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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF EMPLOYMENT AND LABOUR

NO. R. 1887 **16 March 2022**

OCCUPATIONAL HEALTH AND SAFETY ACT, 1993

HAZARDOUS BIOLOGICAL AGENTS REGULATIONS, 20…

The Minister of Employment and Labour has, under section 43 of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993), after consultation with the Advisory Council for Occupational Health and Safety, made the regulations in the Schedule.

MR TW NXESI MP
MINISTER OF EMPLOYMENT AND LABOUR
DATE: 03/03/2022.

SCHEDULE

Definitions

1. In these Regulations any word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context indicates otherwise—

"biohazard" means any potential laboratory source of harm caused by biological agents, microbial by-products or metabolites;

"biological agent" means any microorganism, microbial by-products or metabolites, cell or organic material with plant, animal or human origin, including any which have been genetically modified;

"competent person" means a person who has, in respect of the work or task to be performed, the required knowledge, training, experience and, where applicable, qualifications specific to HBAs;

"control measures" means measures that remove, prevent or reduce the exposure of persons to HBAs at the workplace;

"decontamination" means the procedure that eliminates or reduces biological agents to a level that does not cause harm with respect to the transmission of infection or other adverse effects;

"disinfect" means to render non-viable virtually all recognised pathogenic microorganisms, but not necessarily all microbial forms;

"Facilities Regulations" means the Facilities Regulations, 2004, as published in Government Notice No. R. 924 of 3 August 2004;

"HBA" means a hazardous biological agent which may cause an infection, allergy or toxicity or otherwise create a risk to human health, subdivided into the following groups:

(a) Group 1 HBA, an HBA that is unlikely to cause human disease;

(b) Group 2 HBA, an HBA that may cause human disease and be a hazard to exposed persons, which is unlikely to spread to the

community and for which effective prophylaxis and treatment is usually available;

(c) Group 3 HBA, an HBA that may cause severe human disease, which presents a serious hazard to exposed persons and which may present a risk of spreading to the community, but for which effective prophylaxis and treatment is available; and

(d) Group 4 HBA, an HBA that cause severe human disease and is a serious hazard to exposed persons and which may present a high risk of spreading to the community, but for which no effective prophylaxis and treatment is available;

"laboratory" means a room or part of a building equipped for experimentation, research, testing or manufacture of drugs or chemicals or which may manipulate microbiological agents;

"microorganism" means a microbiological entity, cellular or non-cellular, capable of replication or transferring genetic material;

"monitoring" means the planning and carrying out of a measurement programme and the recording of the results thereof;

"respiratory protective equipment" means a device which is worn over at least the mouth and nose to prevent the inhalation of airborne HBAs, and which conforms to a standard, acceptable to the chief inspector;

"safety equipment" means equipment which is designed to prevent exposure to HBAs;

"standard precautions" means a synthesis of the major features of Universal Precautions (UP) and Body Substances Isolation (BSI) and applies to all persons coming into contact with potentially infected persons, animals or animal products and potentially contaminated blood and other fluids in the workplace and—

(a) apply to—

(i) all blood;

(ii) all body fluids, secretions and excretions, except sweat, regardless of whether they contain visible blood or not;

(iii) non-intact skin;

(iv) mucous membrane; and

(v) tissues; and

(b) are designed to reduce the risk of transmission of HBAs from both recognised and unrecognised sources of exposure to HBAs in the workplace;

"the Act" means the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993);

"Universal Precautions" means an approach to infection control to treat all human blood and certain human body fluids as if they were known to be infectious for HIV, HBV and other blood-borne pathogens;

"ventilation" means the process of supplying or removing air to or from an indoor space for the purpose of controlling air contaminants level, humidity or temperature within the space; and

"verification" means the process of establishing the accuracy or validity of something.

Scope of application

2. (1) Subject to sub regulation (2), these Regulations apply to every employer or self-employed person at a workplace where—

(a) an HBA is produced, processed, used, handled, stored or transported; or

(b) exposure to an HBA may occur.

(2) Regulations 8, 14, 15, 16 and 17 do not apply to an employer or self-employed person at a workplace where the exposure is restricted to a Group 1 HBA.

Classification of biological agents

3. (1) Biological agents must be assigned a classification of Group 1, Group 2, Group 3 or Group 4 according to hazard and categories of contaminant by the chief inspector in consultation with the HBAs health and safety technical committee.

(2) Where a biological agent has not been assigned a classification as contemplated in subregulation (1), the employer or self-employed person must provisionally classify that biological agent in accordance with subregulation (3), having

regard to the nature of the biological agent and the properties of which he or she may reasonably be expected to be aware and must without delay notify the chief inspector of the provisional classification and the reason therefor. The chief inspector may make a decision based on the recommendation of the HBAs technical committee.

(3) When provisionally classifying a biological agent, the employer or self-employed person must conduct a risk assessment and assign that biological agent to one of the groups and if there is doubt according to its level of risk of infection as to which of two alternative groups would be most appropriate, the biological agent must be assigned to the higher of the two.

Information, instruction and training

4. (1) An employer who undertakes work which exposes an employee to HBAs must inform the relevant health and safety representative or the health and safety committee established for that workplace of the—

(a) intention to conduct—

(i) a risk assessment contemplated in regulation 6;

(ii) exposure monitoring contemplated in regulation 7;

(iii) medical surveillance contemplated in regulation 8; and

(iv) training contemplated in subregulation (2);

(b) documented outcomes of the—

(i) risk assessment contemplated in regulation 6;

(ii) exposure monitoring contemplated in regulation 7; and

(iii) medical surveillance contemplated in regulation 8.

(2) An employer must ensure that any employee at risk of being exposed or exposing others to HBAs is comprehensively informed, instructed and trained in both the practical aspects and theoretical knowledge with regard to—

(a) the contents and scope of these Regulations;

(b) the potential risks to health caused by the exposure;

(c) the measures to be taken by the employer to protect an employee against any risk of being exposed;

(d) the importance of good housekeeping at the workplace and personal hygiene requirements;

(e) the precautions to be taken by an employee to protect him or her against the health risks associated with the exposure, including the wearing and use of protective clothing and respiratory protective equipment;

(f) the necessity, correct use, maintenance and potential limitation of safety equipment, facilities and engineering control measures provided;

(g) the necessity of risk-based medical surveillance;

(h) the safe working procedures regarding the use, handling, storage, labelling, and disposal of HBAs at the workplace; and

(i) the procedures to be followed in the event of exposure, spillage, leakage, accidental release, injury or any similar emergency situation, and decontaminating or disinfecting contaminated areas.

(3) The employer must ensure that the information, instruction and training referred to in subregulation (1) are provided before an employee is potentially exposed to HBAs.

(4) The employer must conduct refresher training annually or at intervals that may be recommended by the health and safety committee or the health and safety representative.

(5) An employer or self-employed person must give instructions in writing of the procedures contemplated in subregulation (1)*(a)* to the drivers of vehicles carrying HBAs.

(6) Every employer or self-employed person must ensure that he or she or any person who in any manner assist him or her in the carrying out or conducting of the business duties has the necessary information and has undergone instruction and training in order for him or her to identify potential risks and the precautions that should be taken.

Duties of persons who might be exposed to HBAs

5. (1) Any person who is or might be exposed to HBAs must obey any lawful instruction given by or on behalf of the employer or a self-employed person regarding—

(a) the prevention of an uncontrolled release of an HBA;

(b) the adherence to instructions regarding environmental and health practices, personal hygiene and good housekeeping;

(c) the appropriate use of personal protective equipment and clothing as prescribed by these Regulations and the documented risk assessment;

(d) the appropriate wearing of personal samplers, when necessary, to measure personal exposure to airborne HBAs;

(e) the disposal of materials containing HBAs and the disinfection and decontamination of any workplace contaminated by an HBA;

(f) the reporting during normal working hours for such medical examination or tests as contemplated in regulation 8(1); and

(g) information, instruction and training as contemplated in regulation 4.

(2) Any person must immediately report to the employer, the health and safety representative or self-employed person any possible exposure to an HBA at the workplace.

Risk assessment for HBAs

6. (1) A self-employed person must conduct and document the risk assessment to determine if any person could be exposed to an HBA.

(2) An employer must—

(a) conduct and document the risk assessment to determine if any person could be exposed to an HBA; and

(b) ensure that the HBA risk assessment contemplated in paragraph *(a)* is conducted by a competent person.

