the work;

(xx) Work surfaces must be decontaminated after any spill and at the end of the working day;

(xxi) All contaminated materials, specimens and cultures must be decontaminated before disposal or cleaning for re-use;

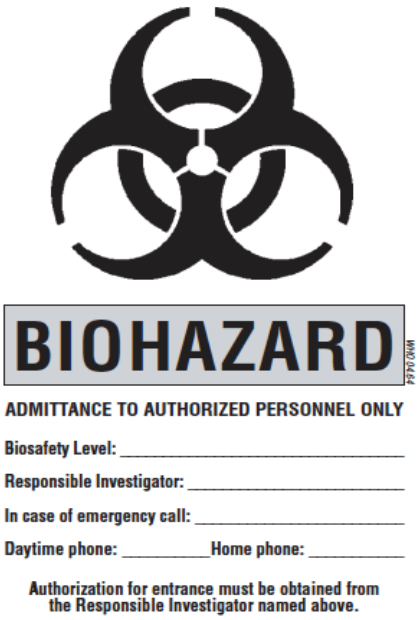
(xxii) Cultures should be stored in appropriate vessels, be clearly labelled and as far as is reasonably practical be stored within the laboratory or nearby;

(xxiii) An autoclave should be available on site if the nature of the GMO requires autoclaving alternatively if waste removal by contractors may be acceptable provided that the transport and disposal method is approved by the Biosafety Council and the Registrar.

4.2.1.2 *Laboratory Containment Level 2*

The information below serves to supplement the information in the application form. In addition to the Containment Level 1 requirements, the following requirements apply:

a) Access to the facility should be restricted and there should be a biohazard sign on the door as in Figure 1 below:



Source: World Health Organization: Laboratory biosafety manual, Third Edition

Figure 1: Design of Biohazard sign

b) There should be no floor drains in the work area, and windows should be kept closed, or if this is not practical there should be arthropod-proof screens;

c) A biological safety cabinet should be available in the laboratory and all procedures likely to generate aerosols should be carried out in the biological safety cabinet;

d) In the planning of new facilities, consideration should be given to the provision of ventilation systems that provide an inward flow of air without recirculation;

e) A stand-by generator is desirable for the support of essential equipment such as incubators, biological safety cabinets, freezers etc., and for the ventilation of animal cages;

f) It is recommended that there should be emergency lighting to permit safe exit in the event of a power cut;

g) Physical and fire security must be considered as the GMOs being researched on maybe a target of vandalism or terrorism;

h) Strong doors, windows and restricted issue of keys are compulsory;

i) Where appropriate, personnel may require immunization. A program of routine medical evaluations should be put in place, and a first aid area should be available.

4.2.1.3 *Laboratory Containment level 3*

The information below serves to supplement the information in the application form. In addition to the Containment Level 1 and 2 requirements, the following requirements apply:

a) At this level the facility should be physically isolated and sealable for fumigation;

b) Separation may be achieved by placing the laboratory at the blind end of a corridor, or constructing a partition and door or access through an anteroom, designed to maintain the pressure differential between the laboratory and its adjacent space;

c) The anteroom should have facilities for separating clean and dirty clothing and a shower may also be necessary;

d) Anteroom doors may be self-closing and interlocking so that only one door is open at a time. A break-through panel may be provided for emergency exit use;

e) There must be a controlled ventilation system that maintains a directional airflow into the facility, with a monitoring device so that staff can at all times ensure that the proper directional airflow is maintained;

f) The ventilation system must be constructed so that air from the facility is HEPA (high-efficiency particulate arresting) filtered, reconditioned and recirculated within the facility and is not recirculated to other areas within the building;

g) Where exhaust air from the facility is discharged to the outside of the building, it must be dispersed away from occupied buildings and air intakes;

h) Biological safety cabinets should be sited away from walking areas and out of cross-currents from doors and ventilation systems;

