AFDC 11 (3020) DTZS
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DRAFT TANZANIA STANDARD

Biotechnology - Guidance for biotechnology laboratory operations

TANZANIA BUREAU OF STANDARDS

0 Foreword

Good biotechnology laboratory practices cover all aspects of the organization of biotechnology work and the conditions under which it is planned, executed, validated and supervised, as well as aspects relating to education and training of personnel.

This Tanzania standard aims at the protection of workers from biological hazards as well as the environment, including plants and animals.

During the development of this Tanzania standard, reference was made to the following documents:

- BS EN 12741:1999 Biotechnology - Laboratories for research, development and analysis - Guidance for biotechnology laboratory operations, published by British Standards Institute (BSI).

1 Scope

This Tanzania Standard gives Good biotechnology laboratory practices for biotechnology operations in research, development and analysis laboratories of containment levels 1, 2, 3 and 4.

2 Normative References

The following referenced documents are indispensable in the application of this Tanzania standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

AFDC 11 (3022) DTZS, Biotechnology - Laboratories for research; development and analysis - Guidance for handling, inactivating and testing of waste.

3 Terms and definitions

For the purposes of this Tanzania standard, the following terms and definitions should apply:

3.1 hazard

intrinsic potential property or ability of something (e.g. any agent, equipment, material or process) to cause harm

NOTE Harm is an injury or damage to health of people and/or the environment.

3.2 laboratory suite

one or more laboratories within a building, not necessarily of the same discipline or containment level, with ancillary rooms and with shared use of facilities

3.3 microorganism

Any microscopic biological entity, cellular or non-cellular, capable of independent replication or replication within host cell

3.4 risk

probability of occurrence of a hazard causing harm and the degree of severity of the harm

3.5 Biosafety Level 1 (BSL-1)

the lowest level of biosafety containment, designed for work with well-characterized agents that pose minimal potential hazard to personnel and the environment, requiring standard microbiological practices and no special equipment or isolation.

NOTE: BSL-1 is suitable for work with agents that are not known to consistently cause disease in healthy adults, or pose minimal risk

3.6 Biosafety Level 2 (BSL-2)

a containment level for laboratories working with moderate-risk infectious agents or toxins that pose a risk if accidentally inhaled, swallowed, or exposed to the skin, requiring enhanced safety measures beyond BSL-1.

NOTE: Containment level 2 (CL 2) is used for work with medium risk biological agents and hazards, genetically modified organisms, animals and plants.

3.7 Biosafety Level 3 (BSL-3)

laboratories handle indigenous or exotic agents that pose a risk of serious or potentially lethal disease through inhalation, requiring specialized engineering and safety practices beyond BSL-2, including controlled airflow and strict access controls.

NOTE: Biosafety level 3 (BSL-3) is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with agents that may cause serious or potentially lethal disease through inhalation, to the personnel, and may contaminate the environment. *Containment level 3 (CL 3) is used for work with high risk biological agents and hazards, genetically modified organisms, animals and plants*

3.8 Biosafety Containment Level 4 (BSL-4)

represents the highest level of biosafety precautions, used for work with extremely dangerous and exotic agents that pose a high risk of aerosol-transmitted infections and life-threatening diseases, often with no available vaccines or treatments

NOTE: BSL-4 labs are extremely isolated, often located in an isolated and restricted zone of a building or in a separate building entirely.

4 Basic practices for biotechnology laboratories

4.1 General

4.1.1 All staff should be informed that good practice is fundamental to safety.

4.1.2 Practices that could transfer hazardous material to mouth or skin should be avoided. Food and drink (other than samples submitted for scientific investigation) should not be taken into, consumed or stored in any area where organisms are handled. Smoking, the use of personal medications or the application of cosmetics should not be permitted in these areas.

4.1.3 Personnel should respect elementary rules of hygiene, should wash their hands when beginning work, whenever they have handled hazardous materials and on leaving the laboratory, after protective

clothing has been removed. Hand drying should be carried out using disposable towels or other suitable materials. Disinfection and cleaning should be carried out as necessary.

4.1.4 Hazards involved in operating laboratory equipment include long hair, jewellery, certain types of footwear and loose clothing that may be a factor in laboratory accidents. Therefore proper attire including protective clothing appropriate for the hazard should be worn at all times.

4.1.5 Mouth pipetting should he expressly forbidden. Pipetting devices should always be used for pipetting.

4.1.6 Aerosol release into the workplace should be minimized. If hazardous aerosols are likely to be generated, the work should be carried out in a microbiological safety cabinet.

