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OCCUPATIONAL HEALTH AND SAFETY ACT 85 OF 1993

REGULATIONS FOR HAZARDOUS BIOLOGICAL AGENTS

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

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1. Definitions

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

“biological agent” means any micro-organism, cell culture or human endoparasite, including any which have been genetically modified, which may cause an infection, allergy or toxicity, or otherwise create a hazard to human health;

“decontamination” means to remove, as far as is reasonably practicable, all inanimate objects by way of sweeping, cleaning, washing, ventilating or any other process aimed at removing the contaminant;

“diagnostic laboratory” means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials;

“disinfect” means to render non-viable virtually all recognised pathogenic micro-organisms, but not necessarily all microbial forms;

“engineering control measures” means control measures that remove or reduce the exposure of persons at the workplace by means of engineering methods;

“Facilities Regulations” means the Facilities Regulations promulgated by Government Notice No. R. 2362 of 5 October 1990 under section 43 of the Act;

“General Administrative Regulations” means the General Administrative Regulations promulgated by Government Notice No. R.1449 of 6 September 1996 under section 43 of the Act;

“HBA” means hazardous biological agents which are micro-organisms, including those that have been genetically modified, pathogens, cells, cell cultures and human endoparasites that have the potential to provoke an infection toxic effects, subdivided into the following groups:

- (a) Group 1 HBA are HBA that is unlikely to cause human disease;
- (b) Group 2 HBA are 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 are 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;
- (d) Group 4 HBA are HBA that causes 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.

“micro-organisms” means microbiological entities, cellular or non-cellular, capable of replication or of transferring genetic material;

“monitoring” means the planning and carrying out of the 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 hazardous biological agents, and which conforms to a standard, acceptable to the chief inspector;

“safety equipment” means a contrivance or a device designed to as far as possible try and prevent injury;

“standard precautions” means a synthesis of the major features of Universal Precautions (UP) and Body Substance Isolation (BSI) and applies to all persons coming into contact with potentially infected persons, animals or animal products and potentially contaminated blood and other body fluids in health care facilities or elsewhere 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 membranes; and
 - (v) tissues; and
- (b) are designed to reduce the risk of transmission of HBA from both recognised and unrecognised sources of infection in workplaces;

“the Act” means the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993)

2. Scope of application

- (1) Subject to subregulation (2), these Regulations shall apply to every employer and self-employed person at a workplace where -

- (a) HBA is deliberately produced, processed, used, handled, stored or transported, or
 - (b) an incident, for which an indicative list is given in Annexure A to these Regulation occurs that does not involve a deliberate intention to work with a HBA but may result in persons being exposed to HBA in the performance of his or her work.
- (2) Regulations 8, 14, 15, 16 and 17 shall not apply to an employer or self-employed person at a workplace where the exposure is restricted to a Group 1 HBA.

3. Classification of biological agents

- (1) The chief inspector may publish in the Government Gazette for the purpose of these regulations a document, which may be revised or reissued from time to time, entitled "Categorisation of Biological Agents according to hazard and categories of containment" (Annexure B) to these Regulation containing a list of biological agents together with the classification of each agent.
- (2) Where a biological agent has not been assigned a classification, the employer and self-employed person shall provisionally classify that agent in accordance with subregulation (3) below, having regard to the nature of the agent and the properties of which he or she may reasonably be expected to be aware.
- (3) When provisionally classifying a biological agent, the employer and self-employed person shall assign that agent to one of the groups and if there is according to its level of risk of infection doubt as to which of two alternative groups would be most appropriate, the HBA shall be assigned to the higher of the two.

4. Information and training

- (1) An employer shall, before any employee is exposed or may be exposed to HBA and after consultation with the health and safety committee established for that section of the workplace, ensure that the employee is adequately and comprehensively informed and trained, on both 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 herself 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 of safety equipment, facilities and engineering control measures provided;
 - (g) the necessity of medical surveillance;
 - (h) the safe working procedures regarding the use, handling, storage, labelling, and disposal of HBA at the workplace;
 - (i) the procedures to be followed in the event of exposure, spillage, leakage, injury or any similar emergency situation, and decontaminating or disinfecting contaminated areas; and
 - (j) the potential detrimental effect of exposure on the human reproductive process.
- (2) An employer or a self-employed person shall give instructions in writing of the procedures contemplated in subregulation (1)(i) to the drivers of vehicles carrying the HBA.
- (3) Every employer and every self-employed person shall ensure that he or she or any person who in any manner assists him or her in the carrying out or conducting of his or her business has the necessary information and has undergone sufficient training in order for him or her to identify the potential risks and the precautions that should be taken.

5. Duties of persons who might be exposed to HBA

- (1) Any person who is or might be exposed to HBA, shall obey any lawful instruction given by or on behalf of the employer of a self-employed person regarding-
 - (a) the prevention of an uncontrolled release of a HBA;
 - (b) the adherence to instructions regarding environmental and health practices, personal hygiene and good housekeeping;
 - (c) the wearing of personal protective equipment and clothing as prescribed by these Regulations;
 - (d) the wearing of personal samplers, when necessary, to measure personal exposure to airborne hazardous biological substances;
 - (e) the disposal of materials containing HBA and the disinfection and decontamination of any site contaminated by an HBA;
 - (f) the reporting during normal working hours for such medical examination or test as contemplated in regulation 8(1); and
 - (g) information and training as contemplated in regulation 4.
- (2) Any person shall immediately report to the employer, the health and safety representative or self-employed person any possible accidental exposure to a HBA at the workplace, and the employer or self-employed person shall ensure that such incident is investigated and recorded in accordance with regulation 8 of the General Administrative Regulations.

6. Risk assessment by employer or self-employed person

- (1) An employer or a self-employed person contemplated in regulation 2 shall, after consultation with the relevant health and safety representative or relevant health and safety committee, cause a risk assessment to be made and thereafter at intervals not exceeding two years, to determine if any person might have been exposed to a HBA.
- (2) An employer shall inform the relevant health and safety representative or health and safety committee in writing of the arrangements made for the assessment contemplated in subregulation (1), give them reasonable time to comment thereon and ensure that the results of the assessment are made available to the relevant health and safety representative or health and safety committee, which may comment thereon.
- (3) When making the assessment, the employer or self-employed person shall keep a record of the assessment and take into account matters such as-
 - (a) the nature and dose of the HBA to which an employee may be exposed and the suspected route of exposure;
 - (b) where the HBA might be present and in what physical form it is likely to be;
 - (c) the nature of the work, process and any reasonable deterioration in, or failure of, any control measures;
 - (d) what effects the HBA can have on an employee; and
 - (e) the period of exposure.
- (4) An employer or a self-employed person shall cause the risk assessment to be conducted on the basis of all available information as far as is reasonably practicable, including-
 - (a) classification of the HBA into the relevant risk group, according to its level of risk of infection;
 - (b) recommendations from the manufacturer, supplier or a competent person regarding the 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 or toxic effects that may result from the activities at the workplace; and
- (e) knowledge of diseases from which an employee might be suffering and which may be aggravated by conditions at the workplace.

(5) An employer shall review the assessment required by subregulation (1) forthwith if there -

- (a) is a reason to suspect that the previous assessment is no longer valid; or
- (b) has been a change in a process involving a HBA or in the methods, equipment or procedures in the use, handling, control or processing of HBA, and the provisions of subregulations (2), (3) and (4) shall apply.

7. Monitoring exposure at workplace

An employer shall ensure that the exposure of employees to a HBA is monitored in accordance with a suitable procedure that is standardised, sufficiently sensitive and of proven effectiveness in any case which it is

- (a) requisite for ensuring the maintenance of adequate control of the exposure of employees to HBA; or
- (b) otherwise requisite for protecting the health of employees.

8. Medical surveillance

(1) An employer shall ensure that an employee is under medical surveillance if-

- (a) the results of the assessment referred to in regulation 6 indicate that an employee might have been exposed to HBA;
- (b) the exposure of the employee to any HBA hazardous to his or her health is such that an identifiable disease or adverse effect to his or her health may be related to the exposure, there is a reasonable likelihood that the disease or effect may occur under the particular conditions of his or her work and there are techniques such as pre-clinical 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 medicine practitioner to ratify the appropriateness of such recommendation.

