University of Reading

Safety Code of Practice 14

Part 7

Clinical and biological Waste

Clinical and biological waste

Contents

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1. Scope

Biological and clinical waste from research and teaching laboratories must be segregated into a number of waste streams to meet legislative requirements and University environmental policies and to reduce costs. These laboratories generate wastes that must be decontaminated before disposal as they contain, or may contain, hazardous microorganisms or because they contain genetically modified organisms. This document provides guidance on how biological and clinical waste from laboratories should be segregated and decontaminated, prior to disposal via an appropriate disposal route.

See also Safety Code of Practice 28 for details of disposal routes for hazardous waste, including discharges from laboratory sinks.

2. Responsibilities

2.1. University wide

The Sub-Committee for Biological Safety is responsible for approving the University's policy on biological & clinical waste, and for monitoring compliance through periodic audits.

Facilities Management Directorate, and its waste contractor, is responsible for supplying waste services in accordance with this CoP, and in particular the adoption of the waste classification/colour coding scheme and disposal routes.

2.2. Duties on Heads of Schools and managers

Heads of Schools and other managers have responsibility for ensuring that:

- local rules are in place for managing biologically hazardous wastes, including disinfection policies and procedures
- all staff and research students receive appropriate information, instruction and training to enable them to follow local rules.

2.3. Principal Investigators

Principal Investigators must ensure that:

- activity risk assessments identify decontamination and disposal methods for all forms of hazardous waste produced.
- where activities involve biological agents in Hazard Group 2 or above, or any genetic modification (GM) work, then these risk assessments must be reviewed and the work approved by the Sub-Committee for Biological Safety.
- all workers under their supervision are given sufficient information, instruction and training regarding waste segregation, decontamination and disposal
- procedures for managing waste are followed.

2.4. Laboratory workers

Laboratory workers have a duty of care to ensure that waste is managed properly and disposed of safely via the correct waste stream. Waste streams must not be mixed.

3. Training

All new members of laboratory staff and students should receive training in local waste disposal procedures as part of their induction. All staff and students should be made familiar with the laboratory local rules specifying waste disposal procedures and any specific procedures required under GM or Biological agents risk assessments.

4. Clinical waste

Clinical waste consists wholly or partly of human or animal tissue, blood, excretions or any other bodily fluids and any other waste which has come into contact with any of the above including plastics and syringes.

There are five separate clinical waste streams:

Table 1 Clinical waste streams

Colour coding	Waste stream
	**Yellow – clinical waste for incineration** only, in a suitably permitted or licenced facility.
	**Orange - clinical waste for alternative treatment** to render it "safe" (off-site autoclave or microwave treatment). May also be disposed of by incineration, in a suitably permitted or licenced facility.
	**Tiger – offensive/hygiene waste** including animal bedding. Disposal is via deep landfill or municipal incineration a suitably permitted or licenced facility.
	**Purple-topped** (or solid purple) - cytotoxic and cytostatic waste, for incineration at a suitably permitted or licenced facility
	**Blue –** medicinal waste, for incineration at a suitably permitted or licenced facility

Typical wastes generated in University facilities are listed in Table 2 overleaf, with an indication of the appropriate waste stream. See also Appendix 1.

Infectious clinical waste must never be sent for disposal to landfill.

A system must be in place to ensure the safe transportation and storage of clinical waste, including ensuring that all clinical waste carts are locked or located in a locked compound.

Materials known, or highly likely to contain, Hazard Group 3 pathogens are not permitted in University laboratories without the express permission of the Sub-Committee for Biological Safety and then only in suitable laboratory facilities.

Table 2 Typical clinical wastes

Human & Animal Tissues	Clinical waste not known to be infectious, and is not genetically modified can be disposed of in the orange "alternative waste" stream. This includes gloves, blue roll, plastics and packaging that have been contaminated with clinical materials.
	Slightly sharper objects such as pipette tips, transfer pipettes, graduated pipettes etc should be disposed of in boxed orange bags (orange cardboard outer, orange heavy duty plastic liner) or in orange cardboard Bio-bins placed inside orange bags. The boxed bags must not be used for the disposal of any item which could pierce the orange bag contained within the cardboard box and should not be filled to more than ¾ full.
	Contaminated sharp objects such as syringe needles, microscope slides, Pasteur pipettes, scalpels etc should be disposed of in orange topped sharps bins. The information panel on sharps bins must be completed before being collected for disposal. Sharps bins should not be over filled.
	Where clinical waste consists of human or animal tissue, or is reasonably suspected to be infectious then the yellow (incineration only) waste stream should be used.
Anatomical waste	Includes (animal) body parts, other recognisable anatomical items and carcasses. Should be stored frozen and disposed of by incineration (yellow waste stream) using the University waste disposal contractor.
Animal housing	Animal bedding may be disposed of as **offensive** waste (**tiger** bag stream, yellow/black) and sent for non-hazardous landfill, **IF** the animals are not known to be infected with hazardous microorganisms.
	Where animals are known to be infected with a hazardous microorganism, items such as cages, bedding, drinking bottles and other items should be decontaminated by **autoclaving or chemical disinfection** before disposal using the **tiger** bag waste stream.
Cytotoxic and cytostatic waste	Any waste that is, or is contaminated by cytotoxic or cytostatic medicines (for example any medicines that are either: toxic, carcinogenic, mutagenic or toxic for reproduction such as hormonal preparations, some anti-viral drugs, antineoplastic agents, immunosuppressants and some antibiotics), should be placed in purple-topped clinical waste bins and disposal arranged via University waste disposal contractor.
Medicinal waste	Any medicines (excepting cytotoxic or cytostatic medicines), pharmaceutical products, drugs, vaccines, sera, and discarded items used in the handling of pharmaceuticals, such as packaging contaminated with residue, gloves, syringe bodies, drug vials etc should be placed in blue/blue-topped bins and disposal arranged via University waste disposal contractor.

