Stichting-ALt
Milieuvergunning USPB

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KAM rule 08 Disposal of used materials from (micro)biological laboratories and production facilities

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3	November 3th, 2022	Regular update and control of current laws and regulations	Stichting-ALt	Management
2	May 17th, 2019	Placed in Stichting format and on agreement with BSO's of the organisations clarifications have been made.	Stichting-ALt	Management
1	1 July 2016	version BBio/NVI/RIVM.	Stichting-ALt	Management
Rev.	Date	Description	Author	Approved by

Changes compared to the previous version

Minor textual changes are not mentioned separately.
All documents indicate that the red roll container can also be a container with a red lid.
Where applicable, the red pop-up caps has been replaced by a colored pop-up cap/melting cap.
Pages 2 and 4: For the discharge of biological materials, the relationship with LAP3 and ADR has been emphasized.
page 3: Added under the responsibilities of the employees who operate the autoclave “check whether melting caps (of stainless steel containers and WIVA vessels with Sterilid) are melted in accordance with a validated process”.
page 6: Added under autoclave processes “The correct operation of the autoclave is regularly checked by the organization itself (Bowie&Dick test) and validated annually by an independent company”.
Appendix 2: disposal of autoclaved waste clarified.
Appendix 4: Modified in diagram and text: the disposal of a Sharps container via a Sterilid WIVA container is permitted, provided that extra attention is paid to ensure that the Sharps container does not end up in the autoclaved waste stream.
Appendix 5: It was already indicated in the text that clothing contaminated with ML-I, ML-II or BA2 must first be autoclaved before it is sent to the laundry. An extra flow has been included for clarification.
Appendix 6: Added to the disposal of the contents of bottles after autoclaving into the sewer “provided the content does not contain any chemical substances/residues, with the exception of the products mentioned in Appendix 3 of KAM35 Requirements for discharge of hazardous substances and mixtures to sewers.
Added: “Chemical waste from a laboratory or production area that is possibly (potentially) contaminated with BSL3/ML-III micro-organisms and cannot be heated (autoclaving) due to its chemical composition – assess per situation whether separate packaging and disposal is the best solution. The BSO/BVF must always assess the situation in advance.”
Appendix 7: Added on page 9 “NB. After proven/documented inactivation/destruction of the contents of the stainless steel container, i.e. check whether the colored cap-up has melted during the validated autoclave process, the contents may be disposed of in the red roll container or container with red lid (see point 6)”.
Appendix 7: Added on page 13 to the discharge of the contents of the dump bpttle after autoclaving into the sewer “provided the content does not contain any chemical substances/residues, with the exception of the products mentioned in Appendix 3 of KAM35 Requirements for discharge of hazardous substances and mixtures to sewers”.

Introduction

The basic principle is, that companies are obliged by environmental legislation and good environmental care to separate all waste, keep it separated and hand them over separately (LAP3).
LAP3 appendix 5 lists the waste flows that must be kept separate, because it is undesirable to mix them with each other and with other waste materials and/or with non-waste materials.
What is or is not hazardous waste is determined by the European Waste List (EURAL). With this European waste list, the distinction between hazardous and non-hazardous waste is harmonized in the European Union and linked to the European regulations for hazardous substances and preparations.
In every (micro)biological laboratory or vaccine production facility, materials are used that must be disposed, or can be reused. The disposal must take place in accordance with ADR 6.2 Infectious substances and in such a manner that during transport and waste processing (the disposal chain) there is no risk to people or the environment.
This KAM rule describes the procedure for disposing of waste from a (micro)biological laboratory or production area and the further routing to autoclave or waste processor.
The disposal of protective clothing from laboratories/production areas and the routing to autoclave and/or laundry are also described.

Objective
Proper compliance with this KAM rule guarantees the health and safety of:

- Employees at the Utrecht Science Park Bilthoven (USPB);
- Employees of the waste processing companies and laundry services

And prevents the spread of micro-organisms in the environment.

Scope of KAM rule
This rule applies to all persons at the USPB who, whilst working, deal with waste and/or clothing from (micro)biological laboratories/ production areas.

Responsibilities

Responsibility for compliance with this KAM rule is as follows:

Line management (the person, who, within his/her organisational unit is responsible for working conditions in accordance with the "Arbowet" is ultimately responsible for compliance with this KAM rule by employees.

Employees working in (micro)biological laboratories and/or production areas are responsible for:

- Correct loading of waste containers (the right waste in the appropriate container, see appendix 7 Explanation of different types of waste containers);
- Correct closure, sealing and labelling of the waste containers (see appendix 7 Explanation of different types of waste containers);
- Cleaning and disinfecting the exterior of the container, if it comes from a laboratory / production area where work is carried out involving Biological Agents belonging to category 2 or 3 (pathogenic) or with GMOs (all containment levels);
- Observing defects on waste containers and making them known by means of a white label (see appendix 8 Rejecting a waste container).