(3) When conducting the risk assessment, as contemplated in subregulation (1) and (2), the employer or self-employed person must take into account, as a minimum, the following matters:

(a) The nature of the HBA and the possible route of exposure;

(b) where the HBA might be present and in what form it is likely to be;

(c) the nature of the work and work processes;

(d) current control measures in place, effectiveness of control measures and any reasonable deterioration in, or failure thereof; and

(e) what effects the HBA can have on an employee, including pregnant, immunocompromised and vulnerable employees.

(4) An employer or a self-employed person must conduct the risk assessment on the basis of all available information, including—

(a) classification of the HBA into the relevant risk group according to its level of risk of infection as contained in Annexure A;

(b) recommendations from the manufacturer, supplier or a competent person regarding additional control measures necessary in order to protect the health of persons against such agents as a result of their work;

(c) information on diseases that may be contracted as a result of the activities at the workplace;

(d) potential allergenic, infectious or toxic effects that may result from the activities at the workplace; and

(e) knowledge of diseases from which employees might be suffering and which may be aggravated by conditions at the workplace.

(5) An employer must, in terms of the risk assessment–

(a) consider the recommendations identified in the risk assessment; and

(b) develop a documented action plan for the implementation of the recommendations.

(6) An employer must review the assessment required by subregulation (1)—

(a) at intervals not exceeding 24 months;

(b) forthwith, if—

(i) the previous assessment is no longer valid;

(ii) there has been a change in a process involving an HBA;

(iii) there has been a change in the methods, plant or machinery, procedures in the use, handling, control or processing of an HBA;

(iv) an incident occurs involving an HBA; or

(vi) medical surveillance reveals an adverse health effect, where an HBA is identified as a contributing factor.

(7) The employer must ensure that all employees, the relevant health and safety representative and health and safety committee are informed of the results of the risk assessment, who may comment thereon.

Exposure monitoring of HBAs

7. (1) An employer must establish and maintain an exposure monitoring programme at the workplace which is representative of the employees' exposure to HBAs.

(2) The exposure monitoring programme must be—

(a) in accordance with a validated procedure, sufficiently sensitive and of proven effectiveness;

(b) conducted by a competent person;

(c) conducted at intervals determined in the risk assessment but not exceeding 24 months; and

(d) conducted when any change occurs which may affect the exposure.

(3) An employer must, in terms of exposure monitoring—

(a) consider the recommendations identified in the exposure monitoring report; and

(b) develop a documented action plan for the implementation of the recommendations.

Medical surveillance

8. (1) An employer must establish and maintain a documented system of medical surveillance of employees, which is overseen by an occupational health practitioner, if—

(a) the results of the HBA risk assessment contemplated in regulation 6 indicate that an employee is at risk of exposure to HBAs;

(b) the exposure of the employee to the HBA is hazardous to his or her health and is such that—

(i) an identifiable disease or adverse effect to his or her health may be related to the exposure;

(ii) there is a reasonable likelihood that the disease or effect may occur under the particular conditions of his or her work; and

(iii) there are techniques such as preclinical biomarkers, where appropriate, for detecting sensitisation to allergens or an inflammatory response associated with exposure to diagnose indications of the disease or the effect as far as is reasonably practicable; or

(c) an occupational health practitioner recommends that the relevant employee should be under medical surveillance, in which case the employer may call upon an occupational health practitioner to confirm the appropriateness of such recommendation.

(2) In order to comply with the provisions of subregulation (1), the employer must, after in-depth counselling and education, ensure that the medical surveillance consists of—

(a) an initial health evaluation, which should be carried out by an occupational health practitioner immediately before or within 14 days after a person commences employment where risk of exposure exists, which comprises—

(i) an evaluation of the employee's medical and occupational history;

(ii) a physical examination; and

(iii) any biological tests and other appropriate medical tests or any other essential examination that in the opinion of the occupational health practitioner is desirable in order to enable the practitioner to do a proper evaluation;

(b) periodic medical examinations and tests which should be carried out by an occupational health practitioner at intervals specified by him or her but not exceeding 24 months and which consists of—

(i) a physical examination; and

(ii) any biological tests and other appropriate medical tests or any other essential examination that in the opinion of the occupational health practitioner is desirable in order to enable the practitioner to do a proper evaluation;

(c) exit medical examinations and tests which should be carried out by an occupational health practitioner and which consists of—

(i) a physical examination; and

(ii) any biological tests and other appropriate medical tests or any other essential examination that in the opinion of the occupational health practitioner is desirable in order to enable the practitioner to do a proper evaluation.

(3) All tests and examinations as contemplated in subregulation (2) must be conducted according to a written medical protocol following current best practice, national or international guidelines.

(4) All occupational health practitioners must submit to the employer for approval a written protocol for procedures to be followed when dealing with abnormal results.

Records

9. (1) An employer must—

(a) keep records of all training, exposure assessments, exposure monitoring reports and medical surveillance reports required by regulations 4, 6, 7 and 8 respectively;

(b) make the records contemplated in paragraph *(a)*, excluding personal medical records, available for inspection by an inspector, a health and safety representative or a health and safety committee;

(c) make the records contemplated in regulation 8(2)*(b)* available to any person subject to the formal written consent of the employee concerned;

(d) keep all records of risk assessments, medical surveillance and exposure monitoring reports for a minimum period of 40 years;

(e) keep all records of the examinations and tests carried out in terms of regulation 12*(c)* and of any repairs resulting from the investigations and tests for a minimum period of five years;

(f) keep all records of training given to an employee in terms of regulation 4 for as long as the employee remains employed at that particular workplace; and

(g) if the employer or self-employed person ceases activities, hand over all the records to the relevant Chief Director: Provincial Operations.

(2) A self-employed person must keep records of all risk assessments for a minimum period of 40 years, and if the self-employed person ceases activities, all those records must be handed over to the relevant Chief Director: Provincial Operations.

Prevention and control of exposure to HBAs

10. (1) A self-employed person must ensure that the risk of exposure of persons to HBAs is reduced through biological containment and where this is not reasonably practicable, control the exposure to as low as possible.

(2) An employer must ensure that the risk of exposure of persons to HBAs is reduced through biological containment and medical fitness restrictions in the workplace or, where this is not reasonably practicable, control the exposure to as low as possible.

(3) The employer or self-employed person must ensure that the standard precautions are implemented to reduce the risk of transmission of HBAs in a workplace, which may include—

(a) hand hygiene;

(b) gloves;

(c) face or eye protection;

(d) protective clothing;

(e) respiratory protective equipment; and

(f) other relevant process safety equipment.

(4) Where reasonably practicable, the employer or self-employed person must control the exposure to an HBA in the workplace by—

(a) implementing measurers identified in the documented risk assessment;

(b) limiting the amount of HBAs used which might contaminate the workplace to the minimum quantity required for the task;

(c) limiting the number of employees;

(d) limiting the duration of exposure of employees;

(e) introducing measures for the control of exposure, which must include any combination of the following contamination control measures:

(i) Separation of different infectious processes from each other and from persons;

(ii) barrier isolation of a process or agent;

(iii) local exhaust ventilation;

(iv) general ventilation;

(v) air and surface disinfection;

(iv) positive static air pressure differential from infectious process to human occupied zones;

(vii) suppression of emissions of an airborne HBA;

(viii) access control to prevent unauthorised access; and

(ix) immediately accessible emergency personal or environmental disinfection;

(f) introducing appropriate work procedures that employees must follow where HBAs are handled, used and processed that could give rise to the exposure of an employee to HBAs, and such procedures must include documented instructions to ensure—

(i) the safe handling, use and disposal of HBAs;

(ii) the proper use and maintenance of machinery, installations, equipment, tools and local exhaust and general ventilation systems;

(iii) the regular cleaning of machinery and work areas with vacuum cleaners fitted with air filters with an arrestance of not less than 99,95%;

(iv) a system is in place that identifies the need for early corrective action from changes to work procedures and practices; and

(v) the decontamination and disinfection of the affected workplace;

(g) making available effective vaccines for those employees who are not immune to the biological agent to which they are exposed or are liable to be exposed;

(h) specifying procedures for taking, handling and processing samples that might contain HBAs; and

(i) displaying the biohazard sign as depicted in Annexure B and other relevant information.

Personal protective equipment and facilities

11. (1) If it is not reasonably practicable to ensure that the exposure of an employee is controlled as contemplated in regulation 10, the employer must, in the case of—

(a) airborne, ingestion and contact transmission, provide the employee with suitable protective equipment and protective clothing; and

(b) HBAs that can be absorbed through the skin, provide the employee with suitable impermeable personal protective clothing.