i) The exhaust air from biological safety cabinets must be discharged in such a way to avoid interference with the air balance of the cabinet or the building exhaust system;

j) It is recommended that backflow-precaution devices are fitted to the water supply;

k) Vacuum lines should be protected with liquid disinfectant traps and HEPA filters, or their equipment. Vacuum pumps should also be properly protected with traps and filters;

l) All laboratory personnel who work at Containment Level 3 is shall undergo a mandatory medical examination. This should include recording of a detailed medical history and an occupationally targeted physical examination;

m) The laboratory should be restricted to authorized personnel only (i.e. trained workers), cleaners and security personnel should be excluded.

4.2.1.4 *Laboratory Containment Level 4*

A maximum containment level laboratory at Containment Level 4 should not be constructed and used without due consideration and consultation between the researchers and the Biosafety Council, since the details of the design and operating procedures may need to be tailored to the risk assessment for the activities to be undertaken. Advice may also be sought from international organizations and institutions with prior experience in operating a Containment Level 4 facility. Consequently, further details of the requirements are not provided here.

4.2.2 Greenhouse Containment Levels

Please refer to the application form for facility registration for details of the physical requirements and work procedures for Greenhouse Containment Levels. The information below serves to supplement the information in the application form.

4.2.2.1 *Greenhouse Containment Level 1*

a) Containment Level 1 is for plants and or plant associated organisms that pose negligible risk to humans or the environment;
b) Discretionary access is generally reserved for maintenance personnel and accompanied visitors who have a special interest in the research;
c) No special clothing is required;
d) Genetically modified seeds should be stored in a locked cabinet located preferably in the greenhouse so as to minimize handling in unconfined spaces;
e) When stored or handled outside the area of confinement, such as in a cabinet or on a potting bench, the seed should be in a spill-proof container;
f) The seed should be clearly identified and labelled to distinguish it from other stored seeds. In cases that activities require a Containment Level 2 this facility can be used by incorporating biological containment practices such covering or removing flower and seed heads to prevent pollen and seed dispersal;
g) Greenhouse personnel should take ordinary precautions to prevent seed germination in unwanted locations;
h) Access to the greenhouse should be restricted at the discretion of the greenhouse manager or principal investigator when experiments are in progress;

i) Pest (both vertebrate and invertebrates) control program, using physical, chemical, or biological control measures, alone or in combination, should be implemented and monitored for effectiveness.

4.2.2.2 *Greenhouse Containment level 2*

For a Greenhouse containment level 2, requirements will take into consideration level 1 requirements as well as the following requirements:

a) Entry ways into a level 2 facility shall be posted with signs indicating that access is limited to authorized personnel only;
b) If the experiment uses organisms that pose a risk to the local ecosystem or agriculture, a sign stating this should be posted on the access door;
c) The sign should provide the contact details of the responsible individual, the plants in use, and any special requirements for using the area;
d) Genetically modified material in the form of seeds or propagules, potted plants, trays of seedlings etc. should be transferred in a closed non-breakable container;
e) Records of all plants and plant associated organisms entering or leaving the greenhouse should be kept;
f) Facilities operated at containment level 2 or higher should preferably be equipped with an alarm system designed to alert someone when mechanical or weather-related events causing a loss of containment occur;
g) Greenhouse systems that monitor automated environmental controls should have built-in local and remote alarms;
h) In the instance of human error or vandalism the facility shall appoint designated people who are promptly alerted to problems shall make timely decisions in regards to contacting or dispatching appropriate response personnel.