(2) In order to comply with the provisions of subregulation (1), the employer shall after extensive counselling and education offer the employee the opportunity to have-

- (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 any exposure exists or might exist, which comprised
 - (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 in cases where a HBA is known to be capable of causing persistent or latent infections which-
 - (i) in the light of present knowledge, are undiagnosable, until signs or symptoms develop;
 - (ii) can have particularly long incubation periods;
 - (iii) can result in an illness which is recurrent in spite of treatment; and

(iv) are known to have serious long-term effects.

(c) All tests and examinations as contemplated in paragraphs (a) and (b) shall be conducted according to a written medical protocol.

(3) The employer shall, in accordance with regulation 8 of the General Administrative Regulations, investigate and record all incidents that result or might result in infections or the death of an employee.

(4) All occupational health practitioners shall submit to the health and safety committee for approval a written protocol for procedures to be followed when dealing with abnormal results

9. Records

(1) An employer shall -

- (a) keep records of all assessments, monitoring results and medical surveillance reports required by regulations 6, 7 and 8 respectively: Provided that personal medical records shall be made available only to an occupational health practitioner;
- (b) subject to the provisions of paragraph (c), make the records contemplated in paragraph (a), excluding personal medical records, available for inspection by an inspector;
- (c) subject to the formal written consent of an employee, allow any person to peruse the records with respect to that particular employee;
- (d) make the records of all risk assessments and monitoring results available for perusal by the health and safety representative or health and safety committee;
- (e) keep all records of risk assessments and monitoring results for a minimum period of 40 years;
- (f) keep all medical surveillance records for a minimum period of 40 years, and if the employer ceases activities, all those records shall be handed over or forwarded by registered post to the relevant provincial director; and
- (g) keep a record of the examinations and tests carried out in terms of regulation 12(b) and of any repairs resulting from these investigations and tests, which records shall be kept for at least three years;

(2) A self-employed person shall keep records of all risk assessments for a minimum period of 40 years, and if the self-employed person ceases activities, all those records shall be handed over or forwarded by registered post to the relevant provincial director.

10. Control of exposure to HBA

(1) An employer and self-employed person shall ensure that the -

- (a) exposure of persons to HBA in the working environment is either prevented or, where this is not reasonably practicable, adequately controlled; and
- (b) standard precautions contained in Annexure C to these Regulation are implemented to reduce the risk of transmission of HBA from recognised and unrecognised sources of infection in a workplace.

(2) Where reasonably practicable, the employer or self-employed person shall control the exposure of persons to a HBA in the working environment by applying the following measures where appropriate:

- (a) Limiting the amount of HBA used which might contaminate the working environment;
- (b) limiting the number of employees who will be exposed or might be exposed;
- (c) introducing engineering control measures for the control of exposure, which may include the following:
 - (i) Process separation, automation or enclosure;

- (ii) the installation of local extraction ventilation systems to processes, equipment and tools for the control of emissions of an airborne HBA;
 - (iii) separate workplaces for different processes;
 - (iv) proper access control to prevent unauthorized access; and
 - (v) immediate personal or environmental disinfection.
- (d) introducing appropriate work procedures that employees must follow where materials are used, processes are carried out, or incidents might occur that could give rise to the exposure of an employee to HBA, and such procedures shall include written instructions to ensure-
- (i) the safe handling, use and disposal of HBA;
 - (ii) the proper use and maintenance of process machinery, installations, equipment, tools and local extraction and general ventilation systems;
 - (iii) the regular cleaning of machinery and work areas by vacuum cleaners fitted with a suitable filter that prevents contamination of the environment; and
 - (iv) that a system whereby changes in work procedures and processes that indicate the need for early corrective action can be readily identified;
- (e) ensuring that emissions to the atmosphere comply with the provisions of the Atmospheric Pollution Prevention Act, 1965 (Act No. 45 of 1965);
- (f) displaying the biohazard sign shown in Annexure D to these Regulation and other relevant warning signs; and
- (g) specifying procedures for taking, handling and processing samples that might contain HBA.

11. Personal protective equipment and facilities

- (1) If it is not reasonably practicable to ensure that the exposure of an employee is adequately controlled as contemplated in regulation 10, the employer shall in the case of-
- (a) airborne HBA, provide the employee with suitable respiratory protective equipment and protective clothing; and
 - (b) HBA that can be absorbed through the skin, provide the employee with suitable impermeable personal protective equipment.
- (2) Where respiratory protective equipment is provided, the employer shall ensure that-
- (a) the relevant equipment is capable of preventing the exposure to the HBA concerned;
 - (b) the relevant equipment is correctly selected and properly used;
 - (c) information, instructions, training and supervision which would be necessary with regard to the use of the equipment are known to the employees; and
 - (d) the equipment is kept in good condition and efficient working order.
- (3) An employer shall 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 sterilised prior to use;
 - (b) provide separate containers or storage facilities for personal 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 shall as far as is reasonably practicable, ensure that all contaminated 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 shall be taken to prevent contamination during handling, transporting and cleaning;
 - (b) where the clothing are sent off the premises to a contractor for cleaning purposes, the clothing shall be placed in impermeable, tightly sealed colour coded containers and such containers shall be clearly identified with a biohazard label as depicted in Annexure D to these Regulations as contaminated; and
 - (c) ensure 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 subregulation (4)(b), an employer shall ensure that no person removes dirty or contaminated personal protective equipment and personal protective clothing from the premises: Provided that where contaminated personal protective equipment has to be disposed of, it shall be treated as HBA waste as contemplated in regulation 17.
- (6) Subject to the provisions of the Facilities Regulations an employer shall, 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 HBA;
 - (b) two separate lockers labelled "protective clothing" and "personal clothing", respectively, and ensure that the clothing is kept separately in the locker concerned; and
 - (c) separate "clean" and "dirty" change rooms if the employer uses or processes HBA to the extent that the HBA could endanger the health of persons outside the workplace.

12. Maintenance of control measures, equipment and facilities

An employer shall ensure that-

- (a) all control measures, equipment and facilities provided in terms of regulations 10 and 11 are maintained in good working order; and
- (b) thorough examinations and tests of engineering control measures are carried out at intervals not exceeding 24 months by an approved HBA inspection authority or by a person whose ability to do the measurements, analysis and tests is verified by such an approved HBA inspection authority.

13. Prohibitions

- (1) No person shall -
 - (a) use compressed air to remove HBA from any surface or person;
 - (b) eat, drink, smoke, keep food or beverages or apply cosmetics in an HBA, workplace 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 protective or contaminated clothing and equipment.
- (2) An employer or self-employed person shall cause a notice to be posted at a conspicuous place prohibiting the provision of (a), (b) and (c).

14. Labelling, packaging, transporting and storage

An employer or self-employed person shall, as far as is reasonably practicable, take steps to ensure that-

- (a) all HBA 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 HBA are transported are clearly marked with a big-hazard sign as depicted in Annexure D to these Regulation and other relevant warning signs that identify the contents; and
- (c) the driver is trained in and equipped with a certificate in emergency procedures.

15. Special measures for health and veterinary isolation facilities

- (1) Subject to the provisions of regulation 6, every employer and self-employed person shall, in the case of health and veterinary isolation facilities, take into account-
 - (a) uncertainties about the presence of HBA in a patient or animal and the materials and specimens taken from them;
 - (b) the hazard represented by HBA known or suspected to be present in a patient, animal, materials and specimens taken from them; and
 - (c) the risks posed by the nature of the work.
- (2) An employer or self-employed person as contemplated in subregulation (1) shall ensure that the correct containment measures as indicated in Annexures C and E to these Regulation are selected for persons and animals in isolation facilities that are suspected of being infected with Group 3 or Group 4 HBA in order to minimise the risk of infecting others.

16. Special measures for laboratories, animal rooms and industrial processes

In the case of laboratories, animal rooms and industrial processes the employer or self-employed person contemplated in regulation 2 shall ensure that the containment measures required in-

- (a) Annexure C and E are implemented in laboratories and in rooms for laboratory animals, including diagnostic laboratories, and in rooms for laboratory animals that have been deliberately infected with Group 2, 3 and 4 HBA or where laboratory animals are suspected of carrying such agents;
- (b) Annexure C and E are implemented in laboratories handling materials in respect of which uncertainty prevails about the presence of HBA that may cause human disease, but that do not have as their aim working with HBA as such: Provided that the containment measures that are required for Group 3 or 4 are implemented where it is known or suspected that it is necessary; and
- (c) Annexure C and F are implemented where Group 2, 3 or 4 HBA are used in industrial processes: Provided that where it has not been possible to carry out a conclusive assessment of HBA, but where the use envisaged might involve a serious health risk for persons, such activities may be carried out only in workplaces where the containment measures correspond to the requirement for Group 3 HBA.