(2) Where respiratory protective equipment is provided, the employer must ensure that—

(a) the relevant safety equipment is capable of preventing the exposure to the HBA concerned;

(b) the relevant safety equipment is correctly selected, fitted and properly used;

(c) information, instructions, training and supervision which would be necessary with regard to the use and disposal of the safety equipment are known to the employees; and

(d) the reusable safety equipment is kept in hygienic condition and efficient working order.

(3) An employer must, as far as is reasonably practicable—

(a) not issue personal protective equipment which has been used to an employee unless it is capable of being decontaminated and disinfected prior to use;

(b) provide separate containers or storage facilities for protective equipment and protective clothing when not in use; and

(c) take steps to ensure that all protective equipment and protective clothing not in use are stored in a demarcated area with proper access control.

(4) An employer must, as far as is reasonably practicable, ensure that all contaminated reusable personal protective clothing issued is cleaned and handled in accordance with the following procedures:

(a) Where such clothing is cleaned on the premises of the employer, care must be taken to prevent contamination during handling, transporting and cleaning;

(b) where clothing is sent off the premises to a contractor for cleaning purposes, the contractor must place the clothing in impermeable, tightly sealed colour coded containers and such containers must be clearly identified with a biohazard label as depicted in Annexure B;

(c) where clothing from facilities handling HBA Risk Group 3 and Risk Group 4 agents is sent off the premises for any purposes, it must first be decontaminated; and

(d) it must be ensured that the contractor as contemplated in subregulation (4)*(b)* is fully informed of the requirements of these

Regulations and the precautions to be taken regarding the handling of contaminated clothing.

(5) Subject to the provisions of the Facilities Regulations, an employer must, where reasonably practicable, provide employees using personal protective equipment and clothing as contemplated in subregulation (1) with—

(a) adequate washing facilities which are readily accessible and located in an area where the facilities will not become contaminated, in order to enable the employees to meet the standard of personal hygiene consistent with the adequate control of exposure, and to avoid the spread of HBAs;

(b) two separate lockers labelled "protective clothing" and "general clothing" respectively, and ensure that the general and protective clothing is kept separately in the lockers concerned; and

(c) separate "clean" and "contaminated" change rooms if the employer uses or processes HBAs to the extent that the HBA could endanger the health of persons outside the workplace.

Maintenance and verification of control measures, plant machinery and facilities

12. The employer must ensure that—

(a) documented risk-based protocols are developed, maintained by a competent person and made available at the workplace for all control measures, plant machinery and facilities provided in terms of regulations 6, 10 and 11, which include—

(i) performance parameters and minimum acceptance criteria;

(ii) performance verification methodology and intervals;

(iii) routine maintenance requirements, specifications and intervals;

(iv) relevant standards, regulations and manufacturer's requirements; and

(v) minimum competency and training required to perform verification and maintenance activities;

(b) all control measures, plant machinery and facilities provided in terms of regulations 6, 10 and 11 are maintained in good working

order and in accordance with the protocols referred to in paragraph *(a)*;

(c) thorough examination and tests of control measures, plant machinery and facilities provided in terms of regulations 6, 10 and 11 are carried out in accordance with the protocols referred to in paragraph *(a)*, but at intervals not exceeding 24 months;

(d) outcomes of tests of control measures are documented and available for inspection; and

(e) the protocols referred to in paragraph *(a)* comply with any applicable guideline issued by the chief inspector.

Prohibitions

13. (1) No person may—

(a) use compressed air to remove HBAs from any surface or person;

(b) eat, drink, smoke, keep food or beverages or apply cosmetics where an HBA is handled or require or permit any other person to eat, drink, smoke, keep food or beverages or apply cosmetics in such a workplace; or

(c) leave a controlled area without prior removal of potentially contaminated protective clothing and safety equipment.

(2) An employer or self-employed person must cause a notice and/or signage to be posted at a conspicuous place containing the provisions of subregulation (1).

Labelling, packaging, transporting and storage

14. An employer or self-employed person must, as far as is reasonably practicable, take steps to ensure that—

(a) all HBAs under his or her control in storage, transit or being distributed are properly contained and controlled to prevent the spread of contamination from the workplace;

(b) the colour coded containers in which HBAs are transported are clearly marked with a biohazard sign as depicted in Annexure B and other relevant warning signs that identify the contents;

(c) transport of HBAs is performed with due consideration of Chapter VIII of the National Road Traffic Act, 1996 (Act No. 93 of 1996), and the International Air Transport Association (IATA) Infectious Substances Shipping Regulations; and

(d) authorisations for the transport and storage of biological agents as required by the National Health Act, 2003 (Act No. 61 of 2003): Regulations Relating to the Registration of Microbiological Laboratories and the Acquisition, Importation, Handling, Maintenance and Supply of Human Pathogens, 2012, as published in Government Notice No. R. 178 of 2 March 2012, the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993), the Animal Health Act, 2002 (Act No. 7 of 2002), and the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), are adhered to where applicable.

Disposal of HBAs

15. An employer or self-employed person must—

(a) lay down written procedures for appropriate decontamination and disinfection;

(b) implement written procedures enabling infectious waste to be handled and disposed of without risk;

(c) provide sufficient hazardous waste containers for disposal of used personal protective equipment;

(d) ensure that all fixtures, plant and machinery including vehicles, reusable containers and covers which have been in contact with HBA waste are disinfected and decontaminated after use in such a manner that it does not cause a hazard inside or outside the workplace concerned;

(e) ensure that all employees involved in the collection, transport and disposal of HBA waste and who may be exposed to that waste are provided with suitable personal protective equipment;

(f) ensure that if the services of a waste disposal contractor are used, a provision is incorporated into the contract stating that the

contractor must comply with the provisions of these Regulations; and

(g) ensure that HBA waste that can cause exposure is treated and disposed of only on sites specifically designated and authorised for this purpose in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), in such a manner that it does not cause a hazard inside or outside the site concerned.

HBAs health and safety technical committee

16. (1) The chief inspector must establish an HBAs health and safety technical committee which must consist of—

(a) a person who is to be the chairperson;

(b) two persons designated by the chief inspector from the employees of the Department of Employment and Labour;

(c) three persons designated by employers' organisations to represent employers;

(d) three persons designated by employees' organisations representing the federation of unions;

(e) one representative of each of the professional bodies recognised by the chief inspector; and

(f) one person from the field of HBAs representing a higher educational institution.

(2) The chief inspector may—

(a) authorise the HBAs health and safety technical committee to co-opt persons who have specialised knowledge of the matters dealt with by the HBAs health and safety technical committee; and

(b) appoint members of the HBAs health and safety technical committee for a period that he or she may determine at the time of appointment.

(3) The HBAs health and safety technical committee must—

(a) advise the chief inspector on HBA related matters, including but not limited to codes, standards and training requirements;

(b) make recommendations and submit reports to the chief inspector regarding any matter to which these Regulations relate;

(c) advise the chief inspector regarding any matter referred to the HBAs health and safety technical committee by the chief inspector;

(d) perform any other function for the administration of a provision of these Regulations that may be requested by the chief inspector; and

(e) conduct its work in accordance with the instructions and rules of conduct framed by the chief inspector.

Offenses and penalties

17. Any person who contravenes or fails to comply with any provision of regulations 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 or 15 will be guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding 12 months and, in the case of a continuous offence, to an additional fine of R200 for each day on which the offence continues or additional imprisonment of one day for each day on which the offence continues: Provided that the period of such additional imprisonment shall in no case exceed 90 days.

Withdrawal of regulations

18. The Regulations for Hazardous Biological Substances, 2001, published as Government Notice No. R. 1390 of 27 December 2001, are hereby withdrawn.

Short title

19. These Regulations are called the Regulations for Hazardous Biological Agents.

ANNEXURE A

CATEGORISATION OF BIOLOGICAL AGENTS ACCORDING TO RISK GROUP

INTRODUCTION

1. The attached list must be read in conjunction with the Hazardous Biological Agents Regulations, and in particular regulation 3.