NOTE Open-fronted cabinets (class I and II) allow some escape of airborne material. Inward airflow may be disturbed by, for example, people passing behind the operator, turbulence of air around equipment within the cabinet or sudden changes in air pressure within the room. Disturbances of this kind may reduce the validity of operator protection and validation of operator safety may be required in specific cases.

4.1.7 The laboratory should be tidy and clean and should not contain anything that is not related to the work.

4.1.8 Working surfaces, including those of biological safety cabinets, should be decontaminated using a validated procedure whenever biological material is accidentally spilled, when an item of work has been completed and at the end of the working day (see clause 10).

4.1.9 The wearing of laboratory coats and/or appropriate special clothing should be compulsory. When personnel leave the laboratory suite, the protective clothing should be removed and left in the changing area. Outdoor clothing should be kept separate from the working areas. When hazardous organisms are, or may be, present in laboratory suites, care should be taken to avoid distributing hazardous material from one unit to another.

4.1.10 In some work areas or while certain operations are being carried out, it may be necessary to ensure that adequate measures exist for contacting workers.

4.1.11 A suitable control policy for insects and rodents should be implemented.

4.1.12 The use of hypodermic needles and other sharp instruments should be minimized and, where possible, avoided. Every worker handling them should develop a safe routine for their use, transport and disposal.

4.1.13 Equipment should be selected on the basis of the possibility of decontamination and of prevention or minimization of internal contamination. The maintenance and repair of equipment and apparatus should only be undertaken by personnel with appropriate experience, who should be issued with a permit to work and who should be made aware of the possibility of contamination with hazardous organisms. Equipment should be positioned so that it is stable and not prone to tipping.

4.1.14 Minor incidents, f for example, spillage of small volumes of culture medium containing hazardous material, should be dealt with effectively, e.g. by covering the affected area and equipment with swabs of disinfectant, Disposable gloves should be worn during this operation; contaminated clothing should be discarded and autoclaved. Broken glass should be swept carefully into a suitable container; all contaminated items of debris and equipment used to collect it should be decontaminated by a validated procedure. Action in the event of accidents and emergencies is considered in Clause 8.

4.1.15 All material contaminated with hazardous material should be decontaminated. If this is done away from the laboratory, the material should be transferred in a durable, leakproof, closed container.

4.1.16 The person in charge of the laboratory should be informed immediately of any accident.

4.2 Instruction and training

4.2.1 Personnel should receive appropriate training for the work that is required of them. Information about safety measures should form an integral part of the induction training of new workers in laboratories. It is important to ensure that the basis of these safety measures is well understood in order to prevent human error and incorrect practices.

4.2.2 Initial training should be supplemented by refresher or continuous training so as to keep up the developments in techniques and equipment. The role of heads of laboratories and of management in training the personnel for which they are responsible should be defined.

4.2.3 The person or persons in charge of safety should take part in any in-house personnel teaching or training and preparation of training material. It is desirable that they should be familiar with laboratory work and the techniques for handling relevant potentially harmful organisms.

4.2.4 A copy of safety instructions should always be available in working areas.

4.3 Hazard management

4.3.1 The work practices of personnel should be designed to ensure safety in respect of general, physical, chemical and microbiological hazards.

4.3.2 Personnel should be instructed and trained in methods to cope with general hazards and they should be informed and instructed of the terms of local and national requirements.

NOTE: Methods for controlling the hazards of handling hazardous material should, in most instances, be also sufficient to prevent the hazard of toxicity or allergy. However, such specific hazards may exist in other operations where pathogenicity is not an issue. In such situations attention to appropriate hygiene conditions should be given. Specific protective clothing and equipment to guard against allergy hazards may be appropriate in some instances. Medical screening may also be appropriate.

4.3.3 Biotechnological work may involve the use of hazardous chemicals, for example mutagens, carcinogens, and teratogenic, radioactive and other toxic products. Personnel should be instructed and know how to apply relevant safety techniques.

4.3.4 All personnel should be instructed on safety measures relating to specific classes of pathogenic microorganisms. Procedures to be applied when using microorganisms handled in specific containment levels are listed in Clause 5.

5 Practices for handling microorganisms, in particular containment levels

5.1 General

Microorganisms to be used should be classified with respect to the hazard they present to humans and the environment. The identity of the microorganisms used should be verified regularly by a competent worker. Microorganisms should be handled in appropriate laboratories of containment levels I, 2, 3 and 4 stipulated by WHO Laboratory biosafety manual as indicated by risk assessment.