17. Disposal of HBA

An employer or self-employed person as contemplated in regulation 2 shall -

- (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) ensure that all fixtures and equipment including vehicles, re-usable 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 premises concerned;
- (d) ensure that all HBA waste that can cause exposure is disposed of only on sites specifically designated for this purpose in terms of the Environmental Conservation Act, 1989 (Act No. 73 of 1989), in such a manner that it does not cause a hazard inside or outside the site 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; and

- (f) ensure that if the services of a waste disposal contractor is used, a provision is incorporated into the contract stating that the contractor shall comply with the provisions of these Regulations.

18. Offences and penalties

Any person who contravenes or fails to comply with any provisions of regulation 3 to 17 shall 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.

19. Short title

These Regulations shall be called Regulations for Hazardous Biological Agents.

ANNEXURE A

[Regulation 2(1)(b)]

INDICATIVE LIST OF INCIDENTS

Incidents or exposure during work-

- (a) in a food production plant;
- (b) where there is contact with animals or products of animal origin;
- (c) in health care, including isolation and post-mortem units;
- (d) in clinical, veterinary and diagnostic laboratories;
- (e) in sewage purification installations; and
- (f) in a general workplace.

ANNEXURE B

HAZARDOUS BIOLOGICAL AGENTS GUIDELINES CATEGORISATION OF BIOLOGICAL AGENTS ACCORDING TO HAZARD AND CATEGORIES OF CONTAINMENT:

INTRODUCTION

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

2. Agents listed are categorised on the basis of their ability to cause disease by infection.

In allocating agents to a hazard Group in the list no account is taken of particular effects on those whose susceptibility to infection may be affected for one or other reason such as pre-existing disease, medication, compromised immunity, pregnancy or breastfeeding. Additional risk to such workers should be considered as part of the assessment required by the Hazardous Biological Agents.

Biological agents that have not been classified for inclusion into Group 2 to 4 in the list are not implicitly classified in Group 1.

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.

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

All viruses that have been isolated in humans and that have not been assessed and allocated to a Group 1 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.

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 for humans.

The list also gives a separate indication where biological agents are capable of causing allergic or toxic reactions, where an effective vaccine is available.

The following notations identify the indications:

A: Possible allergic effects;

T: Toxin production;

V: Effective vaccine available;

NIV: National Institute of Virology.

The selection of control measures for biological agents should take into account the fact that there is no exposure limits for them. Their ability to replicate and to infect at very small 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 could 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 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. All of the measures listed in Annexure E should be considered, and each should be used where and to the extent that-

(a) it is applicable; and

the assessment carried out under regulation 6 shows that it will lead to a non-negligible reduction in risk.

Not all the listed measures will be required in every case. The assessment may indicate, for example, that a specific mode of transmission and route of infection is required, a susceptible host is needed, there is low prevalence of the infection in that particular activity, and that illness is easily treatable, leading to rapid and complete recovery.

In such a case the risk would be relatively low and the control measures required less stringent. Another factor that will determine whether controls are to be applied will be the extent to which the activity involves the handling or deliberate use of a biological agent, or exposure is incidental to the main purpose of the work. However, the level of risk should be the principal consideration - if the risk is sufficiently high and can be reduced by some of the listed measures, they should be applied in full.

Certain special measures are required in health and veterinary care facilities, laboratories, animal rooms and industrial processes to ensure that biological agents are not transmitted to workers or outside the controlled area. For laboratories, animal rooms and industrial processes rules are laid down for the derivation of containment level from the hazard classification of the agent, or from what is suspected about the possible presence of an agent. Laboratories screening for an agent which falls in Group 3 and 4, but which is not ordinarily expected to be present (for example a microbiological laboratory in a food factory screening for salmonella, with the possibility of finding *Salmonella typhi*), should achieve at least containment level 2, but switch to the appropriate higher level if the agent is found and if work is to continue with it. In a laboratory that does not deliberately work with biological agents, but where the presence of agents calling for containment levels 3 or 4 is nevertheless known or suspected, those containment levels should be used.

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 which is non-hazardous to humans, but environmentally harmful, more stringent requirements should be followed.

Where the rules as 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 the risk is not increased by doing so.

Regulation 11 sets out additional requirements in respect of personal protective equipment used to protect employees against biological agents. The object 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 instructions 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 agent 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, it should also be set out on notices displayed in the workplace.

BACTERIA

Key:

A: allergic effects

T: Toxic effects

V: Vaccine available

NIV: National Institute of Virology

Biological Agent	Classification	Notes
<i>Acinetobacter calcoaceticus</i>	2	
<i>Acinetobacter lwoffii</i>	2	
<i>Actinobacillus actinomyces comitans</i>	2	
<i>Actinomyces madurae</i>	2	
<i>Actinomyces pelletieri</i>	2	
<i>Actinomyces spp</i>	2	
<i>Aeromonas hydrophila</i>	2	
<i>Alcaligenes spp</i>	2	
<i>Arcanobacterium haemolyticum</i> (<i>Corynebacterium haemolyticum</i>)	2	
<i>Arizona spp</i>	2	
<i>Bacillus anthracis</i>	3	V
<i>Bacillus cereus</i>	2	
<i>Bacteroides spp</i>	2	
<i>Bartonella spp</i> (<i>Rochalimaea spp</i>)	2	
<i>Bordetella bronchiseptica</i>	2	
<i>Bordetella parapertussis</i>	2	
<i>Bordetella pertussis</i>	2	V
<i>Borrelia burgdorferi</i>	2	
<i>Borrelia spp</i>	2	
<i>Brucella spp</i>	3	
<i>Burkholderia cepacia</i>	2	
<i>Burkholderia mallei</i> (<i>Pseudomonas mallei</i>)	3	
<i>Burkholderia pseudomallei</i> (<i>Pseudomonas pseudomallei</i>)	3	
<i>Burkholderia spp</i>	2	

<i>Campylobacter</i> spp	2	
<i>Cardiobacterium hominis</i>	2	
<i>Chlamydia pneumoniae</i>	2	
<i>Chlamydia psittaci</i> (non-avian strains)	2	
<i>Chlamydia psittaci</i> (avian strains)	3	
<i>Chlamydia trachomatis</i>	2	
<i>Clostridium botulinum</i>	2	T,V
<i>Clostridium perfringens</i>	2	
<i>Clostridium tetani</i>	2	T,V
<i>Clostridium</i> spp	2	
<i>Corynebacterium diphtheriae</i>	2	T,V
<i>Corynebacterium minutissimum</i>	2	
<i>Corynebacterium pseudo-tuberculosis</i>	2	
<i>Corynebacterium</i> spp	2	
<i>Coxiella burnetii</i>	3	
<i>Edwardsiella tarda</i>	2	
<i>Ehrlichia sennetsu</i> (<i>Rickettsia sennetsu</i>)	3	
<i>Ehrlichia</i> spp	3	
<i>Eikenella corrodens</i>	2	
<i>Enterobacter</i> spp	2	
<i>Enterococcus</i> spp	2	
<i>Erysipelothrix rhusiopathiae</i>	2	
<i>Escherichia coli</i> (with the exception of non-pathogenic strains)	2	
<i>Flavobacterium meningosepticum</i>	2	
<i>Fluorobacter bozemanianae</i> (formerly <i>Legionella</i>)	2	
<i>Francisella tularensis</i> (type A)	3	V
<i>Francisella tularensis</i> (Type B)	2	
<i>Fusobacterium</i> spp	2	
<i>Gardnerella vaginalis</i>	2	
<i>Haemophilus ducreyi</i>	2	
<i>Haemophilus influenzae</i>	2	
<i>Haemophilus</i> spp	2	
<i>Helicobacter pylori</i>	2	
<i>Klebsiella oxytoca</i>	2	
<i>Klebsiella pneumoniae</i>	2	
<i>Klebsiella</i> spp	2	
<i>Legionella pneumophila</i>	2	
<i>Legionella</i> spp	2	
<i>Leptospira interrogans</i> (all serovars)	2	
<i>Listeria ivanovii</i>	2	
<i>Listeria monocytogenes</i>	2	
<i>Moraxella catarrhalis</i>	2	
<i>Moraxella lacunata</i>	2	
<i>Morganella morganii</i>	2	
<i>Mycobacterium africanum</i>	3	V
<i>Mycobacterium avium/intracellulare</i>	3	
<i>Mycobacterium bovis</i> (BCG strain)	2	
<i>Mycobacterium bovis</i>	3	V
<i>Mycobacterium chelonae</i>	2	
<i>Mycobacterium fortuitum</i>	2	
<i>Mycobacterium kansasii</i>	3	
<i>Mycobacterium leprae</i>	3	V

