Biological Safety Series

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Waste Inactivation Validation

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UNIVERSITY OF CAMBRIDGE

Waste Inactivation Validation

Definitions

Inactivation: the complete or partial destruction of genetically modified microorganisms (GMMs), HG2 and above organisms and licensed biological material to provide a high level of protection for humans and the environment.

Validation: Establishing documented evidence that a disinfection process will consistently inactivate target organisms under defined conditions of use.

Sterilisation: A process that renders an object effectively free of viable microorganisms (MOs), including those that may survive disinfection treatments (eg spores, prions).

Disinfection: refers to the use of chemical agents to reduce the potential infectivity of a material, but does not imply the elimination of all viable MOs.

Introduction

Microbiological laboratory waste, clinical samples and genetically modified microorganisms (GMOs) and licensed materials including plants and soils must be made biologically inactive before disposal.

The material can be in different forms and of many types which will require different methods to inactivate it.

Control of substances hazardous to health (COSHH) and genetic modification (GM) risk assessments require the assessor to provide specific information for waste disposal.

The method used to inactivate the waste needs to be validated to ensure that there is documented evidence that the required level of inactivation has occurred and that this will be consistent each time.

Methods of Inactivation

There are 2 methods of inactivation - physical and chemical. Physical inactivation includes incineration or autoclaving, and chemical inactivation includes use of substances such as alcohols, peroxygen releasing substances (Virkon), aldehydes (Formalin), quaternary ammonium compounds and hydrogen peroxide.

Physical methods of inactivation are the most reliable way to achieve a high kill rate where sterility is required and both methods - autoclaving and incineration - are relatively easy to validate. Chemical methods of inactivation are more useful where disinfection is required to reduce the potential infectivity of a material, validation of these methods is more complicated.

The use of multiple inactivation methods (ie chemical inactivation followed by autoclaving) should be justified according to risk.

Problems with Inactivation

There are a number of factors which can affect waste inactivation which would require you to show that your particular method is effective. Some examples of which are:

- The density of the waste to be inactivated can prevent penetration of both steam in autoclaves and disinfectants in chemical inactivation.
- The presence of air pockets can prevent steam penetration and chemical contact. The neck of waste bags for autoclaves must be open enough for steam to enter.
- Some chemical disinfectants are ineffective in the presence of organic matter eg blood, serum etc. Others quickly lose their efficacy once diluted.

All of these problems emphasise the need to validate your inactivation method under working conditions.

How to Validate

The procedure for carrying out validation is dependent on the method of inactivation.

Autoclaving

Validation of waste discard cycles must be performed at least annually. This can usually be done as part of the annual maintenance contract.

For more information on autoclave validation and monitoring refer to the Safety Office leaflet 'Autoclaves: Validation and Monitoring HSD164B'.

All autoclaves must undergo pressure vessel testing on an annual basis for insurance purposes. Although the test certificate is valid for 14 months which includes a 2 month grace period, this grace period must not be exceeded. Beyond this it is **illegal** to operate the autoclave. It is advisable to put a note with the 'expiry date' on the lid of the autoclave to inform users. All departments are responsible for registering their autoclaves using the SWIFT database as a means to monitor the service/test status of their autoclaves.

In addition to the autoclave being validated, each run must be monitored by the user to ensure the correct temperature and pressure has been reached and maintained for the correct duration. **The use of 'autoclave tape' is not a suitable means to show that this has occurred.**
Autoclave records for the destruction of waste containing HG2 (or above) agents and other licensed biological material must be retained and archived for auditing purposes.
In the event that an autoclave fails to complete its run or the charts show that the correct and validated autoclaving parameters (temperature, pressure, time) have not been met, then it can be deduced that the waste has not been inactivated. In this event, the waste must be autoclaved again.

Incineration

If waste is inactivated by incineration then the company running the incinerator will have records of burn temperatures and times for their incinerated waste. Incineration is the adopted method for the disposal of human tissues (see HTA Quality Manual for recommended practice: https://www.safety.admin.cam.ac.uk/subjects/biologicals/human-tissue-act/quality-manual)

Chemical Inactivation

Validation is dependent on the level of inactivation required ie 5/6 log reduction or sterilisation. Manufacturers should provide detailed information on the levels of inactivation of various organisms at particular dilutions (efficacy data). This, however, should be validated by in-house testing to ensure that the choice of disinfectant, working concentration, contact times etc are identified. For example, it may be preferable to select a disinfectant with an added detergent for use on spills with a high organic load.

Many disinfectants need to be diluted to working strength. When preparing diluted stocks, the manufacturer's recommendations must be followed to ensure its effectiveness.

Diluted stocks should not be stored for an extended period unless the manufacturer certifies the effectiveness of diluted solutions. The use of freshly prepared stocks is the preferred and recommended method.
Some disinfectants have colour indicators (e.g. Virkon) to indicate their effectiveness. However, incorrect storage or handling can affect the 'shelf-life'. Hence all diluted stocks which are stored for continued use should have a 'Date of Preparation' displayed on the storage container.

Different disinfectants must not be mixed and used concurrently as it could result in hazardous chemical reactions and/or the formation of toxic products.

Care must also be taken when liquid waste is decontaminated first with a disinfectant prior to autoclaving. Toxic gases could be formed during the autoclaving as well as damage to the autoclave could result.

Local inspections should check compliance with disinfection policies to ensure a consistent level of inactivation.

More information

Disposal of Biological/Clinical Laboratory Waste – Policy and Procedures HSD027B
https://www.safety.admin.cam.ac.uk/publications/biological/hsd027b-disposal-biologicalclinical-laboratory-waste

Autoclaves: Validation and Monitoring HSD164B
https://www.safety.admin.cam.ac.uk/publications/biological/hsd164b-autoclaves-validation-and-monitoring

The SACGM Compendium of guidance (particularly section 3.5)
http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/

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