5. Biological and GM waste

Biological waste consists of, or material contaminated with biological agents (i.e. "micro-organism, cell culture, or human endoparasites which may cause any infection, allergy, toxicity or otherwise create a risk to human health"). This includes waste from bacteriology, virology and tissue culture laboratories.

Genetically Modified Organisms (GMO) waste - consists of, or material contaminated with genetically modified microorganisms, cell cultures or other (higher organisms) which may cause any infection, allergy, toxicity or otherwise create a risk to human health or to the environment". **All waste contaminated with GMOs must be inactivated by validated means before disposal.** The waste routes must be specified in the risk assessment and local rules. All risk assessments are approved by the Sub-Committee for Biological Safety.

A summary of the recommended disposal routes is given in Table 3 below:

Table 3 Typical biological and GM wastes

Waste from: **Hazard Group 1 & 2 Biological Agents or** **Class 1 & 2 GMOs**	**Liquids**	**HG1/Class 1**: Liquids can be disinfected with appropriate chemical disinfectant and disposed to drain. Alternatively liquids may be autoclaved before disposal to drain. **HG2/Class 2**: Liquids should be treated with disinfectant and transferred to autoclave for sterilisation. Sterilised liquids can be disposed of to drain.
	Solids	Place in clear autoclave bag. Autoclave. Dispose of sterilized waste in black bin liners and place in skip for landfill.
	Serological pipettes and pipette tips	Place in robust container (such as dispojar). Autoclave. Dispose of sterilized waste in black bin liners and place in skip for landfill.
	Glass Pasteur pipettes	Place in robust container. Autoclave. Dispose of sterilized glass in glass bin.
	Sharps	Placed in orange-topped Sharps bin. Autoclave. Place with clinical waste for final disposal.
Waste from Containment Level 3 laboratories		Disposal routes must be specified in the Local Rules for the facility.

6. Autoclave sterilisation of laboratory wastes

The requirements for autoclaves for the sterilisation of laboratory wastes are specified in the ACDP guidance "The management, design and operation of microbiological containment laboratories 2001" and in the Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended 2005).

Autoclaves must be designed, installed and maintained in accordance with the Provision and Use of Work Equipment Regulations 1998 and Pressure Systems Safety Regulations 2000.

Detailed information on laboratory autoclaves can be found in BS 2646 "Autoclaves for Sterilization in Laboratories" and BS EN 123 47 "Biotechnology: Performance criteria for steam sterilizers and autoclaves".

In line with the above guidance, autoclaves are required in the following locations:

Table 4 Requirements for autoclaves

Containment Level	Requirement for autoclave treatment
Containment level 1	Waste must be treated on-campus. If the autoclave is located in another building, steps must be taken to ensure containment of the load during transportation.
Containment level 2	Autoclaves for should be readily accessible in the same building.
Containment level 3	Autoclave should be preferable be situated within the laboratory. Where this is not reasonably practicable it should be in close proximity to the laboratory and steps made to ensure safe and secure transportation.

6.1. Maintenance and Examination

People in charge of autoclaves must ensure that installation is notified to, and a maintenance and examination scheme agreed with, the Facilities Management Directorate.

6.2. Validation and Calibration

Validation tests the ability of the autoclave to effectively decontaminate with typical user-defined loads. **Autoclaves that are used to deactivate biological or GM waste must have the process of deactivation validated at least annually.** For autoclaves treating waste from containment level 3 laboratories this must be at least 6-monthly, with consideration given to 3 monthly validation.

Where the typical load changes, further validation must be carried out.

Records of validation should be kept for 5 years.