Poonawalla Science Park B.V. (PSP) is responsible for:

- Supplying clean, leak-proof, stainless-steel containers with pop-up caps and WIVA containers;
- Observing incorrect loading, closure or labelling of a stainless-steel or WIVA container and to make it known by means of a white label (see appendix 8 Rejecting a waste container);
- Transporting the full stainless-steel and WIVA containers;
- Handing over full stainless-steel containers to employees at the autoclave facility (e.g. BBio/C&S);
- Collecting empty and flushed out stainless-steel containers from the various organisations at the USPB;
- Having the stainless-steel containers cleaned;
- Weighing the full WIVA containers;
- Collecting full WIVA containers in the central PSP Logistics centre storage;
- Disposing of full WIVA containers via the waste processing company;
- Disposing of autoclaved waste and waste with negligible risk in various bulk containers at PSP.

The employees who operate the autoclave are responsible for:

- Correctly autoclaving/destructing the waste provided;
- checking whether the melting caps (of stainless steel and WIVA containers with Sterilid) have been melted in accordance with the validated process, see appendix 7 Explanation of different types of waste containers

- registering and archiving the autoclave runs (at least in case of processing via the red roll container or container with a red lid route, see appendix 2 and 3 Explanation and flow chart for biological waste with non-negligible risk BA2 and BA3)

Method/measures

Biological materials to be disposed of are mainly released within production facilities and laboratories and must be disposed of under the correct UN code in accordance with ADR (ADR 6.2 Infectious substances), so there is no risk to people or the environment during transport and waste processing (the disposal chain).

Biological waste
The term 'biological waste' refers to all waste originating from laboratories/production areas where materials of a biological nature or origin (micro-organisms, vaccines, toxins, organ material, plants, soil samples, etc.) are used.
These materials can bring risk to people and/or the environment if they are not handled with care, including the disposal of waste (see also KAM-regel 07).
Depending on the risk and the nature of the material, a waste processing route can be selected, or is mandatory. See schedules and references below.

Waste prevention

Strive to minimize waste by:
- only bringing materials into the laboratory/production area that will actually be used;
- removing secondary packaging (cardboard, tempex, plastic) where possible outside of the laboratory/production area.

Overview of waste flows

Biological waste with negligible risk. Biological Agent level 1 (BA1), soil sample, food samples etc.
see appendix 1 Explanation and flow chart for biological waste with negligible risk

Biological waste with non-negligible risk. Biological Agent level 2 (BA2) and GMO level I and II,
with the exception of polio and vaccinia
see appendix 2 Explanation and flow chart of biological waste with non-negligible risk BA2

Biological waste with non-negligible risk. Polio and vaccinia, Biological Agent level 3 (BA3), GMO level III
see appendix 3 Explanation and flow chart of biological waste with non-negligible risk BA3

Biological waste in combination with sharp objects (sharps)
see appendix 4 Explanation and flow chart of biological waste in combination with sharps

Reuse of protective clothing
see appendix 5 Explanation and flow chart of reuse of protective clothing

Special waste flows, such as disposal of disposable hand towels, HEPA filters, special glassware etc.
see appendix 6 Disposal of special materials

Overview of waste containers


Sharps container


WIVA container


Wiva container with Sterilid


Stainless-steel container


Dump-bottle


DPTE container


Red roll container or container with red lid


Grey roll container with orange lid

Rubbish bins for used disposable hand towels (used exclusively for drying hands) are further explained in Appendix 6 Disposal of special materials.

Explanation of different types of waste containers
Appendix 7 describes the different types of containers and how they should be loaded and labelled/identified (see Appendix 7 Explanation of different types of waste containers).

Rejecting an incorrectly delivered container (WIVA container, stainless-steel container, dump-bottle, DPTE container)
Appendix 8 describes how to deal with an incorrectly delivered, empty or filled container (see Appendix 8 Rejecting a waste container).

Interim storage of waste at laboratories and production areas
The table below shows the conditions under which interim storage for a limited period is permitted in the laboratory and production areas:

Waste contains:	Interim storage area	Closed off [1] yes/no	Maximum duration of storage at a given temperature
Material with negligible risk	Lab Test-animal enclosure	no	> 20 °C – 1 week 4-20 °C – 2 weeks < 4 °C – 2 months
BA2 and GMO containment level I and II with the exception of polio and vaccinia	Lab Test-animal enclosure	no	> 20 °C – 1 week 4-20 °C – 2 weeks < 4 °C – 2 months
polio, vaccinia, BA 3 and GMO containment level III	Lab Test-animal enclosure	yes	Max. 3 days in the lab-/production area

[1] 'Closed off' means not accessible to unauthorised persons.
N.B. for the storage of animal cadavers see KAM rule 17 Removal of cadavers and bedding.