<i>Mycobacterium malmoeense</i>	3	
<i>Mycobacterium marinum</i>	2	
<i>Mycobacterium microti</i>	3	
<i>Mycobacterium paratuberculosis</i>	2	
<i>Mycobacterium scrofulaceum</i>	3	
<i>Mycobacterium szulgai</i>	3	
<i>Mycobacterium simiae</i>	3	
<i>Mycobacterium tuberculosis</i>	3	V
<i>Mycobacterium ulcerans</i>	3	
<i>Mycobacterium xenopi</i>	3	
<i>Mycoplasma hominis</i>	2	
<i>Mycoplasma pneumoniae</i>	2	
<i>Neisseria gonorrhoeae</i>	2	
<i>Neisseria meningitidis</i>	2	V
<i>Nocardia spp</i>	2	
<i>Pasteurella spp</i>	2	
<i>Peptostreptococcus spp</i>	2	
<i>Plesiomonas shigelloides</i>	2	
<i>Porphyromonas spp</i>	2	
<i>Prevotella spp</i>	2	
<i>Proteus mirabilis</i>	2	
<i>Proteus penneri</i>	2	
<i>Proteus vulgaris</i>	2	
<i>Providencia spp</i>	2	
<i>Pseudomonas aeruginosa</i>	2	
<i>Pseudomonas mallei</i> - see <i>Burkholderia mallei</i>	3	
<i>Pseudomonas pseudomallei</i> - see <i>Burkholderia pseudomallei</i>	3	
<i>Rhodococcus equi</i>	2	
<i>Rickettsia spp</i>	3	
<i>Rochalimaea quintana</i> - see <i>Bartonella spp</i>	2	
<i>Rochalimaea spp</i> - see <i>Bartonella spp</i>	2	
<i>Salmonella arizonae</i>	2	
<i>Salmonella enteritidis</i>	2	
<i>Salmonella</i> (other serovars)	2	
<i>Salmonella paratyphi</i> A, B, C	2	
<i>Salmonella typhi</i>	3	V
<i>Salmonella typhimurium</i>	2	
<i>Serpulina spp</i>	2	
<i>Serratia liquefaciens</i>	2	
<i>Serratia marcescens</i>	2	
<i>Shigella boydii</i>	2	
<i>Shigella dysenteriae</i> (Type 1)	3	T
<i>Shigella dysenteriae</i> (other than Type 1)	2	
<i>Shigella flexneri</i>	2	
<i>Shigella sonnei</i>	2	
<i>Staphylococcus aureus</i>	2	T
<i>Stenotrophomonas maltophilia</i>	2	
<i>Streptobacillus moniliformis</i>	2	
<i>Streptococcus spp</i>	2	
<i>Treponema spp</i>	2	
<i>Ureaplasma urealyticum</i>	2	
<i>Vibrio cholerae</i> (including El Tor)	2	T,V
<i>Vibrio parahaemolyticus</i>	2	
<i>Vibrio spp</i>	2	
<i>Yersinia enterocolitica</i>	2	

<i>Yersinia pestis</i>	3	V
<i>Yersinia pseudotuberculosis</i>	2	
<i>Yersinia spp</i>	2	

VIRUSES

Biological Agent	Classification	Notes
Adenoviridae	2	
Alphavirus	2* (contact NIV)	V
Arenaviridae:		
Ippya	2	
Lassa fever	4	
Lymphocytic choriomeningitis	3	
Mobala	2	
Mopeia	3	
Astroviridae	2	
Bunyaviridae:		
Akabane	3	
Bunyamwera	2	
Germiston	3	
Hantaviruses [contact NIV]		
Nairoviruses:		
Bhanja	3	
Crimean/Congo haemorrhagic fever	4	
Hazara	2	
Phleboviruses:		
Rift Valley fever	3	V
Other Bunyaviridae known to be pathogenic	2* (contact NIV)	
Caliciviridae:		
Hepatitis E	3	
Norwalk	2	
Other Caliciviridae	2	
Coronaviridae	2	
Filoviridae:		
Ebola Reston (Siena)	4	
Ebola Sudan	4	
Ebola Zaire	4	
Ebola Ivory Coast	4	
Marburg	4	
Flaviviridae:		
Flaviviruses		
Dengue viruses Type 1-4	3	
Israel turkey meningitis	3	
Spondweni	3	
Wesselsbron	3	
West Nile fever	3	
Yellow fever	3	V
Hepatitis C group viruses:		
Hepatitis C	3	
Other Flaviviruses known to be pathogenic	2* [contact NIV]	
Hepadnaviridae:		
Hepatitis B	3	V

Hepatitis D(delta)	3	V
Herpesviridae:		
Cytomegalovirus	2	
Epstein-Barr virus	2	
Herpes simplex types 1 and 2	2	
Herpesvirus varicella-zoster	2	
Herpesvirus simiae (B virus)	3	
Human herpesvirus type 6 - HHV6	2	
Human herpesvirus type 7 - HHV7	2	
Orthomyxoviridae		
Influenza types A, B and C2	2	V (for A,B)
Tickborne orthomyxoviridae:		
Dhori and Thogoto	2	
Papovaviridae:		
BK and JC viruses	2	
Human papillomaviruses	2	
Paramyxoviridae		
Measles	2	V
Mumps	2	V
Newcastle disease	2	
Parainfluenza (Types 1 to 4)	2	
Respiratory syncytial virus	2	
Rinderpest	4	
Canine distemper		
Parvoviridae:		
Human parvovirus (B19)	2	
Picornaviridae		
Acute haemorrhagic conjunctivitis		
Virus (AHC)	2	
Coxsackie viruses	2	
Echoviruses	2	
Polioviruses	2	V
Rhinoviruses	2	
Hepatoviruses:		
Hepatitis A		
(Human enterovirus type 72)	2	V
Poxviridae:		
Buffalopox	2	
Cowpox	2	
Milker's nodes	2	
Molluscum contagiosum virus	2	
Monkeypox	3	V
Orf	2	
Vaccinia	2	
(including strains originally classified as rabbitpox virus)		
Variola(major and minor) (all strains, including "White virus")	4	V
Yatapox (Tana & Yaba)	2	
Reoviridae:		
Coltivirus	2	
Human rotaviruses	2	
Orbiviruses (includes - African horsesickness serogroup L	2	
- Blue tongue serogroup L		
Reoviruses	2	
Retroviridae:		

Human immunodeficiency viruses	3	
Human T-cell lymphotropic viruses (HTLV) types 1 and 2	3	
Simian immunodeficiency virus	3	
Rhabdoviridae:		
Lagos bat	3	
Duvenhage	3	
Makola	3	
Rabies	3	V
Togaviridae:		
Alphaviruses:		
Chikungunya	3	
Middelburg	2	
Ndumu	3	
O'nyong-nyong	2	
Semliki forest	3	
Sindbis	2	
Rubiviruses:		
Rubella	2	V
Toroviridae*	2	
Unclassified viruses:		
Blood-borne hepatitis viruses not yet identified	3	
Equine morbillivirus	3	
Unconventional agents:		
-Associated with:		
Creutzfeldt-Jakob disease	3	
Gerstmann-Strussler-Scheinker syndrome	3	
Kuru	3	
- Including strains isolated from cats and exotic species e.g. elephants, cheetahs.		
- Including strains originally classified as rabbitpox virus.		
- All strains including "whitepox virus".		