For validation a "mock" worse case load should be simulated and temperature probes inserted at various positions (usually "12 point" thermocouple). These are attached to recording equipment which takes readings throughout the decontamination process. The validation tests

should be carried out by a competent engineer using calibrated equipment in accordance with the relevant British Standard.

In addition, autoclaves require calibration, and thorough examination and testing as a pressure system. Calibration is a process which checks that the autoclave control panel is correctly controlling and indicating the various autoclave operating parameters. This is often carried out in conjunction with validation and/or servicing. Thorough examination and testing confirms that the autoclave and its pressure-related safety devices are safe.

Table 5 Validation, Calibration and Examination and Test requirements for autoclaves

Waste from Containment Level	Validation Frequency	Servicing and Calibration Frequency	Thorough Examination and Test (as a pressure system)
Containment Level 1	Annual	In accordance with manufacturer's instructions – normally 6 monthly	Every 14 months
Containment Level 2	At least annually 6 monthly recommended if indicated by risk assessment		
Containment Level 3	At least 6 monthly 3 monthly recommended if indicated by risk assessment		

6.3. Routine monitoring

Autoclaves should be fitted with chart recorders or alternative devices for recording run parameters. These should be checked and kept for each sterilisation run to ensure that the autoclave continues to perform satisfactorily. This procedure must not be used as a replacement for decontamination validation.

Note: autoclave tape indicates that the temperature at the location of the tape reached a certain temperature rather than a load has been sterilised effectively.

Table 6: Minimum recommended autoclaving conditions for decontamination of waste

Temperature	Pressure	Sterilisation Time
121-124°C	15 psi	15 mins
134 °C	30 psi	3 mins

Clear succinct operating instructions, including instructions on procedures to follow in the event of an emergency (including spillage, autoclave failure, etc) must be available to, and understood, by each operator.

Operators should also make weekly checks of the proper function of all safety devices. Particular attention should be paid to door seals. Any leak should be attended to as soon as practicable.

6.4. Waste packaging, transportation and identification

A system should be in place to facilitate collection of items for sterilisation from laboratories and the contained and secure storage of these prior to treatment.

Autoclave bags used for sterilisation should be clear or translucent so that incorrect items can be easily detected. Autoclave bags should be clearly labelled with biohazard. They should be placed in appropriate holders in the laboratories with integral drip trays.

Bags ready for sterilisation should be sealed and removed to a clearly labelled collection point within the laboratory. Bottles containing contaminated liquids (treated with disinfectant as appropriate) should be sealed with foil. All waste should be transported to the autoclave room in rigid sealed containers to contain any leaks, and should be clearly labelled with the original laboratory details. Waste should only be transported to the autoclave room immediately prior to treatment and care should be taken to prevent stockpiling of waste. Waste must not be left in unsecured locations (including corridors). Arrangements must be made to ensure that general cleaning staff know not to handle this waste.

Note: Liquids containing radioactive material, toxic or flammable chemicals should not be autoclaved and may require alternative treatment. This treatment must be considered on a case-by-case basis. Contact H&S Services for more advice.

7. Chemical disinfection

Chemical disinfection may be used routinely for the decontamination of liquids containing Hazard Group 1 and Class 1 genetically modified microorganisms.

It is recommended that HG2 and GM Class 2 liquid wastes are chemically disinfected in the laboratory prior to transportation from the laboratory to the autoclave.

Chemical disinfection in the laboratory prior to transfer to the autoclave is required for HG3 and Class 3 GM.

The following points should be considered when selecting disinfectants:

- All disinfectants are hazardous substances in their own right. Disinfectants with the lowest risk to human health possible should be used where practical, in accordance with the principles of COSHH. Where practical liquid or tablet forms should be purchased in preference to powder forms to prevent inhalation.

- Efficacy
    - the ***spectrum of activity*** of disinfectants varies against different microorganisms, users must check with the manufacturers' activity data.
    - ***contact time*** – sufficient time is required for the disinfectant to be in contact with the material to enable effective decontamination.
    - ***concentration*** –the FINAL DILUTION should be taken into account when disinfecting liquids to ensure that the concentration of disinfectant remains in the effective range.
    - disinfectants can be affected by factors such as the presence of organic matter, chemicals, pH, temperature and age.

- Validation – disinfectants should be used in accordance with manufacturers' instructions. For HG or Class 3 materials the disinfectant must be validated under working conditions using in-house experimental data.