4.2.2.3 *Greenhouse Containment Levels 3 and 4*

For a Greenhouse containment levels 3 and 4, requirements will take into consideration level 2 requirements as well as the following requirements:

a) Construction of a greenhouse containment level 3 and 4 should be done with permission from the Biosafety Council and in consultation with researchers;
b) Entry into a level 3 or 4 greenhouse is restricted to authorized personnel only;

c) For level 3, a disposable lab gown or the equivalent may be required based on the risk assessment. If required, it must be removed before leaving the facility and decontaminated (usually by autoclaving) before washing or disposal;

d) Personnel should wash their hands before leaving the facility;

e) For Containment Level 4, all street clothing must be removed and protective clothing donned, and when exiting the facility, the protective clothing must be removed before leaving;

f) Genetically modified materials transported into or out of level a 3 or 4 facility shall be double sealed inside two non-breakable containers;

g) The exterior surface of the secondary chamber shall be decontaminated either chemically or in a fumigation chamber if the same plant, host, or vector is present within the effective dissemination distance of the propagules of the experimental organisms;

4.2.3 PERSONNEL

a) For each facility conducting Contained Use of GMOs a Biosafety Officer must be identified;

b) All the personnel must be appropriately trained and provided with technical assistance as necessary;

c) The Biosafety Officer must act as adviser to the head of the establishment or department in all matters relating to the containment of GMOs and the safety of staff;

d) In the event that the Biosafety Officer is involved as principal investigator, appropriate deputizing arrangements should be made;

e) The Biosafety Officer should not be the head of the establishment or department.

4.2.3.1 *Responsibilities of the Biosafety Officer*

The Biosafety Officer is to be answerable to the head of the establishment or department, in so far as genetic modification work is concerned as well as ensure the following:

a) Good laboratory practices (GLPs) and Good Manufacturing Practices (GMPs) where applicable are followed;

b) All personnel are appropriately trained in aspects GMO biosafety and supervision of new entrants for an adequate period of time. The permit holder shall ensure that all personnel involved with handling the genetically modified plant materials from receipt of the shipment through to devitalization are trained on the nature of the material being handled and on other requirements of the permit condition;

c) Together with the principal investigator, that SOPs are in place and they give effective guidance on working practices and procedures as determined by the risk assessment for which the respective activity is approved;

d) All staff members are well versed on the SOPs and overall Quality Management System of the facility undertaking contained use of GMOs;

e) After which workers should be required to sign a document to confirm that they have received and understood the training;

f) Maintain a record of all personnel working in the facility;

g) Emergency response plans, chemical hygiene plans and waste management plans are developed and implemented;

h) Investigation of all accidents and spillage in the laboratory and taking what action he/she considers necessary;

i) Record each incident and corresponding action taken together with the name of the personnel involved;

j) The safe storage of GMOs, and pathogenic or potentially pathogenic material;

k) That an inventory of the GMO is maintained as well as the respective biosafety classification of these GMOs;

l) The appropriate transport of all GMOs (transfer of organisms constructed at containment level 2 or above should be recorded);

m) Liaison with the Supervisory Medical Officer;

n) Laboratories are appropriately disinfected prior to the start of a new experiment or the entry of maintenance personnel;

o) The Biosafety Officer shall carry out regular safety audits and supervise a regular testing program for all laboratory equipment, where applicable;

p) Physical security of the laboratory.

4.3 STANDARD OPERATING PROCEDURES (SOPS)/ RECORDS

a) A Safety File shall be kept on sight and consist of genetically modified organism risk assessments, standard operating procedures (SOPs), emergency procedures and any other relevant health and safety documents;

b) Key SOPs and emergency procedures shall be displayed in the laboratory;

c) There should be a programme of internal safety inspections and active monitoring by the Biosafety Officer to ensure that compliance with general rules of the facility are satisfactorily implemented;

d) Maintenance schedules for apparatus such as isolators, safety cabinets and ventilation systems should be strictly adhered to;

e) The procedures shall include decontamination and disposal of waste procedures which shall be routinely adhered to;

f) Where seed or other propagative material is being harvested, a permit holder shall ensure that no such material unintentionally trapped in workers' clothing or bodies is removed from the site.