PARASITES

Biological Agent	Classification	Notes
<i>Acanthamoeba spp</i>	2	
<i>Ancylostoma duodenale</i>	2	
<i>Angiostrongylus cantonensis</i>	2	
<i>Angiostrongylus costaricensis</i>	2	
<i>Ascaris lumbricoides</i>	2	A
<i>Ascaris suum</i>	2	A
<i>Babesia divergens</i>	2	
<i>Babesia microti</i>	2	
<i>Balantidium coli</i>	2	
<i>Blastocystis homines</i>	2	
<i>Brugia spp</i>	2	
<i>Capillaria spp</i>	2	
<i>Clonorchis</i> - see <i>Opisthorchis</i>		
<i>Cryptosporidium spp</i>	2	
<i>Cyclospora cayetanensis</i>	2	
<i>Cyclospora spp</i>	2	
<i>Dientamoeba fragilis</i>	2	
<i>Dipetalonea</i> - see <i>Mansonella</i>	2	
<i>Diphyllobothrium latum</i>	2	
<i>Dracunculus medinensis</i>	2	

<i>Echinococcus granulosus</i>	3	
<i>Echinococcus multilocularis</i>	3	
<i>Echinococcus vogeli</i>	3	
<i>Entamoeba histolytica</i>	2	
<i>Enterobius vermicularis</i>	2	
<i>Enterocytozoon bieneusi</i>	2	
<i>Fasciola gigantica</i>	2	
<i>Fasciola hepatica</i>	2	
<i>Fasciolopsis buski</i>	2	
<i>Giardia lamblia</i> (<i>Giardia intestinalis</i>)	2	
<i>Hymenolepis diminuta</i>	2	
<i>Hymenolepis nana</i>	2	
<i>Isopora belli</i>	2	
<i>Leishmania brasiliensis</i>	3	
<i>Leishmania donovani</i>	3	
<i>Leishmania major</i>	2	
<i>Leishmania tropica</i>	2	
<i>Leishmania spp</i>	2	
<i>Loa loa</i>	2	
<i>Mansonella ozzardi</i>	2	
<i>Mansonella perstans</i>	2	
<i>Mansonella streptocerca</i>	2	
<i>Naegleria fowleri</i>	3	
<i>Necator americanus</i>	2	
<i>Onchocerca volvulus</i>	2	
<i>Opisthorchis sinensis</i> (<i>Clonorchis sinensis</i>)	2	
<i>Opisthorchis viverrini</i> (<i>Clonorchis viverrini</i>)	2	
<i>Opisthorchis felinus</i>	2	
<i>Opisthorchis spp</i>	2	
<i>Paragonimus spp</i>	2	
<i>Plasmodium falciparum</i>	3	
<i>Plasmodium spp</i> (human & simian)	2	
<i>Sarcocystis suihominis</i>	2	
<i>Schistosoma spp</i>	2	
<i>Strongyloides spp</i>	2	
<i>Taenia saginata</i>	2	
<i>Taenia solium</i>	3	
<i>Toxocara canis</i>	2	
<i>Toxocara cati</i>	2	
<i>Toxoplasma gondii</i>	2	
<i>Trichinella nativa</i>	2	
<i>Trichinella nelsoni</i>	2	
<i>Trichinella pseudospiralis</i>	2	
<i>Trichinella spiralis</i>	2	
<i>Trichomonas vaginalis</i>	2	
<i>Trichostrongylus orientalis</i>	2	
<i>Trichostrongylus spp</i>	2	
<i>Trichuris trichiura</i>	2	
<i>Trypanosoma brucei brucei</i>	2	
<i>Trypanosoma brucei gambiense</i>	2	
<i>Trypanosoma brucei rhodesiense</i>	3	
<i>Trypanosoma cruzi</i>	3	
<i>Trypanosoma rangeli</i>	2	
<i>Wuchereria bancrofti</i>	2	

ANNEXURE C

[Regulations 10(1)(b), 15(2) and 16(a), (b) and (c)]

PRECAUTIONS FOR WORKPLACES

FIVE MAIN ROUTES OF TRANSMISSION:

1. Contact

The most important route of transmission in a workplace is by-

- (a) direct contact with an infected or contaminated body surface or fluid; and
- (b) indirect contact via contact with an object previously contaminated with organisms from an infected person or animal.

2. Droplet Transmission

Droplets are generated during coughing, sneezing, talking and during procedures such as suctioning.

Droplets may carry organisms that can infect a new host if they are deposited on conjunctivae, nasal mucosa or the mouth.

Droplets do not remain suspended in the air.

Droplets do not travel more than one metre.

3. Airborne Transmission

Small particles (droplet nuclei) that remain suspended in air for long periods of time have a far greater potential for spreading disease than large droplets.

Few organisms are carried by this route, the most important being *Mycobacterium tuberculosis* and the viruses causing measles and chickenpox.

Prevention of spread requires an enclosed area with at least six air changes per hour, or an open window that provides adequate ventilation.

4. Common Vehicle Transmission

Transmission by items such as food, water, devices and equipment.

Normal hygienic practices and proper sterilisation or disinfection of equipment should make this type of spread a rare event in certain workplaces, e.g. hospitals.

5. Vector-Borne Transmission

Vectors such as mosquitoes, flies, fleas, etc. are hopefully not frequently encountered in workplaces as a cause of outbreaks.

In areas where there is a problem the appropriate measures, e.g. screens on windows and the use of insecticides must be instituted.

Two levels of precautions are recommended:

(a) Standard Precautions

These are applied at all times to all patients irrespective of their diagnosis. All body fluids (except sweat) are regarded as potentially infectious.

(b) Transmission-Based Precautions

These are applied when a specific infectious disease is diagnosed or suspected.

The route by which the disease is transmitted will determine the category of precautions that must be applied.

PRECAUTIONS

A. Administrative Controls

1. Education and Training
2. Adherence to precautions

B. Precautionary measures

1. Standard Precautions
2. Airborne Precautions
3. Droplet Precautions
4. Contact Precautions
5. Formidable Epidemic Disease (e.g. viral haemorrhagic fevers) Precautions

A. ADMINISTRATIVE CONTROLS

1. EDUCATION AND TRAINING

A system must be developed to ensure that hospital patients, employees, contractors and visitors are educated about:

- * the use of precautions.
- * their responsibility for adhering to the precautions.

2. ADHERENCE TO PRECAUTIONS

Periodic evaluation of adherence to precautions must be carried out. The findings are to be used to implement improvements.

B. PRECAUTIONARY MEASURES

1. STANDARD PRECAUTIONS

Standard precautions are used for the protection of all people exposed to HBA.

1.1 HAND WASHING

Wash hands after touching blood, body fluid, secretions, excretions and contaminated items, whether or not gloves are worn.

- * Wash hands (when working with patients):

immediately after gloves are removed.

between patient contact.

where indicated to prevent cross-contamination of different body sites.

- * Use plain (non-antimicrobial) soap for routine hand washing.

Use an antimicrobial agent or an alcohol hand disinfectant for specific circumstances (e.g. control of outbreaks or hyperendemic infections) as defined by the infection control program. (See contact precautions.)

1.2 GLOVES

Wear gloves (clean, intact non-sterile gloves are adequate) when touching blood, body fluid, secretions, excretions and contaminated items.

Put on clean intact gloves just before touching mucous membranes and non-intact skin.

- * Change and dispose of gloves between tasks and procedures

on the same person.

after contact with material that may contain high concentration of micro organisms.

- * Remove gloves promptly after use-

before touching non-contaminated items and environmental surfaces.

before attending to another person.

Wash hands immediately to avoid transfer of micro-organisms to other persons and environments.

1.3 MASK, EYE PROTECTION, FACE SHIELD

- * Wear a mask and eye protection or a face shield-

to protect mucous membranes of the eyes, nose and mouth.

during procedures and activities that are likely to generate splashes or sprays of blood or body fluid, secretions and excretions.

1.4 PROTECTIVE CLOTHING

Wear appropriate protective clothing to protect skin and to prevent soiling of clothing during procedures and activities that are likely to generate splashes or sprays of blood, body fluid, secretions and excretions.

Select protective clothing that is appropriate for the activity and amount of fluid likely to be encountered.

Remove soiled protective clothing as promptly as possible and consider it contaminated.

Wash hands immediately after removal of protective clothing to avoid transfer of micro-organisms to other people or environments.

1.5 PATIENT-CARE EQUIPMENT

Handle patient-care equipment soiled with blood, body fluids, secretions and excretions in a manner that prevents skin and mucous membrane exposures.

contamination of clothing.

transfer of micro-organisms to other environments.