NOTE For operations using microorganisms only pathogenic for the environment (plant or some animal pathogens, e.g. foot and mouth disease virus), this Tanzania Standard should be implemented according to the risk for the environment and taking into account the recommendations of the national competent authorities.

5.2 Practices in containment level 1

The basic practices given in 4.1, 4.2 and 4.3 should be observed.

5.3 Additional practices in containment level 2

The following should be observed, in addition to 5.2, for handling microorganisms in laboratory facilities of containment level 2.

i. Laboratories should be clearly and prominently labelled on the outside by attaching to the doors of the laboratories biohazard warning signs conforming to relevant standards regarding their graphical presentation and the combination of geometric form and safety colour, and indicating the containment level.
ii. The international biohazard symbol should be also affixed on closed incubation and conservation equipment such as incubators, refrigerators or freezers, in particular when this equipment is situated outside the work area.
iii. Access should be restricted to authorized personnel.
iv. When appropriate, all contact between skin and contaminated materials should be avoided by the wearing of gloves or oversleeves.
v. The injection and aspiration of hazardous material should be carried out with needle-locking syringes or with disposable syringe-needle units. Precautions should be taken and considerable care exercised when using syringes, in order to avoid accidental self-inoculation or the formation of aerosols. Constant attention should be paid to gestures and in particular to the position of the hand not holding the syringe. Needles should never be broken or bent by hand or be replaced in their original covers. Before their removal or re-use, used needles and other pointed or sharp-edged tools should be carefully placed in containers that cannot be perforated, for disposal or decontamination by a validated method.
vi. It is recommended that biological material be kept or stocked in a clearly indicated safe place, which is labelled and exclusively accessible to authorized persons.
vii. When laboratory animals are deliberately contaminated by one or several pathogenic agents, they should be handled or housed on premises that correspond to the conditions and containment levels required according to the classification of the microorganisms) used.
viii. Waste or materials to be decontaminated should be placed on a far-off" site in correctly labelled leak proof resistant containers.
ix. Equipment that is likely to be contaminated, such as microbiological safety cabinets or centrifuges, should be decontaminated before being taken out of the laboratory.
x. Animals or plants that are not involved in experiments should not be admitted to the laboratory.

5.4 Additional practices in containment level 3

The following should be observed, in addition to 5.2 and 5.3, for handling microorganisms in laboratory facilities of containment level 3.

i. Fastened gowns, gloves, laboratory shoes and safety glasses should be worn. Whenever it is necessary, appropriate additional personal protective equipment should be used, such as oversleeves, masks, visors, ventilated cagoules, breathing masks, face shields.

ii. All liquid or solid waste and contaminated materials, whatever their volume, should be decontaminated before leaving the laboratory; in the exceptional case of the autoclave being situated close to the laboratory, appropriate validated procedures, which are checked when put into practice, should be applied, in order to allow the transfer of waste and contaminated materials to this autoclave. This process involves the use of leakproof containers, which are externally decontaminated in a material airlock before being rapidly transferred to the autoclave for sterilization by an authorized person.

iii. The transfer of live biological material coming from a containment level 3 laboratory should be carried out according to a defined procedure in leakproof resistant containers (see AFDC 11(3022) DTZS).

iv. Laboratory clothes should be decontaminated before being cleaned; additional personal protective equipment should be taken off before leaving the laboratory and decontaminated before re-use or removal.

5.5 Additional practices in Containment level 4

For handling of microorganisms in laboratory facilities of containment level 4, special safety measures should be set case-by-case in agreement with national competent authorities. The following should be observed as a minimum, in addition to 5.2,5.3 and 5.4.

i. Access should be restricted to authorized workers, only through the airlock.

ii. A complete change of clothing including undergarments should be performed in the controlled area. The clothing should be removed after work in the dirty side of the changing area and placed in a container for autoclaving. A shower should be taken before leaving the workplace.

iii. Appropriate respiratory protective equipment in sufficient quantity should be available.

6 Waste and effluent disposal

Safe waste and effluent disposal is an integral part of the operation of a biotechnology laboratory,

NOTE Guidance on methods of waste disposal is given in AFDC 11 (3022) DTZS

7 Health and medical surveillance

7.1 The health of employees handling hazardous biological materials should be regularly checked; health surveillance examinations should be carried out before the work is started and at regular, specified intervals thereafter. For occupational health surveillance, generally accepted national guidelines/legislation should be used.