4.4 EQUIPMENT

a) All equipment used to plant genetically modified plants in a greenhouse shall be cleaned of any propagative genetically modified plant material before being moved from the facility;

b) Appropriate cleaning methods may include, brushing, compressed air, vacuuming or water;

c) All planting equipment shall be inspected after cleaning and verified to be free of propagative plant material by facility personnel;

d) Disassembly may be required when necessary to verify that the equipment is free of propagative plant material.

4.5 TRANSPORTATION, STORAGE AND PACKAGING OF GENETICALLY MODIFIED MATERIALS

No person shall handle, transport or store genetically modified organisms in a means of containment that is not permitted by this section unless the means of containment is designed, constructed, filled, closed, secured and maintained so that under normal conditions of transport, including handling, there will be no accidental release into the environment of the genetically modified organisms that could cause harm to human health and the environment.

4.5.1 Transportation

a) Transportation of genetically modified organisms for contained use shall only be permitted with a valid permit issued by the Minister in accordance with Biosafety Regulations: Biosafety Act 2016 (Government Notice No. 210);

b) Every permit holder shall ensure that every consignment of genetically modified organisms being transported into, within or through Namibia is accompanied by a transport document that contains information set out in Annexure A of the Biosafety Regulations: Biosafety Act 2016 (Government Notice No. 210).

4.5.2 Storage

Every permit holder shall ensure that:

a) all genetically modified organisms are stored and maintained in such manner as to preserve its identity, security and integrity, and to prevent it from being consumed by humans, livestock or other animals;
b) access to the storage facility is restricted to authorized personnel or inspectors of the National Commission on Research, Science and Technology (NCRST);
c) the storage facility which may be a store in the laboratory or a section in the screen house is appropriately labelled in the manner prescribed under these regulations or conditions issued under the permit.

4.5.3 Packaging and labelling

A person handling, transporting or storing a genetically modified organism shall ensure that the genetically modified organism is:

a) packed in such manner as to prevent the genetically modified organism to escape into the environment;
b) accompanied by document which shall bear such marks as will identify the importer, the exported and the approval unique identification number or code;
c) if two or more inner containers are carried in the same outer container, every permit holder shall ensure that each inner container shall be separately packaged in shock-absorbent and fluid-absorbent material;
d) every permit holder shall ensure that the outer container is watertight, sealed and fracture proof, etc. in order to prevent any unintentional leakage of the contents.

4.5.3.1 *Packaging of Plant material*

A person issued with a permit to pack a genetically modified plant for transportation shall ensure that-

i. there shall always be an inner and an outer container, both of which shall be impervious to spores and pollen;

ii. The outer container shall be sealed and fracture proof, in order to prevent any unintentional leakage of the contents.

4.5.3.2 *Containment of Animals*

Every permit holder shall ensure that a genetically modified animal -

i. is herded or led between two authorized physical containment facilities, or between a transport vehicle and an authorized physical containment facility;
ii. is supervised and adequately controlled to prevent their escape; and
iii. the containment consists of either a cage or a container that ensures that the animals are not able to escape or contact other animals outside the cage or container.

4.5.3.3 *Packaging of Microorganisms*

i. A permit holder shall ensure that the packaging for genetically modified microorganisms is watertight, sealed and fracture proof, in order to prevent any unintentional leakage of the contents.
ii. Every permit holder shall ensure that for microorganisms where the activity is classified in biosafety level 2 to biosafety level 4 there shall always be an inner and an outer container, both of which shall be waterproof.
iii. A permit holder shall ensure that the packaging between the inner and the outer containers shall be fluid-absorbent material capable of absorbing a quantity of fluid equivalent to that in the container.