- * Ensure that reusable equipment is not used for the care of another patient until -
it has been cleaned.

it has been reprocessed appropriately.

- * Ensure that-

sufficient disposable syringes and needles are at all times available for use.

provision is made for their safe disposal.

1.6 ENVIRONMENTAL CONTROL

Ensure that adequate procedures are in place for routine care, cleaning and disinfection of environmental surfaces, and other frequently used or potentially contaminated surfaces.

Disinfection of environmental surfaces is not routinely required. Simple cleaning is adequate unless there has been significant soiling by potentially infectious body fluids.

1.7 LINEN

Process, handle and transport used linen contaminated with blood, body fluid, secretion and excretions in colour coded, impervious containers and all, possible measures should be observed to prevent-

skin and mucous membrane exposure.

contamination of clothing.

transfer of micro-organisms to other persons and environments.

1.8 OCCUPATIONAL HEALTH

1.8.1 Injuries

- * Take care to prevent injuries when

using needles, scalpels and other sharp instruments or devices.

handling sharp instruments after a procedure.

cleaning instruments.

disposing of used needles.

Never

Re-cap needles or manipulate them using both hands, if it is absolutely necessary to resheath a needle. A variety of mechanical devices that are commercially available must be used.

Use any other technique that involves directing the point of a needle toward any part of the body.

Do not

- * Remove used needles from disposable syringes by hand.
- * Bend or break or otherwise manipulate needles by hand.

Do

Place used disposable syringes and needles, scalpel blades and other sharp objects in appropriate puncture-proof containers that are as close as possible to the area in which the procedure is carried out.

- * Transport them safely to the disposal area.

1.8.2 Resuscitation

Use mouthpieces, resuscitation bags or other ventilation devices as an alternative method to mouth-to-mouth resuscitation in areas where the need for resuscitation is predictable.

1.9 PATIENT PLACEMENT

- * Place in an isolation area (single or private room) patients who-

contaminate the environment.

do not or cannot be expected to assist in maintaining appropriate personal hygiene or environmental control.

If an isolation area is not available, consult infection control professionals regarding patient placement or other alternatives.

2. AIRBORNE PRECAUTIONS

In addition to Standard Precautions, use Airborne Precautions for-

patients known or suspected of being infected with micro-organisms transmitted by airborne droplet nuclei, i.e. small particle residue of evaporated droplets containing micro-organisms that-

remain suspended in the air;

can be widely dispersed by air currents within a room or over a long distance.

2.1 PATIENT PLACEMENT

Ideally place patients in a private room that has -

- * monitored negative air pressure in relation to the surrounding areas.
- * 6-12 air changes per hour.

Appropriate discharge of air outdoors or monitored high-efficiency filtration of room air before the air is circulated to other areas of the hospital.

Where this is not possible

- * Use -

a room with a simple extraction fan providing at least six air changes per hour.

a room with an open window, and adequate ventilation.

When an isolation area is not available, place the patient in a room with another patient who has active infection with the same micro-organism, and no other infection, unless otherwise recommended.

When a private room is not available and cohorting is not desirable, consultation with infection control professionals is advised before patient placement.

- * Keep the patient in the room and keep the door closed.

2.2 RESPIRATORY PROTECTION

Tuberculosis:

Respiratory protection may be worn when entering the room of a patient known or suspected to have infectious pulmonary tuberculosis.

- * Measles (rubeola) and chickenpox (varicella).

Susceptible persons should not enter the room of patients known or suspected of having measles or varicella if other immune caregivers are available.

If susceptible persons must enter the room they must wear respiratory protection.

- * Persons immune to measles or varicella need not wear respiratory protection.

2.3 PATIENT TRANSPORT

Movement and transport of the patient should be kept to a minimum.

If transport or movement is necessary, the patient must wear a surgical mask to minimise dispersal of droplet nuclei.

4. ADDITIONAL PRECAUTIONS FOR PREVENTING TRANSMISSION OF TUBERCULOSIS

- * Respirators -

must be worn by all who enter the room.

must be able to filter particles 1 micron or less in size with a filter efficiency of 95%.

- * Effective treatment of the patient

- * Isolation-

there is significant clinical improvement in the patient's condition.

ideally, two negative acid fast bacilli smears must be obtained.

ideally a smear positive patient will require isolation for a minimum of two weeks.

3. DROPLET PRECAUTIONS

In addition to Standard Precautions, use Droplet Precautions for patients known or suspected to be infected with micro-organisms transmitted by droplets (large particle droplets that can be generated during coughing, sneezing, talking or respiratory therapy).

3.1 PATIENT PLACEMENT

Place the patient in an isolation area, e.g. private or single room

When a private room is not available and cohorting is not achievable, maintain spatial separation of at least one metre between the infected patient and other patients and visitors.

Additional ventilation measures are not necessary and the door may remain open.

3.2 MASKS

Wear a mask when working within one metre of the patient. However, logistically some hospitals may want to implement the wearing of a mask to enter the room.

3.3 PATIENT TRANSPORT

Movement and transport of the patient from the room should be kept to a minimum. If transport or movement is necessary, minimise dispersal of droplets by masking the patient.

4. CONTACT PRECAUTIONS

In addition to Standard Precautions use Contact Precautions for-

specified patients known or suspected to be infected or colonised with epidemiologically important micro-organisms that can be transmitted by direct contact with the patient (hand to skin contact occurs when performing patient care activities that required touching the patient's dry skin) - or indirect contact (touching) environmental surfaces or patient care items in the patient's environment.

4.1 PATIENT PLACEMENT

Place the patient in an isolation area, e.g. private or single room

When a private room is not available, place the patient in a room with patients who have active disease with the same microorganism but no other infection (cohorting).

When neither a private room nor cohorting is achievable, consider the epidemiology of the microorganism and the patient population when determining patient placement.

Consultation with infection control professionals is advisable before patient placement.

4.2 GLOVES AND HAND WASHING

In addition to wearing gloves and washing hands as outlined in Standard Precautions-

- * Wear clean gloves when entering the room.
- * Change gloves after having contact with infective material.
- * Remove gloves before leaving the patient's environment.

Wash hands immediately after glove removal with an antimicrobial or an alcohol hand rub.

Ensure that hands do not touch potentially contaminated environmental surfaces or items in the patient's room to avoid transfer of micro-organisms to other patients or the environment.

4.3 PROTECTIVE CLOTHING

In addition to wearing a gown or plastic apron as outlined in Standard Precautions-

- * Wear a clean, non-sterile gown and/or plastic apron as appropriate-

when entering a room where soiling of clothing is anticipated.

following substantial contact with the patient.

following contact with environmental surfaces or items in the patient's room.

if the patient is incontinent or has diarrhoea, an ileostomy or a colostomy.

where wound drainage is not contained by a dressing.

- * Remove the gown or plastic apron before leaving the patient's environment.

After gown or plastic apron removal, ensure that clothing does not make contact with potentially contaminated environmental surfaces to avoid transfer of microorganisms to other patients or environments.

4.4 PATIENT TRANSPORT

- * Movement and transport of the patient from the room should be minimised.

Ensure that precautions are maintained to minimize the risk of transmission of micro-organisms to other patients and contamination of environmental surfaces or equipment.

4.5 PATIENT-CARE EQUIPMENT

Where possible dedicate the use of non-critical patient-care equipment to a single patient (or cohort of patients infected or colonised with the pathogen requiring precautions).

Avoid sharing equipment between patients

If the use of common equipment or items is unavoidable, then these must be cleaned and disinfected before use for another patient.

ADDITIONAL PRECAUTIONS FOR PREVENTING THE SPREAD OF MULTI-DRUG-RESISTANT MICRO-ORGANISMS

- * Limit antibiotic use and prevent misuse.
- * Educate staff.

Detect multi-drug-resistant micro-organisms early by laboratory and infection control surveillance.

- * Consult an Infection Control Practitioner regarding further management.

5. FORMIDABLE EPIDEMIC DISEASE (FED) ISOLATION

Standard and contact precautions plus additional items such as respirators, visors, water repellent gowns and boots, caps, double gloves are required.

Standard precautions are adequate during the non-haemorrhagic phase in cases of haemorrhagic fevers, such as Ebola and Congo-Crimean haemorrhagic fever.

5.1 ISOLATION AREA

This may be a dedicated viral haemorrhagic fever (VHF) unit or a dedicated sideward or private room, preferably with an anteroom.

