BEST PRACTICE

This is part of a series of guidance documents produced by the NADIR FP7 project. There are various international and national standards in place for undertaking infectious work in animals with pathogens that require high containment facilities. These guidance documents be examples of how these can be practically interpreted

Best Practice on the Selection, Validation and Use of Disinfectants in High Containment Animal Facilities

Contents

1. INTRODUCTION 3
   1.1 Scope of this Best Practice 3
   1.2 Legislation, Definitions, Roles and Responsibilities **Error! Bookmark not defined.**
2. GENERAL 3
   2.1 Disinfectant selection 3
   2.2 Identification of Safety Critical Steps 4
   2.3 Validation of Disinfectants 4
   2.4 Management Control 6
3. REFERENCES 7

1. INTRODUCTION

1.1 Scope of this Best Practice Guideline

1.1.1 Good disinfection procedure is a prerequisite for a safe working environment, but also valid experimental trials. It requires those working in containment facilities to be proactive in contributing to the disinfection of their particular areas..

1.1.2 This Best Practice Guidance covers the requirements for the selection and validation of disinfectants for use in containment level 3 (CL3) farm animal facilities It is important any disinfectant used in CL3 animal facilities must be selected and validated as fit for purpose with regard to both the target organism and also the situation of use.

2. GENERAL

2.1 Disinfectant selection

2.1.1 Disinfectant choice should be determined by:

- the general type or identity of agents for which the disinfectant has demonstrated efficacy;
- the presence of substances, particularly organic matter, in an animal facility likely to reduce efficacy or be chemically incompatible with the disinfecting agent; ; and
- consideration on the potential health risks to users or those present nearby.

2.1.2 Disinfection is used for treating liquid waste, surface decontamination and for removing contamination from equipment and other reusable items that may be damaged by heat or steam.

2.1.3 Disinfection is not considered as effective as steam sterilisation in destroying biological agents and should not be used for treating waste which could or does contain spores of Hazard Group (HG) 3 agents.

2.1.4 National Veterinary Field Services often have lists of approved disinfectants e.g.Defra approved disinfectants. These should be considered for use, but it must be remembered that these have been selected for use in particular circumstances e.g. disease outbreak containment and prevention in field environments and are used as part of a range on controls. Therefore it is recommended that these must still be locally validated by in house testing or by review of published data (refer to 2.3.4) as fit for purpose.

2.1.5 Only those disinfectants which have been validated as fit for purpose can be used. For example there are many variants of the disinfectant 'Virkon' (e.g. Virkon®S, Rely+On™ Virkon® etc), only that variant that has been validated as fit for purpose must be used. Also, be aware that manufacturers periodically change formulations of disinfectants. Batch checks on disinfectants received from suppliers must be made to ensure that the formulation that has been validated as 'fit for purpose' is still being used.

2.2 Identification of Safety Critical Steps

2.2.1 The following steps have been identified as safety critical in decontamination using disinfectants:

- choice of the most efficacious disinfectant;
- validation of the disinfectant against representative conditions e.g. pathogen (type and concentration), temperature, contact time, presence of organic matter;
- method of preparation
- method of use;
- method of storage
- appropriate record keeping of disinfectant preparation;
- adequate documented procedures including for routine use and for spillages; and
- staff training, competence and supervision.

2.3 Validation of Disinfectants

2.3.1 Validation of a disinfectant needs to consider the following:

- Working strength / concentration
- Contact time
- Environmental Temperature
- Surface characteristics
- Shelf life of working strength preparation (i.e. expiry date, storage temperature, light, and the particular container)

2.3.2 Disinfectant efficacy may also be determined by examination of the manufacturers' literature and validation data or by examining relevant peer reviewed literature.

2.3.3 If insufficient evidence available the following study has been recommended for the validation of disinfection processes. These procedures and/or formulations should be tested against the viruses or bacteria currently being worked with in the facility.

- If no existing information a suspension test should be performed by mixing liquid disinfectants and a viral or bacterial suspension for a specific contact time.

- If suspension test of the disinfectant has succeeded, a further carrier test using relevant or model pathogens desiccated onto model surfaces (glass, plastic, coupons of the main representative materials present inside the animal facility) should be performed.