Types of disinfectants available include:

- Hypochlorites
    - Chlorine based disinfectant which is highly effective against vegetative bacteria, viruses and fungi. Inactivated by organic matter. Has limited shelf life. Should not be mixed with acids or formaldehyde as toxic gas is released. Incompatible with cationic detergents. Corrodes some metals and damages rubber. Recommended concentration 2500 ppm for discard jars.
- Peroxygen disinfectants (e.g Vikon)
    - Wide ranging efficacy against bacteria and viruses, may cause corrosion on metal.
    - Virkon is available in liquid, tablet and powder form (note the powder is a respiratory irritant). The solution has a built-in colour indicator can be stable for up to 7 days when diluted and must be replaced when colour fades. The usual effective dose is 2% final conc. Highly concentrated solutions have reduced efficacy (>4%). Autoclaving should be avoided or only undertaken in an autoclave that is connected to the mains water supply and that is externally exhausted as Virkon can generate sulphur dioxide when heated.
- Trigene Advanced
    - This is a micro-emulsion disinfectant with broad-range bacterial and virucidal activity. Trigene is available as a low-hazard solution with a diluted shelf life of 6 months. For disinfection of liquids a final concentration of 10% is recommended.

8. Further advice and information

- ACDP guidance "The management, design and operation of microbiological containment laboratories 2001.
- Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended 2005).
- Provision and Use of Work Equipment Regulations 1998.
- Pressure Systems Safety Regulations 2000.
- BS 2646 "Autoclaves for Sterilization in Laboratories".
- BS EN 123 47 "Biotechnology: Performance criteria for steam sterilizers and autoclaves".
- BS EN 12740: 1999. "Biotechnology. Laboratories for research, development and analysis. Guidance for handling, inactivating and testing of waste".
- Safe management of healthcare waste. Version 2.0 England. Department of Health, March 2011.
- "Working with Biological Agents". Medical Research Council 2003.

Appendix 1 Summary of key clinical and biological waste streams

Waste category	Waste stream & colour coding	Material
Non-hazardous waste 	Black Bag 'Safe Waste'	Paper, card, outer packaging from laboratory consumables Paper towels from handwashing Non-hazardous plastic chemical containers (rinsed out and labels removed)
	Recycling	Winchesters, some plastic chemical bottles (rinsed out and labels removed, unless otherwise instructed by the recycling company/supplier)
	Dedicated glass bin	Uncontaminated broken glass
Clinical waste 	For **alternative treatment** - not known to be infectious	
	Clinical waste – orange bags or boxes	Gloves, disposable plastics (not sharp) such as centrifuge tubes, flasks, micro-titre plates.
	Clinical waste – orange biobins	(Serelogical) pipettes and pipette tips
	Clinical waste – orange sharps bin (NB may be yellow with orange lid)	Needles and syringes, glass slides and cover slips, scalpels, glass pasteur pipettes.
	**Clinical waste which requires incineration** – incineration bins	Anatomical waste (human/animal, infected or uninfected) Blood and other bodily fluids (contained to prevent leakage) Sample (blood) collection tubes
	**Tiger** – offensive/hygiene waste for landfill	All non-hazardous, non-infectious lab consumables and other materials which may cause offence to those coming into contact with it e.g. may contain recognisable lab waste items or bodily fluids, animal faeces and bedding etc.
	**Purple-topped** (or solid purple) - cytotoxic and cytostatic waste, for incineration	Cytotoxic and cytostatic waste. Defined as any medicinal product that possesses one or more of the following properties: H6: Toxic; H7: Carcinogenic; H10: Toxic for reproduction H11: Mutagenic May also be contaminated with biological material.
	**Blue** - medicinal waste for incineration	Non-cytotoxic and cytostatic waste, including unused or expired pharmaceutical products and lab supplies & packaging contaminated with residues.
Biological waste Note: all waste for autoclaving must be labelled	Chemical disinfection and sewer	GM class 1 liquids and HG 1 liquids
	Chemical disinfection recommended in the laboratory, then autoclave sterilisation and sewer	GM class 2 liquids, HG 1 liquids

Waste category	Waste stream & colour coding	Material
as 'biohazard'.	Biological waste - autoclave bags (clear) Final disposal via black bin waste OR as Tiger waste if deemed to be offensive	Solid waste contaminated with all GM organisms Solid waste contaminated with HG1-3 microorganisms e.g. Gloves, disposable plastics (not sharp) such as centrifuge tubes, flasks, micro-titre plates, petri dishes, GM soil and plant material, tissue culture contaminated waste
	Autoclave jars	(Serological) pipettes and pipette tips
	Autoclave containers	Glass pasteur pipettes

Note: Municipal waste

Occasionally small quantities of clinical waste from municipal i.e. non-laboratory, sources, may need to be disposed of (for example needles and swabs from cosmetic body art or piercing, drug litter, minor first aid supplies such as contaminated dressings or bandages, human and animal hygiene wastes). Where this waste is generated in a **non-laboratory environment**, **and where they are similar to household wastes,** it is permissible to dispose of them in the general, black bag, waste.

However sharps must be disposed of safely, even if not contaminated with body fluids, and hence the orange sharps bins for clinical waste should be used.

Where generation of these types of waste is a regular occurrence, consideration should be given to implementing a clinical waste stream.