- * The door must be kept closed, and strict access control must be implemented.

5.2. GOWNS

- * Impervious disposable gowns must be worn over a theatre scrub suit.

5.3 GLOVES

- * Two pairs are worn, the one pair on top of the other.

Sterile latex gloves are used because of the thicker quality and longer non-roll cuff.

5.4 BOOTS

- * Impervious boots or overshoes are worn in the isolation room.

They must be -

high enough to cover the area of skin below the trouser legs.

strong enough to withstand wear and tear.

5.5 THEATRE CAPS/GOGGLES OR VISORS

- * Worn inside the isolation room.
- * Theatre caps.

A theatre cap worn with a visor providing full protection of the head and neck is preferred.

5.6 MASKS AND RESPIRATORS

- * Masks - good quality, high-filtration respirators are necessary.

5.7 Formidable Epidemic Disease Pack (FED Pack)

A FED pack contains all the isolation gear necessary, must be safely stored in an area not accessible to unauthorised persons. The FED pack must be immediately replenished after every usage.

This pack is available immediately, is portable and is used until the patient is diagnosed or transferred to an isolation unit or an infectious diseases hospital. The pack is kept in a box or in a trolley. The box (or trolley) is distinctive and kept in an easily accessible place. The pack contents are replenished as required by the infection control staff.

Instruction posters provide instructions for untrained personnel until infection control professionals arrive to provide guidance and instruction in VHF procedures.

Contents -

- * Sterile latex gloves of varying sizes.
- * Disposable impermeable gowns.
- * Goggles or visors.
- * Masks.
- * Shoe covers (half-leggings).

‡Theatre caps.

Blood tubes, labels, big-hazard plastic specimen bags, a rigid, walled container for transportation of specimens and big-hazard stickers.

- * Masking tape used for-

sealing boxes of refuse.

fixing instruction posters to the wall.

securing tops of plastic shoe covers.

- * Plastic refuse bags for contaminated refuse.
- * Autoclavable bags for non-disposable items.
- * Clear plastic bags.
- * Sodium-hypochlorite sachets of powder (NaOCl) and liquid 1% hypochlorite.
- * Plastic-covered instruction posters containing detailed instructions on how to-

put on isolation gear.

undress safely.

collect and handle specimens safely.

mix disinfectants.

disinfect and handle contaminated equipment.

dispose of linen and refuse.

deal with a blood spill.

The infection control professionals must ensure that staff follows correct procedures and that equipment is available for disposal of refuse.

All refuse bags are colour coded, double bagged and are placed into cardboard boxes.

- * Refuse bags are sealed and labelled with big-hazard stickers and tape.
- * Containers are escorted to the incinerator.
- * Their immediate incineration is ensured.

5.9 Transporting VHF specimens

These specimens require a special container and packaging:

- * The specimen is placed in a big-hazard bag.

- * The patient's label is placed in the outer pouch.

The specimen is then wrapped in absorbent material and placed in an unbreakable screw-top container.

The container is labelled with a big-hazard sticker and the destination (name of the receiving laboratory).

- * It is preferably delivered by hand.

If the specimen has to be posted or sent by courier a second unbreakable container is used and labelled accordingly.

5.10 Management of soiled linen, refuse and equipment

Bedding

All bedding used is either disposable or condemned linen that is subsequently incinerated.

- * Mattresses must be covered with durable plastic covers

The covers are disposable.

If the mattress becomes soiled with blood or body substance it must be destroyed.

Linen and Refuse

- * All linen (disposable and condemned) is placed into plastic refuse bags

The person inside the cubicle or room takes the sealed bag and places it in a second bag held by another person outside the room.

This bag is then sealed and sent for incineration.

Terminal disinfection of equipment

- * All equipment is washed down well with a hypochlorite-detergent.
- * It is then dried, using a paper towel.

If the equipment is not autoclavable, it must be wrapped in clear plastic bags, then-

double bagged into a clean bag held by a second person outside the cubicle.

clearly labelled with the contents and a biohazard sticker attached.

sent to Central Sterilizing Service Department (CSSD) for ethylene oxide gas sterilization.

- * Autoclavable items must be placed in Asepto type bags -

labelled as above.

sealed in clean plastic bags for transport to CSSD.

autoclavable plastic bags may be used if available.

Furniture or environment

All furniture, walls and floors are washed down well with hypochlorite-detergent.

TABLE I

Abbreviations used

Type of precautions:

Standard precautions (S) are applied at all times in addition to either:

A Airborne

C Contact

D Droplet

VHF Viral haemorrhagic fever

Duration of precautions:

CN until antibiotics are discontinued and culture-negative

DH duration of hospitalization

DI duration of illness (with wound lesions, DI means until they stop draining)

U until time specified in hours (hrs) after initiation of effective therapy.

F footnote number under type

Meaning of superscript number (i.e. ^{FE} Standard precaution is applied at all times)

^a No dressing, or dressing does not contain drainage adequately.

^b Dressing covers and contains drainage adequately.

^c Also see syndromes or conditions listed in Table 2.

^d Install screens in windows and doors in endemic areas.

^e Maintain precautions until all lesions are crusted. The average incubation period for varicella is 10-to 16 days, with a range of 10 to 21 days. After exposure, use varicella-zoster immune globulin (VZIG) when appropriate and discharge susceptible patients if possible. Place exposed susceptible patients on Airborne Precautions beginning 10 days after exposure and continuing until 21 days after last exposure (up to 28 days if VZIG has been given). Susceptible persons should not enter the room of the isolated patient on precautions if other immune caregivers are available.

^f Isolate all infants on precautions during any admission until one year of age, unless nasopharyngeal and urine cultures are negative for virus after age three months of age.

^g Additional special precautions are necessary for handling and decontamination of blood, body fluids and tissues, and contaminated items from patients with confirmed or suspected disease.

^h Until two cultures are taken at least 24 hours apart are negative.

ⁱ Consult the National Institute of Virology for guidelines issued by provincial health departments. Use Contact Precautions for diapered or incontinent children less than six years of age for duration of illness. Maintain precautions in infants and children under three years of age for duration of hospitalisation; in children three to fourteen years of age, until two weeks after onset of symptoms; and others, until one week after onset of symptoms. For infants delivered vaginally or by Caesarean section and if mother has active infection and membranes have been ruptured for more than four to six hours.

^m Persons susceptible to varicella are also at risk for developing varicella when exposed to patients with zoster lesions; therefore, susceptibles should not enter the room if other immune caregivers are available.

ⁿ Many hospitals encounter logistic difficulties and suspected or diagnosed limitations when admitting multiple patients with suspected influenza during community outbreaks. If sufficient private rooms are unavailable, consider cohorting patients or, at the very least, avoid room sharing with high-risk patients.

^o Patients should be examined for evidence of current (active) pulmonary tuberculosis. If evidence exists, additional precautions are necessary (see tuberculosis 3).

^p Resistant bacteria judged by the infection control program, based on current state, regional or national recommendations, to be of special clinical and epidemiologic significance.

For nine days after onset of swelling.

Maintain precautions for duration of hospitalisation when chronic disease occurs in an immunodeficient patient. For patients with a transient plastic crisis or red cell crisis, maintain precautions for seven days.

Maintain precautions for five days after patient is placed on effective therapy.

Avoid cohorting or placement in the same room with a cystic fibrosis (CF) patient who is not infected or colonised with *B. cepacia*. Persons with CF who visit or provide care and are not infected or colonised with *B. cepacia* may elect to wear a mask when within one metre of a colonised or infected patient.

Avoid placement in the same room with an immunocompromised patient.

Until seven days after onset of rash.

Discontinue precautions only when TB patient is improving clinically and has three consecutive negative sputum smears collected on different days or TB is ruled out.

Maintain all precautions until the patient stops bleeding.