7.2 When the work may produce illness not readily recognized by standard medical examinations, specific surveillance should be introduced. If work is carried out with pathogenic microorganisms which cause disease in man and a vaccine is available all employees should be offered immunization as per relevant national regulation.

7.3 Pregnant women and mothers breast-feeding their children should be made aware that some pathogenic microorganisms may be especially harmful to them and their child. National provisions/regulations concerning pregnant and breast-feeding women handling pathogenic microorganisms should be observed.

8 Management of laboratory accidents

8.1 General

8.1.1 A specific organization should be set up in accordance with national requirements to deal with personnel injury and accidents likely to be harmful to the environment,

8.1.2 Emergency plans should be developed jointly with the appropriate emergency services. Periodic exercises should be performed to test accident procedures.

8.1.3 In particular, methods of disinfection and a precise procedure applicable to personnel should be set up and first-aid personnel should receive specific training with regular updating.

8.1.4 Emergency equipment should be available outside but close to the potential areas of hazard.

8.1.5 Action to be taken in the event of accidents should be described in an accessible document which is to be brought to the attention of all personnel. These actions should be appropriate to the organisms handled and without prejudice to general safety measures.

8.1.6 All employees who will work in biotechnology laboratories should be educated and counselled regarding the management of laboratory accidents when they are employed and annually thereafter.

8.1.7 Any accident resulting in a danger to health should be reported to the supervisor and the routine policies of health care within the institution should be carried out Medical advice should be sought as soon as possible, where appropriate.

8.2 Major breakages and spillages involving hazardous material

8.2.1 The formation of aerosols creates the greatest risk when an infectious culture is spilled.

8.2.2 In the case of a major spill the following action should be taken.

i. Evacuate personnel from the area, but avoid spreading contamination.
ii. Confine the contamination.
iii. Make a report to the responsible person.
iv. If it is necessary to re-enter an area when aerosols may be present, i.e. before they have had time to settle, suitable protective clothing/equipment should be worn.
v. The area of the spill of hazardous material should be covered with disposable absorbing materials soaked in suitable disinfectant; the area should be flooded with disinfectant or the room fumigated.
vi. After allowing a suitable time for the disinfectant to act, the area should be cleaned.
vii. All equipment used for cleaning should be decontaminated by a validated method.

NOTE: If there is doubt about the severity of an incident, it should be treated as a major spill.

9 Cleaning and maintenance

9.1 Those laboratory and ancillary staff responsible for an area and equipment where cleaning, repair or servicing may be required should ensure that staff are not directly exposed to biological hazards that could arise.

9.2 The member of laboratory staff responsible for an area that is cleaned on a regular basis by contractors should ensure that it is safe for the work to be carried out.

9.3 If circumstances (e.g. laboratory work continuing during the time designated for cleaning) prevent this assurance being given, cleaners and ancillary staff should be prevented from entering. Surfaces such as walls and floors should be cleaned routinely. Horizontal surfaces (e.g. work surfaces and hard-surface flooring) in laboratories should be cleaned on a regular basis, and whenever soiling or spills occur.

NOTE Cleaning schedules and methods vary according to the area of the laboratory, the type of surface to be cleaned, the amount and type of soil present, the frequency of contact with personnel.

10 Decontamination

10.1 Appropriate decontamination methods should be used. In physical containment levels 3 and 4, validated decontamination methods can be required.

NOTE 1 Decontamination by autoclave is the best procedure whenever practicable.

10.2 A notice should specify the method of decontamination to be used. Where disinfection is recommended, the notice should specify the nature of the disinfectant suitable for a particular purpose and its concentration.

10.3 Contaminated components which are intended to be autoclaved or incinerated outside the laboratory should be placed in leakproof containers fitted with lids which should be closed before the containers are taken outside the laboratory (see AFDC 11 (3022) CD1).

10.4 Contaminated material to be re-used should be decontaminated. Any cleaning or repair which may be necessary should be performed after autoclaving or equally effective alternative treatments.

10.5 Disposable equipment should be placed in a container with an appropriate lid close to a work station before being autoclaved or disinfected.

10.6 Disposal bins should not be overfilled.

10.7 Bins for incineration should be marked so that their source can be identified.

10.8 External surfaces of instruments that are frequently handled and might be exposed to infectious material should be routinely treated using detergent solution, a disinfectant, or both. This strategy can be applied generally to laboratory instruments as well as to telephones, computers, etc.

NOTE: Toxicity and compatibility with humans should be factors considered when selecting a cleaning or decontamination procedure.