2. Biological agents listed are categorised into the following risk groups on the basis of their ability to cause human disease by infection, allergy and/or toxicity, potential to cause epidemics or pandemics, endemicity in South Africa and availability of curative or prophylactic treatment:

   Risk group 1: a microorganism known not to or unlikely to cause human disease.
   Risk group 2: a pathogen that may cause human disease but unlikely to pose serious hazard to laboratory workers, the community and the environment. Specific treatment or vaccines may be available to manage or prevent infection with these pathogens.
   Risk group 3: a pathogen that may cause serious human disease but does not typically spread from human to human. Treatment and vaccines may be available to manage or prevent infection with these pathogens.
   Risk group 4: a pathogen that may cause serious human disease and may be readily transmissible from human to human. Specific treatment and preventative measures are typically not available for the diseases caused by these pathogens.

3. In allocating biological agents to a risk group, account is not taken of effects on those whose susceptibility may be affected for one or other reason such as pre-existing disease, medication, compromised immunity, pregnancy or breastfeeding. Workplace specific risk to such workers should be considered per risk assessment as in regulation 6.

4. Biological agents that have not been classified for inclusion in groups 2 to 4 of the list are not implicitly classified as Group 1. All viruses that have been

isolated in humans and that have not been assessed and allocated to a group in the list are to be classified in group 2 as a minimum, except where there is evidence that they are unlikely to cause disease in humans.

5. If more than one species of any particular agent is known to be pathogenic to humans, the most prominent of these is generally named, together with the wider reference "species" (spp.) to indicate the fact that the other species of the same genus may be hazardous. If a whole genus is mentioned in this way, it is implicit that species and strains that are non-pathogenic to humans are excluded.

6. When a strain is attenuated or has lost known virulence genes, then the containment required by the classification of its parent strain need not necessarily apply, subject to risk assessment as per regulation 6, for example, when such strain is used as a product or as part of a product for prophylactic or therapeutic purposes (see point 2).

7. The requirements as to containment consequent upon the classification of parasites apply only to stages in the life cycle of the parasite in which it is liable to be infectious, allergic or toxic to humans.

8. The list also gives a separate indication where biological agents are capable of causing allergic or toxic reactions, and where a registered vaccine is available for use in the Republic of South Africa.

   The indications are identified by the following notations:

   - A: possible allergic effects;
   - T: toxin production; and
   - V: vaccine available.

9. The selection of control measures for biological agents should take into account the fact that there are no exposure limits for them. Their ability to replicate and to infect, cause allergic or toxic effects, at very low doses, means that exposure may have to be reduced to levels that are diminishingly low.

   For each activity the first consideration should be whether it can be carried out in a way that involves exposure to a less harmful biological agent. This may be

practicable, for example, in teaching and some types of research. If there is more than one way of carrying out the activity, then the method carrying the least risk should be chosen.

If the least harmful alternative still involves exposure or potential exposure to a biological agent, or the nature of the activity is such that there is no choice, and it is not reasonably practicable to prevent exposure by some other means, then exposure should be adequately controlled.

10. Agents with reduced virulence may be used at a lower than normal level of containment if the alteration has effectively changed their classification.

A biological agent that falls or is treated as falling into hazard Group 1 may be a Group 3 genetically modified organism because of environmental risks associated with it or because, though now unlikely to cause human disease, it is derived by genetic modification from a pathogenic parental organism. In the latter case, the selection of containment measures appropriate to the agent's reduced virulence and corresponding group may be permitted. Where there is a mismatch, as in the case of a genetically modified organism or biological agent that is non-hazardous to humans but environmentally harmful, the more stringent requirements should be followed.

Where the rules set out lead to a particular containment level for an activity, all the measures appropriate to that level should normally be used. Some selection may be done, however, to suit individual circumstances, provided that by doing so the risk is not increased.

Regulation 11 sets out additional requirements in respect of personal protective equipment used to protect employees against biological agents. The objective of these requirements is to prevent the equipment itself from acting as the means by which agents are transmitted, and they should be followed accordingly.

Where workers are exposed to biological agents, the information and instruction given to them, if applicable, should be set down in the form of written instructions, outlining procedures to be followed after a serious incident

involving the handling of a biological agents as well as the procedure for handling any Group 4 agent.

If the nature of the workplace and the activity are such that employees may need instant access to this information, or where a reduction in risk may be expected by having the information conspicuously displayed in the workplace then it should also be set out on notices displayed in the workplace.

Table 1:

Prescribed risk groups for parasitic agents (in alphabetic order)

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Helminths			
Ancylostoma spp.	2	*Hymenolepis* spp.	2
Angiostrongylus spp.	2	*Loa* spp.	2
Anisakis spp.	2	*Mansonella* spp.	2
Ascaris lumbricoides	2 (A)	*Metagonimus* spp.	2
Brugia spp.	2	*Necator* spp.	2
Capillaria spp.	2	*Onchocerca* spp.	2
Clonorchis spp.	2	*Opisthorchis* spp.	2
Contraceacum osculatum	2	*Paragonimus* spp.	2
Dicrocoelium dendriticum	2	*Pseudoterranova decipiens*	2
Dipetalonema spp.	2	*Schistosoma* spp.	2
Diphyllobothrium spp.	2	*Strongyloides* spp.	2
Dipylidium caninum	2	*Taenia* spp.	2
Dracunculus medinesis	2	*Taenia solium*	3
Echinococcus spp.	3	*Ternidens deminutus*	2
Enterobius spp.	2	*Toxocara* spp.	2
Fasciola gigantica	2	*Trichinella* spp.	2
Fasciola hepatica	2	*Trichostrongylus* spp.	2
Fasciolopsis buski	2	*Trichuris trichiura*	2
Heterophyes spp.	2	*Wuchereria* spp.	2
Protozoa			
Acanthamoeba spp.	2	*Leishmania* spp.	2
Babesia spp.	2	*Leishmania brasiliensis*	3
Balantidium spp.	2	*Leishmania donovani*	3
Blastocytis hominis	2	*Linguatula* spp.	2
Coccidia spp.	2	*Macracanthorhynchus* spp.	2
Cochliomyia hominivorax	2	*Microsporidia* spp.	2
Cryptosporidium spp.	2	*Naegleria fowleri*	3
Cyclospora spp.	2	*Naegleria* spp. (other than *fowleri*)	2
Cysticerus cellulosae	2	*Oesophagostomum dentalum*	2
Dientamoeba fragilis	2	*Plasmodium* spp. (human and simian)	2
Encephalitozoon spp.	2	*Plasmodium falciparum*	3
Entamoeba spp.	2	*Pneumocystis carinii*	2
Enterocytozoon bieneusi	2	*Sarcocystis* spp.	2

Giardia spp.	2	*Toxoplasma* spp.	2
Gnathostoma spinigerum	2	*Trichomonas vaginalis*	2
Gongylonema pulchrum	2	*Trypanosoma* spp.	2
Haemonchus contortus	2	*Trypanosoma brucei gambiense*	3
Isospora spp.	2	*Trypanosoma brucei rhodesiense*	3

Table 2:

Prescribed risk groups for fungal agents (in alphabetic order)

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Absidia spp.	2	*Lacazia loboi*	3
Acremonium spp.	2	*Leptosphaeria* spp.	2
Ajellomyces spp.	3	*Lichtheimia corymbifera*	2
Arthroderma spp.	2	*Madurella* spp.	2
Aspergillus spp.	2	*Malassezia* spp.	2
Basidiobolus haptosporus	2	*Microsporum* spp.	2
Blastomyces dermatitidis	3	*Mucor* spp.	2
Candida spp.	2	*Neotestudina rosatii*	2
Cladophialophora bantiana	3	*Paecilomyces variottii*	2
Other *Cladophialophora* spp	2	*Paracoccidioides brazilensis*	3
Cladosporium spp.	3	*Penicillium marneffei*	3
Coccidioides and Paracoccidioides spp.	3	*Pseudallescheria boydii*	2
Cryptococcus spp.	2	*Rhinocladiella mackenziei*	3
Dermatophilus congolensis	2	*Rhizomucor pusillus*	2
Emmonsia crescens	2	*Rhizopus* spp.	2
Emmonsia parva	2	*Saksenaea vasiformis*	2
Epidermophyton spp.	2	*Scedosporium* spp.	2
Exophiala spp.	2	*Scopulariopsis brevicaulis*	2
Filobasidiella spp.	2	*Sporothrix schenckii*	2
Fonsecaea spp.	2	*Stachybotrys chartarum*	2
Fusarium spp.	2	Trichophyton spp.	2
Geotrichum spp.	2	Trichosporon spp.	2
Histoplasma spp.	3	*Xylohypha bantiana*	3

Table 3:

Prescribed risk groups for bacteria, rickettsiae and mycoplasmas (in alphabetic order)