TABLE II

CLINICAL SYNDROMES OR CONDITIONS WARRANTING ADDITIONAL EMPIRIC PRECAUTIONS TO PREVENT TRANSMISSION OR EPIDEMIOLOGICALLY IMPORTANT PATHOGENS PENDING CONFIRMATION OF DIAGNOSIS*

Clinical Syndrome or Condition**	Potential Pathogens	Empiric Precautions
Diarrhoea		
Acute diarrhoea-like infections: Contact cause in an incontinent or diapered patient.	Enteric pathogens***	Contact
Diarrhoea in an adult with a history of recent antibiotic use Rash or exanthems, generally, etiology unknown	<i>Clostridium</i>	Droplet
Petechial or ecchymotic with fever	<i>Neisseria meningitidis</i>	Droplet
Vesicular	Varicella	Airborne and contact
Maculopapular with coryza and fever	Measles	Airborne
Respiratory infections		
Cough/fever/upper lobe pulmonary infiltrate in an HIV-negative patient or a patient at low risk for HIV infection	<i>Mycobacterium tuberculosis</i>	Airborne
Cough/fever/pulmonary infiltrate in any lung location in an HIV-infected patient or a patient at high risk of HIV infection	<i>Mycobacterium tuberculosis</i>	Airborne
Paroxysmal or severe persistent cough during periods of pertussis activity	<i>Bordetella pertussis</i>	Droplet
Particularly bronchiolitis and croup in infants and young children	Respiratory syncytial virus or parainfluenza virus	Contact
Risk of multidrug-resistant micro-organisms		
History of infection or colonisation with multidrug-resistant organisms	Resistant bacteria	Contact

Skin and wound if urinary tract infection in a patient with a recent hospital or nursing home stay in a facility where multidrug-resistant organisms are prevalent Resistant bacteria Contact

Skin and wound infection

Abscess or draining wound that can not be covered *Staphylococcus aureus*, Group A *streptococcus* Contact

Infection control professionals are encouraged to modify or adapt this table according to local conditions. To ensure that appropriate empiric precautions are always implemented, hospitals must have systems in place to evaluate patients routinely according to these criteria as part of their pre-admission care.

Patients with the syndromes or conditions listed below may present atypical signs or symptoms (e.g. pertussis in neonates and adults may not have paroxysmal or severe cough). The clinician's index of suspicion should be guided by the prevalence of specific conditions in the community, as well as clinical judgement.

The organisms listed under "Potential Pathogens" are not intended to represent the complete, or even the most likely, diagnosis, but rather possible etiologic agents that require additional precautions beyond Standard Precautions until they can be ruled out.

SYNOPSIS OF TYPES OF PRECAUTIONS AND PATIENTS REQUIRING THE PRECAUTIONS^a

Abbreviations used in list of precautions.

See Table I for a complete list of infections requiring precautions, including appropriate footnotes.

Certain infections require more than one type of precaution.

See "Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities" available from the Department of Health.

1. Standard Precautions

Use Standard Precautions for the care of all patients.

2. Airborne Precautions

In addition to Standard Precautions, use Airborne Precautions for patients known or suspected to have serious illnesses transmitted by the airborne droplet nuclei. Examples of such illnesses include-

Measles

Varicella (including disseminated zoster)^β

Tuberculosis^Γ

3. Droplet Precautions

In addition to Standard Precautions, use Droplet Precautions for patients known or suspected to have illnesses transmitted by large-particle droplet.

Examples of such illnesses include:

Invasive *Haemophilus influenzae* Type B disease, including meningitis, pneumonia, epiglottitis and sepsis.

Invasive *Neisseria meningitidis* disease, including meningitis, pneumonia and sepsis.

Other serious bacterial respiratory infections spread by droplet transmission, including:

Diphtheria (pharyngeal)

Mycoplasma pneumonia

Pertussis

Pneumonic plague

Streptococcal pharyngitis, pneumonia or scarlet fever in infants and young children

Serious viral infections spread by droplet transmission, including-

Adenovirus β

Influenza

Mumps

Parvovirus B12

Rubella

4. Contact Precautions

In addition to Standard Precautions, use Contact Precautions for patients known or suspected to have serious illnesses easily transmitted by direct contact or by contact with items in the patient's environment. Examples of such illnesses include-

Gastrointestinal, respiratory, skin or wound infections or colonisation with multidrugresistant bacteria judged by the infection control program, based on current state, regional, or national recommendations, to be of special clinical and epidemiologic significance.

Enteric infections with a low infectious dose or prolonged environmental survival, including:

Clostridium difficile

For diapered or incontinent patients: enterohaemorrhagic *Escherichia coli* 0157: H7, Shigella, Hepatitis A or Rotavirus

Respiratory syncytial virus, parainfluenza virus or enteroviral infections in infants and young children.

Skin infections that are highly contagious or that may occur on dry skin, including:

Diphtheria (cutaneous)

Herpes simplex virus (neonatal or mucocutaneous)

Impetigo

Major (non-contained) abscesses, cellulitis or decubitus ulcers

Pediculosis (lice)

Scabies

Staphylococcal furunculosis in infants and young children.

Zoster (disseminated or in the immunocompromised host)

Viral/haemorrhagic conjunctivitis

Viral haemorrhagic infections (Ebola, Lassa, Marburg, Congo-Crimean) (during early non-haemorrhagic stages)

5. Formidable Epidemic Disease (FED) Precautions

In addition to Standard Precautions and Contact Precautions, use FED precautions for persons proven or suspected of having a viral haemorrhagic fever. Examples of such diseases are:

- Ebola Viral Haemorrhagic Fever
- Marburg Haemorrhagic Fever
- Congo-Crimean Haemorrhagic Fever
- Lassa Fever

ANNEXURE D BIO-HAZARD SIGN

ANNEXURE E

[Regulations 15(2) and 16(a) and (b)]

INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS

The measures contained in this Annexure shall be applied according to the nature of the activities, the assessment of risk and the nature of the HBA concerned.

A. CONTAINMENT MEASURES		B. CONTAINMENT LEVELS	
	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
1. The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
2. Input air and extract air in the workplace are to be and filtered using High Efficiency Particulate Air (HEPA) Filter or likewise	No	Yes, or extract air and safe discharge of air	Yes, on input and extract air and safe discharge of air
3. Access is to be restricted to authorised persons only	Recommended	Yes	Yes, via airlock
4. The workplace should be sealable in order to permit disinfection	No	Recommended	Yes
5. Specified disinfection procedures	Yes	Yes	Yes
6. The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
7. Efficient vector control, e.g. rodents and insects	Recommended	Yes	Yes
8. Surfaces impervious to water and easy to clean	Yes, for bench	Yes, for bench and floor	Yes, for bench, walls, floor and ceiling
9. Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
10. Safe storage of a biological agent	Yes	Yes	Yes, secure storage
11. An observation window or alternative is to be present so that occupants can be seen	Recommended	Recommended	Yes
12. A laboratory is to contain own equipment	No	Recommended	Yes

13.	Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable container	Where appropriate	Yes, where infection is by airborne route	Yes
14.	Incinerator for disposal of animal carcasses	Recommended	Yes(available)	Yes, on site

ANNEXURE F

[Regulation 16 C]

CONTAINMENT FOR INDUSTRIAL PROCESSES

Group 1 biological agents

For work with group 1 biological agents, including life-attenuated vaccines, the principles of good occupational safety and hygiene should be observed.

Group 2, 3 and 4 agents

It may be appropriate to select and combine containment requirements from different categories below on the basis of a risk assessment related to any particular process or part of a process.

A. CONTAINMENT MEASURES		B. CONTAINMENT LEVELS		
		<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
1.	Viable organisms should be handled in a system, which physically separates the process from the environment	Yes	Yes	Yes
2.	Extracted air from the closed system should be treated so as to -	minimise release	prevent release	prevent release
3.	Sample collection, addition of materials to a closed system and transfer of viable organisms to another closed system should be performed so as to-	minimise release	prevent release	prevent release
4.	Bulk culture fluids should not be removed from the closed system unless the viable organisms have been-	inactivated by validated means	inactivated by validated chemical or physical means	inactivated by validated chemical or physical means
5.	Seals should be designed as to-	minimise release	prevent release	prevent release
6.	Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose- built
(a)	Biohazard signs should be posted	Optional	Yes	Yes
(b)	Access should be restricted to nominated personnel only	Optional	Yes	Yes, via an airlock
(c)	Personnel should wear protective clothing	Yes, work clothing	Yes	A complete change
(d)	Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes

(e)	Personnel should shower before leaving the controlled area	No	Optional	Yes
(f)	Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g)	The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
(h)	The controlled area should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i)	Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j)	The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Optional	Yes
(k)	The controlled area should be sealable in order to permit fumigation	No	Optional	Yes
(l)	Effluent before final discharge	inactivated by validated means	inactivated by validated chemical or physical means	inactivated by validated chemical or physical means