4.5.3.4 *Labelling*

Every permit holder shall ensure that;

i. the container displays a label in the English language with the words "Contains genetically modified organisms";
ii. the container's label displays the commercial name, name and address of the person in Namibia responsible for the genetically modified organism and information about where further information can be obtained about the genetically modified organism;
iii. No person shall display a mark on a container or at a facility, if the mark is misleading as to the presence of the genetically modified organisms;
iv. No person shall load or pack genetically modified organisms into a large means of containment for transport unless, immediately before the loading or packing the large

means of containment has displayed on it the words" contains genetically modified organisms" that will be required when the loading or packing is complete;

v. the outermost container carrying the genetically modified organisms is visibly marked and displayed to clearly show the name, address and contact details of the sender, so that the sender can be contacted should the container be lost, damaged or misdirected;

vi. a unique identification bar code is displayed in the accompanying document;

vii. Each side of a label to be placed on a container carrying genetically modified organisms shall be at least 10mm in length;

viii. Every permit holder shall ensure that a genetically modified animal shall, while being transported;

ix. is tagged so as to identify the animal; and

x. the container displays a label in the English language with the words "Contains genetically modified organisms"

4.6 RESEARCH AT FIELD TRIAL LEVEL

For Field Trial research a new permit is required. Requirements for such Field Trial Guide are outlined in the Field Trial Guidelines.

5. PROCEDURE

5.1 APPLICATION PROCESS

An application for registration of a facility must be submitted to the Registrar on the relevant form.

The application form must be accompanied by the following:

(a) Application fee of N$ 1000.00;

(b) Information as set out in Annexure 2 of the Biosafety Regulations: Biosafety Act, 2016

An application for a contained use permit must be submitted to the Registrar on the relevant form.

The application form must be accompanied by the following:

(a) Application fee of N$ 1000.00;

(b) An emergency response plan as set out in regulation 50 of the Biosafety Regulations: Biosafety Act, 2016;

(c) The risk assessment report and risk management plan prepared in accordance with and containing the information set out in Annexure 3 of the Biosafety Regulations: Biosafety Act, 2016;

5.1.1 Submission of applications

Completed applications with all relevant technical documentation must be hand delivered in hard copies (at least 10 copies) and electronic format to the Office of the Registrar at:

Registrar: Biosafety Council
National Commission on Research Science and Technology
ERF 490, Platinum Street, Prosperita
Windhoek

5.1.2 Advertisement of Application

According to regulation 27 an applicant must advertise his/her intention to apply for a contained use permit as contemplated in section 22(4) of the Biosafety Act. A copy of the advertisement together with written confirmation that it has been advertised must be submitted to the office of the Registrar no later than 7 days after submission of the application.

5.1.2.1 *Purpose of the Advertisement*

The purpose of the advertisement is to inform the public that the applicant is applying for permission to conduct a certain activity, and to request the public to submit comments or objections to the application made.

5.1.2.2 *Publishing of the Advertisement*

a) The advertisement must be under a clearly marked heading stating "Advertisement of Application for Permit for Contained Use of a Genetically Modified Organism".
b) The application must be advertised once a week for two consecutive weeks in at least two newspapers circulated widely in Namibia.

5.1.2.3 *Content of the Advertisement*

The advertisement must contain the following particulars:

a) Full name, identification, nationality, address and contact details of the applicant;
b) Type of contained use activity to which the application relates;
c) Description of the GMO involved;

d) Description of the genetic modification techniques or technology involved;

e) Location and type of facility in which the proposed activity will be conducted;