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Abiotrophia spp.	2	*Kingella* spp.	2
Achromobacter spp.	2	*Klebsiella* spp.	2
Acidaminococcus fermentans	2	*Kluyvera* spp.	2
Acidovorax spp.	2	*Koserella trabulsii*	2
Acinetobacter spp.	2	*Lactobacillus* spp.	2
Actinobacillus spp.	2	*Lactococcus garvieae*	2
Actinobaculum schaalii	2	*Leclercia adecarboxylata*	2
Actinomadura spp.	2	*Legionella* spp.	2

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Actinomyces spp.	2	*Leptospira* spp.	2
Aeromonas spp.	2	*Levinea malonatica*	2
Afipia spp.	2	*Liberobacter* spp.	2
Alcaligenes spp.	2	*Listeria* spp.	2
Alloiococcus otitis	2	*Mannheimia* spp.	2
Allomonas enterica	2	*Megasphaera elsdenii*	2
Alteromonas haloplanktis	2	*Melissococcus pluton*	2
Amycolata autotrophica	2	*Microvirgula aerodenitrificans*	2
Anaerobiospirillum spp.	2	*Mima polymorpha*	2
Anaerorhabdus furcosus	2	*Mitsuokella multacida*	2
Anaplasma spp. R41	2	*Mobiluncus* spp.	2
Arachnia spp.	2	*Moraxella* spp.	2
Arcanobacterium spp.	2	*Morganella morganii*	2
Arcobacter butzleri	2	*Morococcus cerebrosus*	2
Arizona spp.	2	*Mycobacterium africanum*	3 (V)
Arsenophonus nasoniae	2	*Mycobacterium avium/intracellulare*	2
Arthrobacter spp.	2	*Mycobacterium bovis*	3 (V)
Atopobium spp.	2	*Mycobacterium bovis* (BCG strain)	2
Bacillus anthracis	3 (V)	*Mycobacterium chelonae*	2
Bacillus cereus	2	*Mycobacterium fortuitum*	2
Bacteroides spp.	2	*Mycobacterium kansasii*	2
Balneatrix alpica	2	*Mycobacterium leprae*	3 (V)
Bartonella spp. (except *B. bacilliformis*)	2	*Mycobacterium malmoense*	3
Bartonella pertussis	2 (V)	*Mycobacterium marinum*	2
Bartonella bacilliformis	3	*Mycobacterium microti*	3*
Beneckea spp.	2	*Mycobacterium paratuberculosis*	2
Bergeyella zoohelcum	2	*Mycobacterium scrofulaceum*	2
Bifidobacterium dentium	2	*Mycobacterium simiae*	2
Bilophila wadsworthia	2	*Mycobacterium szulgai*	3
Bordetella spp.	2	*Mycobacterium tuberculosis*	3 (V)
Borrelia spp.	2	*Mycobacterium ulcerans*	3*
Brachyspira spp.	2	*Mycobacterium xenopi*	2
Brevibacterium spp.	2	*Mycoplasma* spp.	2
Brevinema andersonii	2	*Myroides* spp.	2
Brevundimonas diminuta	2	*Neisserria* spp.	2
Brucella spp.	3	*Neisseria meningitidis*	2 (V)
Burkholderia spp. (except *B. mallei*)	2	*Nocardia* spp.	2
Burkholderia mallei	3	*Nocardiopsis dassonvillei*	2
Burkholderia pseudomallei	3	*Ochrobactrum anthropi*	2
Calymmatobacterium granulomatis	2	*Oligella* spp.	2
Campylobacter spp.	2	*Orientia tsutsugamushi*	3
Capnocytophaga spp.	2	*Pasteurella* spp.	2
Cardiobacterium hominis	2	*Peptococcus* spp.	2
Catonella morbi	2	*Peptostreptococcus* spp.	2
Cedecea spp.	2	*Photobacterium* spp.	2
Cellulomonas hominis	2	*Plesiomonas shigelloides*	2
Centipeda periodontii	2	*Porphyromonas* spp.	2

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Chlamydia spp. (except *C. psittaci*, avian strains)	2	*Prevotella* spp.	2
Chlamydia psittaci (avian strains)	3	*Propionibacterium* spp.	2
Chlamydophila spp.	2	*Proteus* spp.	2
Chromobacterium violaceum	2	*Providencia* spp.	2
Chryseobacterium spp.	2	*Pseudomonas* spp.	2
Citrobacter spp.	2	*Pseudoramibacter alactolyticus*	2
Clavibacter michiganensis	2	*Psychrobacter phenylpyruvicus*	2
Clostridium spp.	2	*Rhodococcus* spp.	2
Clostridium botulinum	2 (T, V)	*Rickettsia* spp.	3
Clostridium tetani	2 (T, V)	*Riemerella columbina*	2
Clostridium diphtheria	2 (T, V)	*Rochalimaea* spp.	2
Comamonas terrigena	2	*Saccharopolyspora rectivirgula*	2
Corynebacterium spp.	2 (T, V)	*Salmonella* spp.	2
Coxiella burnetii	3	*Salmonella* Paratyphi A	3*
Curtobacterium flaccumfaciens	2	*Salmonella* Paratyphi B/java	3*
Dermatophilus congolensis	2	*Salmonella* Paratyphi C/Choleraesuis	3*
Dialister pneumosintes	2	*Salmonella typhi*	3* (V)
Dichelobacter nodosus	2	*Selenomonas* spp.	2
Dolosigranulum pigrum	2	*Serpulina* spp.	2
Edwardsiella spp.	2	*Serratia* spp.	2
Ehrlichia spp.	2	*Serratia liquefaciens*	2
Ehrlichia sennetsu	3	*Shewanella algae*	2
Eikenella corrodens	2	*Shigella* spp.	2
Empedobacter brevis	2	*Shigella dysenteriae* (type 1)	3 (T)
Enterobacter spp.	2	*Sphaerophorus necrophorus*	2
Enterococcus spp.	2	*Sphingobacterium* spp.	2
Eperythrozoon spp.	2	*Sphingomonas* spp.	2
Erwinia spp.	2	*Spiroplasma mirum*	2
Erysipelothrix spp.	2	*Sporichthya brevicatena*	2
Escherichia spp.	2	*Staphylococcus* spp.	2
Escherichia coli verocytotoxigenic strains (e.g. O157:H7)	3 (T)	*Staphylococcus aureus*	2 (T)
Eubacterium spp.	2	*Stenotrophomonas* spp.	2
Ewingella americana	2	*Streptobacillus* spp.	2
Facklamia hominis	2	*Streptococcus* spp.	2
Faenia rectivirgula	2	*Streptomyces somaliensis*	2
Falcivibrio spp.	2	*Sutterella wadsworthensis*	2
Elizabethkingia meningoseptica	2	*Suttonella indologenes*	2
Flexibacter spp.	2	*Tatlockia* spp.	2
Fluoribacter spp.	2	*Tatumella ptyseos*	2
Francisella tularensis	3 (Type A, V)	*Tissierella praeacuta*	2
Fusobacterium spp.	2	*Treponema* spp.	2
Gardnerella vaginalis	2	*Tsukamurella* spp.	2
Gemella spp.	2	*Turicella otitidis*	2
Globicatella sanguinis	2	*Ureaplasma* spp.	2

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Gordonia spp.	2	*Veillonella parvula*	2
Haemophilus spp.	2	*Vibrio* spp.	2
Hafnia alvei	2	*Vibrio cholera*	2 (T, V)
Hallella seregens	2	*Waddlia chondrophila*	2
Helcococcus spp.	2	Yersinia spp. (except *Y. pestis*)	2
Helicobacter spp.	2	*Yersinia pestis*	3 (V)
Johnsonella ignava	2		
Jonesia denitrificans	2		

** Routine diagnosis of M. tuberculosis infection based on microscopy, PCR and primary culture can be conducted under level 2 conditions, whereas culture manipulation for identification, drug-susceptibility testing and line probe assays on cultured isolates should be conducted under level 3 conditions.*

Table 4:

Prescribed risk groups for viruses. This list pertains primarily to human pathogens, but also includes other viruses that may be frequently used in experimentation (for example baculovirus for protein expression) or veterinary pathogens that will be likely processed in medical laboratories (for example BSL 4 agents) (*unassigned species refer to species not specifically listed here) (in alphabetic order per family).