Autoclave processes
At the USPB, destruction autoclaves are in use at various locations (at different organisations). These autoclaves (destructors) perform validated destruction processes to destroy living micro-organisms in the waste.
The starting point for using an autoclave for inactivation/destruction of waste is, that the autoclave's capacity is sufficiently large enough to be able to process the amount of waste material provided in an adequate/validated manner.
The proper functioning of the autoclave is regularly checked by the organization itself (Bowie&Dick test) and annually validated by an independent company. The validation is performed according to a predetermined and approved plan and documented in a validation report.
Use of the autoclave has also been validated for:

- the micro-organism(s) that will be inactivated;
- the method of loading;
- the type of material to be inactivated in the autoclave.

Filling the autoclavable waste containers in the lab/production area, loading the autoclave and operating the autoclave are **described in local SOPs** of the relevant organisations at the USPB.

In general, autoclaves (destructors) have at least 2 destruction programs:
1 for porous and hard materials (also suitable for small volumes of liquids) and 1 for liquids.

Abbreviations and terms

Abbreviations	
ADR	European agreement with regard to the international transport of hazardous goods by road
BA	Biological agent
BA1	Biological agent level 1; = **non-modified** (micro)organisms in risk group 1.
BA2	Biological agent level 2; = **non-modified** (micro)organisms in risk group 2.
BA3	Biological agent level 3; = **non-modified** (micro)organisms in risk group 3.
BBio	Bilthoven Biologicals
BVF/BSO	Biologische veiligheidsfunctionaris/Biosafety Officer
C&S	Cleaning & Sterilisation (a BBio department)
DPTE	Double Porte pour Transfert Etanche = double lid for leakproof transfer
GMO	Genetically modified organisms
HEPA	High efficiency particulate air
KAM	Kwaliteit, Arbo en Milieu (Quality, Health, Safety and Environment)
LAP	Landelijk Afval Plan (National Waste Plan)

Terms	
Biological agent	For description and category classification: see KAM rule 13 Biological Safety.
Biological waste category 3	All biological waste originating from a laboratory/ production area where work is carried out using BA category 3 (the same applies if work is carried out using BA category 2 in the same area).
Genetically modified organisms	For description and containment level: see KAM rule 13 Biological Safety.
Large quantities/ volumes	Quantities /volumes exceeding 3 litres.
Pliersholder/ label manager	For labelling containers with a metal seal 'CONTAMINATED', a pliers is used with a unique (pliers)number or other unique seal. This unique seal is held by the so-called pliersholders, who also ensure proper labelling. Management of the pliers is the responsibility of PSP. If there is an important requirement for obtaining further information about the content of a container, this can be done through the tool number/label to ascertain where the container comes from.
Hospital waste	Hospital waste is waste that is released during medical treatment or research performed on people or animals. At the USPB, this waste may not contain BA belonging to category 3 or higher and no level III GMOs. No polio or vaccinia either.

Appendices and references

Appendices to KAM rule 08:

Appendix 1 Explanation and flow chart of biological waste with negligible risk
Appendix 2 Explanation and flow chart of biological waste with non-negligible risk BA2
Appendix 3 Explanation and flow chart of biological waste with non-negligible risk BA3
Appendix 4 Explanation and flow chart of biological waste in combination with sharps
Appendix 5 Explanation and flow chart of reuse of protective clothing
Appendix 6 Disposal of special materials
Appendix 7 Explanation of different types of waste containers
Appendix 8 Rejecting a waste container

References:

1. "Landelijk afvalbeheerplan" LAP3, sector plans 19 (Afval van gezondheidszorg bij mens of dier) and 65 (Dierlijk afval).
2. Mandatory separation of waste streams according to the National Waste Plan LAP3 bijlage 5
3. European classification of hazardous or not hazardous waste Europese afvalstoffenlijst (EURAL).
4. Appendix 9 from the Regeling genetisch gemodificeerde organismen milieubeheer 2013 en appendix 5 to KAM rule 13).
5. ADR-Requirement for the safe transport of hazardous substances by road.
6. KAM rule 07 Disposal of (hazardous) waste.
7. KAM rule 13 Biological safety.
8. KAM rule 15m Reporting (near) environmental incidents.
9. KAM rule 16 Risk statement.
10. KAM rule 17 Removal of cadavers and bedding.