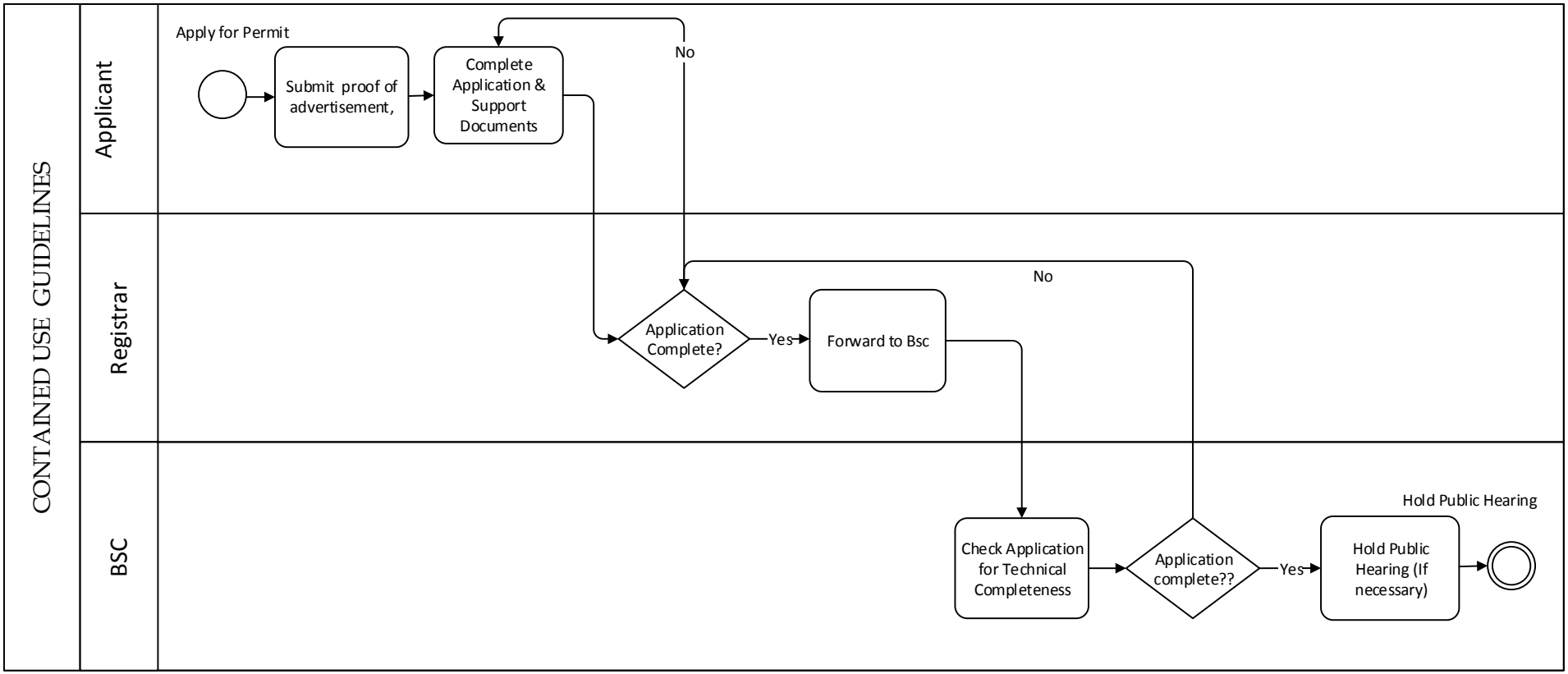
f) Containment level of facility;