- In both cases, the initial infectious (viral or bacterial) titer must be higher than 10^6 (CFU/ml or pfu/ml or $TCID_{50}$/ml) to allow track infectivity reductions higher than 5 $\log_{10}$. Only total removal of infectivity should be accepted.

- In certain circumstances the viruses or bacteria required to be inactivated by the disinfectant could be replaced by others from the same family or genera (called the model pathogens). Correctly managed such substitutions have been performed with an extremely high safety record in the biological manufacturing field from more than a decade.

- The limitations of the disinfectant should be appreciated and a safety margin put into the SOP for their use e.g dilution of concentration of the disinfectant, occurrence of inhibitory substances as organic matter, colder temperaturesAll validation and ongoing validation must be documented and recorded.

    - A time course study (e.g. 0, 5, 10, 15, 30 & 60 minutes) at the indicated concentration for a selection of contact times is recommended. It is important to ensure that the selected contact time is both sufficient and provides a large margin for error.

    - Studies must also take into account the growth stage of micro organisms and whether it is more resistant to killing at certain stages of growth (e.g. logarithmic, stationary or senescence phase of growth, or if in sporalation).

    - Provision of data with replicates for numbers of bacteria or titre of the virus at the start of the study is required and throughout the time course of the study. Representative volumes of samples must be taken (e.g. 1ul is too small and prone to errors). Statistical analysis of data should be undertaken

    - Each study must be carried out in duplicate as a minimum.

2.3.4 Records must be kept to demonstrate that the disinfectant has been assessed for its efficacy under in-use conditions.

2.3.5 Shelf life of a disinfectant can be determined from published data but this must for the same dilution as the working strength preparation in use and with defined storage conditions.

2.4 Management Control

2.4.1 SOPs must be prepared for disinfection and these must specify:

- the wastes and contaminated articles that are to be disinfected, e.g. disposable or reusable articles that are heat sensitive, liquid wastes and effluents other than cultures;
- the disinfectant that is to be used, its working strength dilution, shelf life and how often it must be changed;
- the contact times to ensure inactivation;
- procedures to prepare the working strength disinfectant including the use of local exhaust ventilation and personal protective equipment (PPE);
- the methods, frequency and need (as determined by risk assessment) for routine or occasional validation of the disinfection process, including innocuity testing;
- factors likely to affect the disinfection process e.g. hypochlorites are readily inactivated in the presence of organic matter
- materials that are incompatible with the disinfectant;
- disinfection protocols for both routine use and in the event of a spillage;
- the safe disposal of used disinfectants and the need for decontamination of the containers;
- the means for the safe removal and disposal of treated waste; and

2.4.2 A **Risk Assessment** must be in place for each disinfectant

2.4.3 **Training and instruction** – Disinfectants must only be prepared and used by persons who have been trained and instructed in their use. Staff must also be trained on the principles of disinfection and factors that will influence their efficacy. Assessment of the competence, knowledge and understanding of users must be recorded in an individual's Training Record.

2.1 Record Keeping

2.5.1 **Undiluted Disinfectants** – the following must be recorded in the relevant log book, form or be clearly labelled on each container:

- Date of receipt – if stated in SOP
- Batch number
- Date of opening
- Expiry date

2.5.2 **Working Strength Preparations** – the following must be recorded in the relevant logbook, form or be clearly labelled on each container:

- Date of preparation
- Batch number, or reference number – if applicable
- Preparation details e.g. volumes used
- Expiry date
- Operator

2.6 Storage and Labelling

2.6.1 Both undiluted disinfectants and working strength preparations must be stored appropriately in accordance with the manufacturers' instructions or material safety data sheet (MSDS). Storage instructions must be included in SOPs or Risk Assessments.

2.6.2 Containers must carry the appropriate hazard symbol as well as the type and strength of the disinfectant, batch number, preparation and expiry dates and operator.

2.7 Use

In order to facilitate disinfection in the different areas of the facility, the areas to be disinfected must be clean and tidy with no clutter or unnecessary items left on work surfaces, benches and floors.

3. REFERENCES

CPMP/BWP/268/95: *Revised CPMP Guideline on Virus Validation Studies*. London, European Medicines Agency: 1996.

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