1. PURPOSE

1.1. The purpose of this SOP is to ensure that potentially infectious waste materials are adequately sterilized when subjected to autoclaving. Discard autoclave validation process is defined such the BMW waste is processed in validated Autoclave equipment

2. SCOPE

2.1. This procedure applies to all personnel and work areas of the laboratory – handling processing of infectious biomedical medical waste

2.2. This document is available near the discard autoclave that is used to decontaminate infectious materials.

2.3. Sterilization of wastes is conducted in accordance with the parameters defined in this document and as per latest biomedical waste guidelines

2.4. This SOP applies to all autoclaves that are used to decontaminate infectious waste materials that must be made biologically inactive prior to disposal into BMW segregation process.

2.5. The SOP is displayed in a visible location near autoclaves that are used to decontaminate infectious waste

3. REFERENCE

3.1. Quality Manual

3.2. Latest Biomedical Waste management rules and regulations

3.3. Discard Autoclave SOP

4. ABBREVIATIONS/DEFINITIONS

4.1. SOP: Standard Operating Procedures

4.2. QSP: Quality System Procedure

4.3. HOD – Head of the Department

4.4. QM: Quality Manual

4.5. Bio-medical Waste**:** Waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps

5. RESPONSIBILITY

5.1. Laboratory – In charges

5.2. Quality Manager

5.3. Laboratory Director

6. PROCEDURE:

6.1. Each autoclave must have a functional monitoring or measuring device (electronic or dial) to ensure that the recommended temperature is achieved for the proper length of time on each load

6.2. Each waste bag or container decontaminated by autoclaving should have a heat sensitive indicator such as autoclave tape or strip attached to the outside of the bag. These should be visualized before disposal of each bag and should remain with the bag. A piece of the heat sensitive indicator strip is maintained as evidence in the respective log register as evidence of the process

6.3. Every week the autoclaves that are used to decontaminate waste is validated by using a biological indicator (such as endospores from the bacterium Geobacillus stearothermophilus)

6.4. Validation Procedure:

6.4.1. Secure a biological indicator test containing endospores

6.4.2. Tie a piece of string to the testing vial containing spores to facilitate retrieval of the vial after the autoclave run.

6.4.3. Add vial containing spores to the bag of waste, burying it within the waste (see Precautions section of this SOP about reducing potential exposures during this step). Leave the other end of the string attached to the vial trailing out of the opening of the waste bag.

6.4.4. Secure the waste bag and start the autoclave run.

6.4.5. Post autoclaving and once the bag has cooled, retrieve the vial.

6.4.6. To activate the media, with gloves on hold the indicator in an upright position, gently squeeze to break the glass ampoule.

6.4.7. Follow incubation instructions to complete the test at 55-60 Deg for up to 48 hours

6.4.8. Read the results of the indicator according to manufacturer instructions. General reading guidelines are as below:

6.4.8.1. If after 24 hours the media is yellow then that is a failed test (the endospores grew, they were not killed)

6.4.8.2. If after 24 hours the media is still purple then it is a presumptive pass, but continue to incubate until 48 hours

6.4.8.3. If after 48 hours the media is still purple then it is a passed test (all endospores were killed)

6.4.8.4. If spores survived the autoclave process, growth will lead to fermentation and the production of acid turning the media yellow

6.4.8.5. Record date, run parameters, autoclave tested, and test results on the Discard Autoclave – Log Register

7. PRECAUTIONS:

7.1. Always wear thermal protection gloves when handling items that have recently been autoclaved

7.2. Use caution when opening the door of the autoclave after a run, as steam will be released

7.3. Personnel must use precautions to ensure placement and retrieval of test vials within a bag of potentially infectious waste does not result in exposures to infectious materials.

7.4. Precautions should include as a minimum the use of appropriate PPE and mechanical methods (forceps, etc.) to place and retrieve the autoclaved waste

8. RECORDS:

S No	Record	Responsibility	Review Period
1	Discard Autoclave Log Record	Lab In-charge	1 Year
2	Autoclave Cleaning Record	Lab In-charge	1 Year
3	Biomedical Waste Management Register	Lab In-charge	1 Year
4	Employee Training Record	Lab In-charge	1 Year
5	Biomedical Waste Processing Bills	Lab In-charge	1 Year
6	Discard Autoclave – Chemical Indicators Log Register	Lab In-charge	1 Year
7	Discard Autoclave – Biological Indicators Log Register	Lab In-charge	1 Year