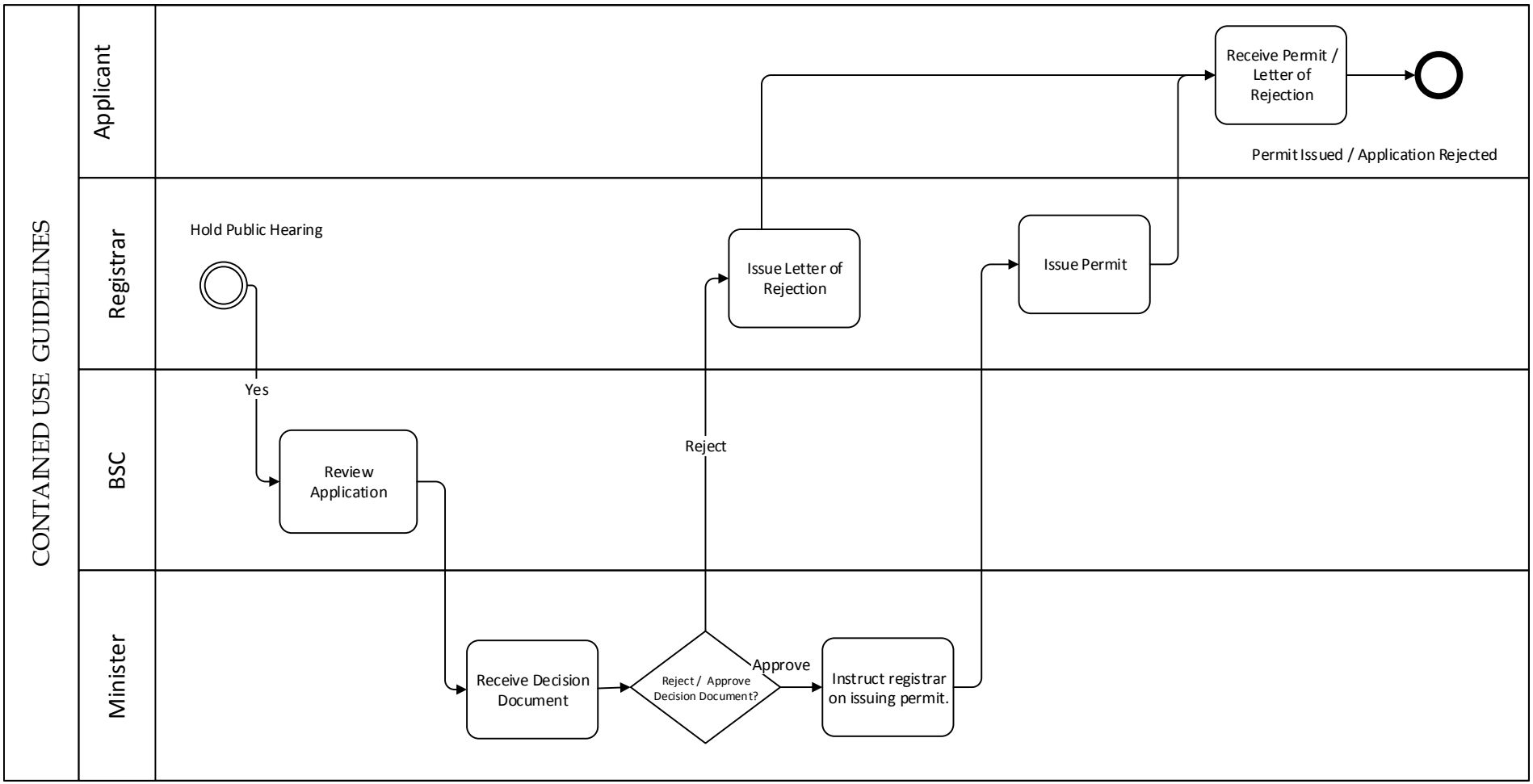
g) Date on which the application was submitted, together with a list of all information submitted with the application to the Registrar and the physical address and business hours of the Registrar;

h) An invitation for interested parties to submit comments or objections, in connection with the application, to the Registrar at the address below, within 30 days after the date of the last advertisement:

Hand Delivery:	*Postal Submission:*	*Electronically:*
Registrar: Biosafety Council	Registrar: Biosafety Council	For attention of:
National Commission on Research Science and Technology	National Commission on Research Science and Technology	Registrar: Biosafety Council
ERF 490, Platinum Street, Prosperita	Private Bag 13253	Email: registrarbiosafety@ncrst.na
Windhoek	Windhoek	Fax: + 264 61 216 531

5.1.3 Summary of Application Process





6. FORMS

BSC -F001 Application for registration of facility

BSC – F002 Application for GMO Contained Use Permit

7. REPLACEMENT AND WITHDRAWAL

None

8. REVISION/AMENDMENT HISTORY

Version number	Revision Date	Nature of Amendment