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Adenoviridae (human, all types)	2	Lymphocytic choriomeningitis (non-neurotropic)	2
Alphaviridae:		Machupo	4
Chikungunya	3	Mopeia	3
Middelburg	3	Mobala	3
Ndumu	3	Oliveros	4
O'nyong-nyong	3	Paraná	4
Semliki forest	3	Pichinde	4
Shuni	3	Tamiami	4
Sindbis	3	Sabiá	4
Ross river	3	Putative *arenaviridae* species or unassigned species	4
Eastern equine encephalitis	4	*Astroviridae*	
Western equine encephalitis	4	*Baculoviridae*	2
Venezuelan equine encephalitis	4	*Birnaviridae*	2
Putative *alphaviridae* species or unassigned species*	3	*Bornaviridae*	2
Arenaviridae (mammarenaviruses):		*Bunyaviridae:*	
Amapari	2	Bunyamwera	3
Guanarito	4	California encephalitis	3
Flexal	3	Crimean-Congo Haemorrhagic fever	3**

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Ippy	3	Hanta (all species)	4
Junín	4	Nairobi sheep disease	3
Lassa	4	Rift Valley fever	3
Lujo	4	Sandfly fever	3
Lymphocytic choriomeningitis (neurotropic)	3	St Floris	3
		Putative *bunyaviridae* species or unassigned species (not Hanta)	3
Caliciviridae:		Japanese encephalitis	3
Hepatitis E	2	Kadam	3
Noro	2	Koutango	3
Sapo	2	Kokobera	3
Putative *caliciviridae* species or unassigned species	2	Kumlinge	4
Coronaviridae (human):	2	Kyasanur Forest	4
Severe acute respiratory syndrome-2 (SARS CoV2)	3*(V)		
Severe acute respiratory syndrome (SARS) (or SARS-like) Middle Eastern respiratory syndrome (MERS) (or MERS-like)	3	Langat	4
Putative *coronaviridae* species or unassigned species		2	Louping ill 4
Filoviridae:	Murray Valley encephalitis	3	
Ebola	4	Ntaya	3
Marburg	4	Negishi	3
Putative *filoviridae* species or unassigned species		4	San Perlita 3
Flaviviridae:	Spondweni	3	
Absettarov	4	Omsk	4
Bagaza	3	Uganda S	3
Banzi	3	Usutu	3
Bouboui	3	Powassan	3
Central European encephalitis	4	Rocio	3
Dengue	3	Russian spring-summer encephalitis	4
Hanzalova	4	St Louis encephalitis	3
Hepatitis C	2	Tick-borne encephalitis	4
Hepatitis G	3	Wesselsbron	3
Hypr	4	West Nile (including Kunjin)	3
Israel turkey meningoencephalitis	4	Yellow fever, wild type Vaccine strain	3(V) 2
Zika	3	Human metapneumo	2
Putative *flaviviridae* species or unassigned species	3	Hendra	4
Hepadnaviridae:		Measles	2 (V)
Hepatitis B	2 (V)	Menangle	2
Hepatitis D	2	Mumps	2 (V)

BIOLOGICAL AGENT	RISK GROUP	BIOLOGICAL AGENT	RISK GROUP
Herpesviridae:		Nipah	4
Cytomegalo	2	Parainfluenza	2
Epstein-Barr	2	Respiratory syncytial	2
Herpes simplex	2	Rinderpest	4
Herpes 6-8	2	Sendai	2
Herpes simiae (Herpes B)	4	*Parvoviridae:*	
Varicella-zoster	2 (V)	Parvovirus (Human B19)	2
Human B-lymphotropic	2	*Picornaviridae:*	
Pseudorabies	4	Acute haemorrhagic conjunctivitis	2
Putative *herpesviridae* species or unassigned species	2	Coxsackie	2
Orthomyxoviridae:		Echo	2
Influenza (human)	2 (V)	Entero	2
Avian influenza	3	Encephalomyocarditis	2
Dhori	3	Hepatitis A	2 (V)
Tick-borne orthomyxo	2	Polio (Type 1, 3) (Type 2)	2 (V) 3
Thogoto	3	*Poxviridae:*	2
Papovaviridae:		Buffalopox	2
JC/BK	2	Camelpox	2
Papilloma	2 (V)	Cowpox/Milker's nodule virus	2
Polyoma	2	Elephantpox	2
Simian virus 40 (SV40)	2	Horsepox	2
Paramyxoviridae:		Goatpox	2
Avian paramyxo	2		

BIOLOGICAL AGENT	RISK GROUP
Molluscum contagiosum	2
Monkeypox	4
Orf	2
Rabbitpox	2
Variola (minor and major)	4
Pseudopox	2
Yatapox (Tana- and Yabapox)	3
Reoviridae:	
Bluetongue	2
Colti	2
Orbi (including Colorado tick fever)	3
Reo	2
Rota	2 (V)
Putative *reoviridae* species or unassigned species	3
Retroviridae:	
Human immunodeficiency	3*
Human T-cell lymphotropic	3
Simian Immunodeficiency	3

BIOLOGICAL AGENT	RISK GROUP
Rhabdoviridae:	
Bovine ephemeral fever	3
Rabies	2 (V)
Rabies related (including new, unassigned species)	3
Vesicular stomatitis	3
Putative *rhabdoviridae* species or unassigned species	3
Togaviridae:	
See alphaviruses	
Rubella	2 (V)

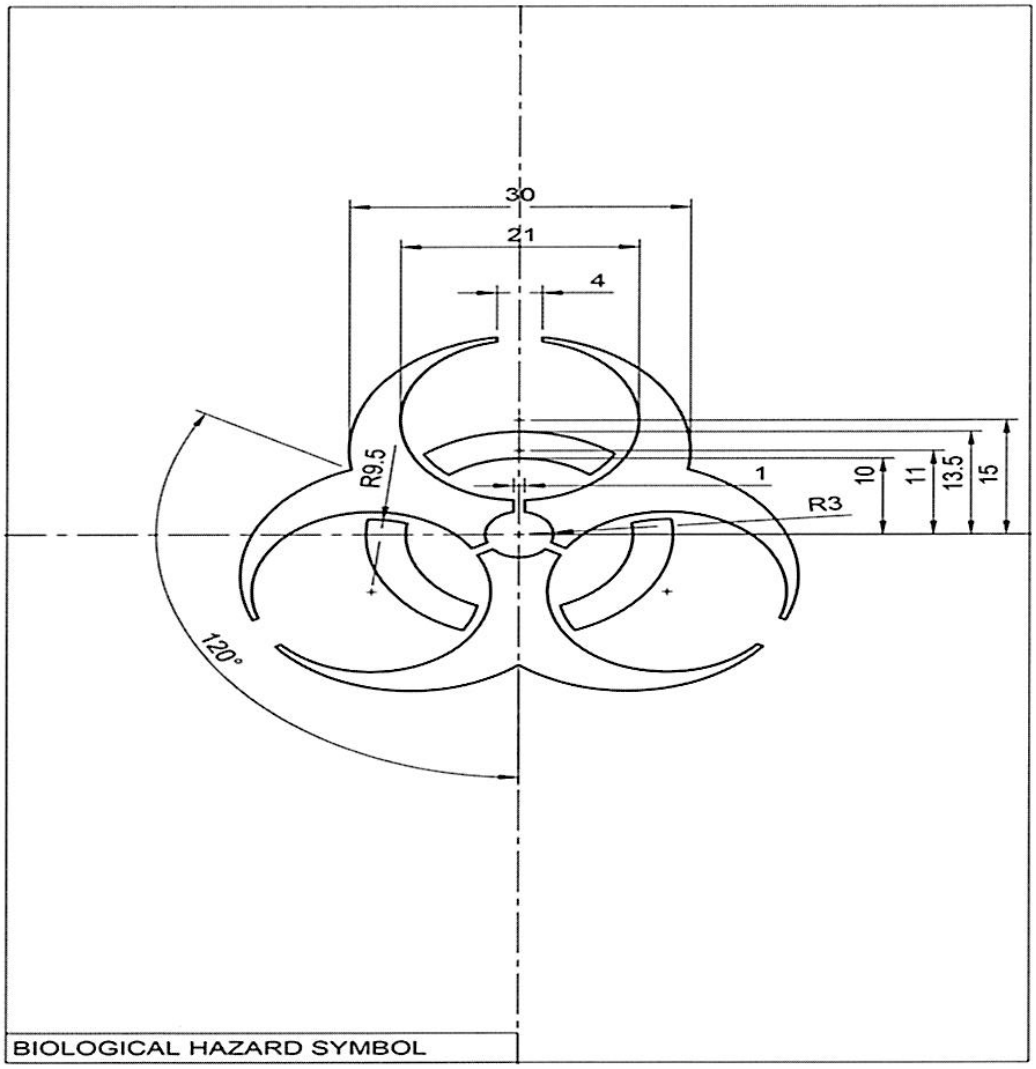
** Biosafety level 2 conditions are applicable to clinical specimens and non-culture procedures. Biosafety level 3 conditions are required for all culture procedures.*

*** Biosafety level 3 conditions are applicable to clinical specimens and non-culture procedures. Biosafety level 4 conditions are required for all culture procedures.*

ANNEXURE B

[Regulations 10(2)*(f)*, 11(4)*(b)* and 14*(b)*]

BIOHAZARD SIGN



Explanatory notes to the Regulations for Hazardous Biological Agents

The purpose of this document is to provide guidance to all employers and employees who are responsible for or concerned with the control and prevention of hazardous biological agent risks in the workplace.

