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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2	May 17th, 2019	Placed in Stichting format and on agreement with BSO's of the organisations clarifications have been made.	Stichting-ALt	Management
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Rev.	Date	Description	Author	Approved by

Changes compared to the previous version

The KAM rule has been placed in the Stichting-ALt format. In addition a few updates were introduced:

- "ALT" (Antonie van Leeuwenhoekterrein) is now: USPB (Utrecht Science Park Bilthoven).
- "Head of the organisational unit ('laboratory head'; 'department head', 'head of centre' or 'plant manager')" has changed to: Line management.
- "The L&O employees" is now: PSP (Poonawalla Science Park B.V.) Logistics centre.
- Under responsibilities for employees: 'labelling' has been added to 'closing, sealing and labelling waste containers'. For PSP: 'and/or labelling' has been added to 'observing incorrect loading and/or closure'.
- Under Overview of waste containers: "the section for the removal of special materials below" has been changed to: Appendix 6 Disposal of special materials.
- Update of references in the Appendices and references chapter, and various hyperlinks added.
- Deleted references:
    - "FAQ Waste, What should and can I do with contaminated material and waste that contains genetically modified micro-organisms, originating from contained rooms?", December 2010 (via http://www.vrom.nl/ggo-vergunningverlening)"; the link is outdated and there are no FAQs on https://www.ggo-vergunningverlening.nl/ .
    - "KAM rule 004 on working safely with radioactive substances and ionizing radiation"; because this is specific to RIVM.
- Added reference: KAM rule 13 Biological safety.
- Flow charts added to appendices, so that there are fewer documents.
- An incorrect EURAL code (180104) in the BA1 biological waste flow chart, adjusted in the new Annex 1.
- In connection with the order of the text and references in this document, appendices 6, 7 and 8 have been renumbered to appendices 7, 8 and 6 respectively.
- In the section 'Autoclave processes at the USPB' it has been clarified that by autoclave in this KAM rule is meant a destructor. 'Maintenance' has been replaced by 'validation' and that validation takes place according to a 'predetermined and approved plan' (instead of 'predetermined method'). In the explanation of the two destruction programs, 'solids' has been changed to 'porous and hard materials'.
- In the terminology list, added to 'Tool holder' that he or she also ensures correct labelling.

Introduction

In every (micro)biological laboratory or vaccine production facility, materials are used that must be disposed of as waste or laundry. This disposal must take place in such a manner that during transport and waste processing (the disposal chain) there is no risk to people or the environment or that this risk is negligibly small.
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 and not too full);
- 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;
- registering and archiving the autoclave runs (at least in case of processing via the red roll container route, see appendix 2 and 3 Explanation and flow chart for biological waste with non-negligible risk BA2 and BA3)

Method/measures

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


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 (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)

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. Appendix 9 from the Regeling genetisch gemodificeerde organismen milieubeheer 2013 (see also appendices 5a, 5b and 5c to KAM rule 13).
3. ADR-Requirement for the safe transport of hazardous substances by road.
4. KAM rule 07 Disposal of (hazardous) waste.
5. KAM rule 13 Biological safety.
6. KAM rule 15m Reporting (near) environmental incidents.
7. KAM rule 16 Risk statement.
8. KAM rule 17 Removal of cadavers and bedding.