This guide does not replace the Hazardous Biological Agents Regulations of 2021. It is intended to give practical insight into the applications of the Regulations. It should always be read in conjunction with the HBA regulations and the Occupational Health and Safety Act of 1993.

Wearing and use of protective clothing and respiratory protective equipment.

1. Where the HBA exposure cannot be prevented by other means, individual protection measures including PPE must be used. Workers have to be provided with appropriate protective clothing or other appropriate special clothing (ref: Directive 2000/54/EC of 18 September 2000 of the European Parliament on the protection of workers from risks related to exposure to biological agents at work). According to standard EN 14126, protective clothing against biological hazards is classified in accordance with leak tightness and is recognised by the suffix B, e.g. type 3-B.
2. In the selection of the protective clothing, one should note that the efficacy offered by the protection. The larger the number of the protection class, the better is the clothing for that specific property.
3. The user has to be able to perform all the movements, assume the working positions he or she will have when performing the work, and be able to use the working tools. In order to ease the work load, the clothing should be selected so that its donning and removal are easy. The removal has to be straightforward also since different kind of emergencies may arise, and the clothing may need to be taken off quickly. A poor fit of the clothing may result in reduced efficacy of the clothing.
4. If other PPE are needed together with the protective clothing, the efficacy of the entire PPE has to be ensured. Special care has to be taken to ensure that the wearer, who has to wear hearing protection will be protected and be able to communicate and hear warning signals. Wearer trials are needed to ensure the usability of the protective clothing. An evaluation of the maintainability of the clothing is also needed before the selection. The purchase of protective clothing should always be based on a risk assessment.
5. User training must include donning and removal of the protective clothing. Also, pre-use checks (e.g. checking for defects in ensemble assembly, garment and components, accessory, interface (closure, zippers), sufficiency of ventilation rate (gas-tight clothing)), safe work methods and monitoring the clothing while in use. The training should be carried out under realistic conditions and with actual equipment following the same procedures as in the real work task. In user training, the final check of size, fit, and compatibility must be investigated.

6. Decontamination permits the reuse of the types of protective clothing and equipment that are reusable. It can be made through physical or chemical methods to inactivate the contaminant or by using combination of these techniques. The decontamination procedure should not put other people or the environment at risk or damage the PPE. The effectiveness of decontamination should be checked e.g. visually searching for signs of discolorations, swelling, corrosive effects, stiffness or degradation of the material. Single use clothing is used when the contamination cannot be effectively removed from the clothing. Single use clothing is commonly used against microbiological agents.
7. The storage must be arranged to prevent damage to the protective clothing and equipment. Exposure to sunlight, dust, moisture, chemicals, extreme temperatures and mechanical damages e.g. folding must be prevented. Potentially contaminated protective clothing and equipment must be stored separately from unused protective clothing.
8. Regular inspection is necessary and should include inspection when the protective clothing and equipment is first received, inspection when it is selected for a particular task, inspected after use and previous maintenance. Records must be kept of all inspection procedures containing item identification number, date of inspection, person conducting the inspection, results, and unusual findings.
9. In all repair work, the manufacturer's instruction must be followed or the personal protective clothing and equipment must be sent to repair location authorised by the manufacturer.

The emergency preparedness plan

1. The development of an emergency preparedness plan should be based on all-hazards and assessments of risks, and of the available capacity to manage the priority risks. The objective of an emergency response plan is to provide practical ways to reduce the risk of employee's exposure to the disease in the workplace and to deal with any unforeseen situations. The plan should outline actions that employers and employees must take in the event of an emergency situation to ensure their health and safety. The plan should be communicated to all employees, contractors and suppliers. Everyone must be aware of what they should do – or not do – based on the plan, including their duties and responsibilities.
2. The plan must clearly outline the procedures to be followed in the event of an emergency. Such procedures should include:
    - risk assessment;
    - ways to alert employees;
    - Evacuation;
    - emergency response;
    - designated assembly locations;
    - contact people and their telephone numbers;

- first aid and medical assistance;
- clean-up and business resumption;
- reporting emergencies (reporting exposures, incidents, accidental release);
- employee training;
- exposure control procedures (engineering controls, employee training and workplace practices, personal protective equipment)
- ways of testing the plan (drills).

Duties of persons who might be exposed to HBA

1. In addition to the duties indicated in the regulation 5, employees' must report any deviations in the adherence to control measures put in place by the employer to mitigate exposure of a medical nature. This allows employees exposed to HBA to take responsibility to inform the employer of any challenges experienced with control measures put in place as opposed to employee not adhering to measures or being subjected to ill effects of measures without the employer's knowledge.

Competent person

1. Is a person who has, in respect of the work or task to be performed, the required knowledge, training and experience and, where applicable, qualifications specific to hazardous biological agents: Provided that, where appropriate qualifications and training are registered in terms of the National Qualifications Framework Act, 2008 (Act No. 67 of 2008), Skills Development Act, (Act No 97 of 1998) Chapter 6C as well as the Continuing Education and Training Act 16 of 2006, those qualifications and that training must be regarded as the required qualifications and training; and
2. is familiar with the Act and the applicable regulations made under the Act;
3. In general, for people to be competent in the health and safety aspects of their work, they will have a combination of the following requirements:
    - be qualified because of knowledge, training, and experience to do the assigned work;
    - have knowledge about the hazards and risks associated with the job or task to be performed (e.g., knows what hazards and risks are present);
    - know how to recognize, evaluate and control these hazards and risks (e.g., knows what precautions to take or controls to use/are in place for the different hazards or risks);
    - have the ability to work so that their health and safety and the health and safety of others is not in danger;
    - have knowledge of the laws and regulations that apply to the work being done.
4. The level of competence required will depend on the complexity of the situation and the task involved.

5. In all cases, it is the employer who should be able to justify the basis on which a worker is considered to be "adequately qualified", "suitably trained" or "sufficient experience". It is not possible to provide a general list of the exact knowledge, training and experience required. Every organisation must determine the requirements for each position or task to be done. Frequency of competency assessment will depend on the trends of risk outcomes (e.g. incidents), changes in technology or contraventions by the inspectorate which may indicate a need to increase the level of competency.

Confidentiality in relation to records

1. Confidentiality is the right of an individual to have personal, identifiable medical information kept private.
2. Health records are different to medical records in that they should not contain confidential medical information. Health records and medical records must therefore be kept separate to avoid any breaches of medical confidentiality. Any personal medical information should be kept in confidence and held by the occupational health professional responsible for the health surveillance programme. The doctor or nurse should only provide employers with information on fitness to work and any restrictions that may apply in that respect.
3. Medical records can only be released to third parties, such as the employer, in accordance with the Protection of Personal Information (POPI) act and constitution is also applicable.

Biological containment and medical fitness restrictions

1. Biocontainment is a component of biorisk management. The overall objective of biological containment is to confine a hazardous biological agent, thereby reducing the potential for exposure to workers or other persons, and the likelihood of accidental release to the environment.
2. A medical fitness certificate is a document completed by a qualified occupational health practitioner or an occupational medical practitioner. The employee fitness certificate is to ensure that the employee is fit for the task or job he or she is to perform according to his job specification

Safety equipment (Primary Barriers and Personal Protective Equipment)

1. The primary means of physical containment include the use of containment equipment including safety equipment includes biosafety cabinets (BSCs), personal protective equipment (PPE), enclosed containers, and other controls designed to remove or minimise exposures to hazardous biological materials.

2. Personal protective equipment is specialised clothing or equipment worn by workers to provide another layer of protection while handling hazardous biological agents. PPE may include respirators, gloves, safety glasses, lab coats or gowns, and other protective clothing. Biosafety Cabinets are primary containment devices designed to contain hazardous biological agents.

Facility Design and Construction (Secondary Barriers)

1. The facility design and physical features should provide primary barrier protection from the accidental release of hazardous biological agents outside the facility or to the environment. The design and construction of the facility contribute to the laboratory workers' protection. It also provides a barrier to protect people, animals, and the environment outside of the facility from hazardous biological agents that may be accidentally released from the facility. Small and large animal laboratories require additional design considerations to allow for feeding, housing, handling, and containment. These facilities are defined by Animal Biosafety Levels (ABSL) or Biosafety Level – Agriculture (BSL-Ag).

2. The use of specific containment equipment and procedures is determined through risk assessmentsconducted at individual institutions. Important differences exist between risk assessment criteria for public health and worker protection, and requirements for animal, wildlife, plant, and agricultural containment.

Control measures related to appropriate disinfection

Disinfectants must be appropriate for the relevant biological agents or hazards identified and must be used in accordance with the manufacturer's instructions to ensure adequate contact time. Always refer to the safety data sheets to ensure safe use of the product. The following documents will provide further information:

1. Practical Manual for Implementation of the National Infection Prevention and Control Strategic Framework, NDOH, March 2020.
2. COVID-19 Disease: Infection Prevention and Control Guidelines, NDOH, April 2020

Fit testing of Personal Protective Equipment

1. To ensure that a respirator is effective at reducing risk, it is important to conduct respirator fit testing in order to match the user according to their facial characteristics with the correct size and style of the respirator, especially for those working in high risk environments. Respirator fit testing can be either qualitative or quantitative and it is an important element of a respiratory protection programme. Fit testing forms a key part of achieving the objective filtration of hazardous biological agents in protecting the user.
2. Quantitative fit testing is defined in ANSI Z88.2-1992 as "A fit test that uses an instrument to measure the challenge agent inside and outside the respirator." This procedure is more precise than the qualitative fit test. Qualitative fit testing is defined in ANSI Z88.2-1992 as "a pass/fail test that relies on the subject's response to detect the challenge agent.' Since this test relies on the subjective response of the user, the reproducibility and accuracy may vary.
3. Fit testing should be performed at least once annually for workers who is required to wear a particular respirator per specific respirator brand and size. It is also recommended immediately if the user experiences a weight change of 10kg or more, has significant dental changes, or has reconstructive surgery or a facial disfigurement (scarring).

4. Fit testing should not be confused with a respirator fit check. ANSI Z88.2-1992 defines a fit check as "a test by the user to determine if the respirator is properly sealed to the face." It is recommended that a fit check be performed each time the respirator is donned or adjusted. The fit check is a quick method to determine if the respirator is properly sealed to the face. Under part A.6 of ANSI Z88.2-1992, procedures for conducting a fit check are described. The two most commonly performed methods are the positive and negative pressure tests.
5. The positive pressure check requires the user to cover the exhalation valve (if present in the case of elastomeric filtered respirators suggested in times of extremely constrained supply) of the tight-fitting respirator (placing the palm over the valve is usually sufficient) and exhale. If there is no indication of air escaping, the fit is considered satisfactory. The wearer then inhales. If no leakage is detected, the face piece seal is satisfactory.
6. For valved masks during a negative pressure fit check, the inlet opening of the respirator's cartridges or filters are covered prior to inhalation. Fit checking requires exposing the wearer to a challenge agent (isoamyl acetate, saccharin mist, irritant fume). If the wearer does not detect the challenge agent, the fit check is successful. This method is the only way respirators without valves can be effectively tested.

Reference: NDOH. Policy for the regulation of quality respiratory protective equipment (RPE) supply in healthcare. 2020.

Transport of HBA

In addition to the legislation mentioned in the regulations, the employer shall ensure that transport of biological materials internally or externally is in accordance with the organization's risk assessments. The employer shall address all applicable international, national and local transportation requirements and ensure that a system is in place to maintain appropriate controls on shipping packages and transport containers that contain biological materials in accordance with the organization's risk assessments.

INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS

For group 1 biological agents, including life-attenuated vaccines, no physical containment measures are prescribed below. For work with group 1 biological agents the principles of good occupational safety and hygiene should be observed.

Where hazardous biological agents can be transmitted through suspended aerosols over long distances they are classified as airborne spread in the table below. Mechanism of transmission including contact, droplet and vector spread are considered as non-airborne spread below.

	Containment measures	**Containment levels** **✚ Mandatory for animal containment facilities** **► Mandatory for industrial processes** **⊙ Mandatory for Suite Laboratories**			
		2	**3** **(HBA Not Airborne Spread)**	**3** **(HBA Airborne Spread)**	**4**
1.	Viable microorganisms should be contained in a system which physically separates the process from the environment (closed system).	►Yes	►Yes	►Yes	►Yes
2.	The workplace is to be separated from other areas of the same building.	No	Yes	Yes	Yes
3.	Exhaust and vent gasses, vapours or air should be treated so as to –	Minimise release	Prevent release	Prevent release	Prevent release
4.	Sample collection from a closed system, addition of materials to a closed system and transfer of viable microorganisms to another closed system, should be performed so as to –	►Minimise release	►Prevent release	►Prevent release	►Prevent release

5.	Bulk culture fluids should not be removed from the closed system unless the viable microorganisms have been –	►Inactivated by validated means	►Inactivated by validated chemical or physical means	►Inactivated by validated chemical or physical means	►Inactivated by validated chemical or physical means
6.	Equipment Seals should be designed so as to –	Minimise release	Prevent release	Prevent release	Prevent release
7.	Closed and potentially contaminated systems should be located within controlled areas –	Optional	Yes	Yes	Yes, and purpose-built
8.	biohazard signs should be posted (SANS 1186-1);	Yes	Yes	Yes	Yes
9.	personnel should wear protective clothing;	Yes, work clothing	Yes	Yes	Yes, a complete change ⊙ positive pressure protective suits
10.	decontamination and washing facilities should be provided for personnel (e.g. hand and eye wash, safety showers)	Yes	Yes	Yes ⊙ Suite decontaminatio n at containment perimeter	Yes ⊙ Suite decontaminatio n at containment perimeter
11.	personnel should shower before leaving the controlled area;	No	Optional	Optional ✚ Yes	Yes
12.	effluent from sinks and	No	Optional	✚ Yes	Yes

	showers should be collected and inactivated before release;				
13.	the controlled area should be adequately ventilated to minimise air contamination;	Optional	Optional	Yes	Yes
14.	the controlled area should be maintained at an air pressure negative to atmosphere;	No	Optional	Yes	Yes
15.	air supplied the controlled area should be HEPA filtered;	No	Optional	Optional ►Prevent backflow	Yes
16.	all air extracted from the controlled area should be HEPA filtered;	No	Optional	Yes	Yes (Double HEPA Filtered)
17.	the controlled area should be designed to contain spillage of the entire contents of closed system;	Optional	Yes	Yes	Yes
18.	the controlled area should be sealable to permit fumigation.	No	Optional	Optional ✚ Yes	Yes
19.	Effluent treatment before final discharge.	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means	Inactivated by validated physical means

20.	Access is to be restricted to authorised persons only.	Yes	Yes	Yes, via air-lock	Yes, via air-lock key procedure
21.	The workplace is to be sealable to permit disinfection.	No	Yes	Yes	Yes
22.	Specified disinfection procedure.	Yes	Yes	Yes	Yes
23.	The workplace is to be maintained at an air pressure negative to atmosphere.	No	Yes	Yes	Yes
24.	Efficient vector control, eg rodents and insects.	Recommended ✚ Yes	Recommended ✚ Yes	Yes	Yes
25.	Surfaces impervious to water and easy to clean.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes	Yes, for bench, floor, walls and ceiling
26.	Surfaces resistant to acids, alkalis, solvents, disinfectants.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes	Yes, for bench, floor, walls and ceiling
27.	Safe and secure storage of biological agents.	Yes	Yes	Yes	Yes, secure storage
28.	An observation window, or alternative, is to be present, so that occupants can be seen.	No	Yes	Yes	Yes
29.	A laboratory is to contain its own equipment.	No	Yes	Yes, so far as is reasonably practicable	Yes

30.	Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable containment.	Yes, where aerosol produced	Yes	Yes, where aerosol produced	Yes
31.	Incinerator for disposal of animal carcases.	Accessible service	Accessible service	Accessible service	Yes, on site

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