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Milieuvergunning USPB
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KAM-rule 20 Access to lab and production rooms

Contents

3	March 8, 2021	Changes in used names / indications	St. AL-terrein	Management
2	November 15, 2017	Version of RIVM from 2016 implemented and agreed with advisory group members of BBio/Intravacc/RIVM/Micreos/Cipla.	St. AL-terrein	Management
1	July 1, 2016	Version BBio (NVI)/RIVM from 2012	St. AL-terrein	Management
Rev.	Date	Description	Author	Approved by

Introduction

This KAM-rule describes the access to at risk laboratory and production rooms with colour marks and changing a colour mark.
The KAM-rule is intended for all persons who bear responsibilities or (will) carry out work in or third parties who needs acces at risk rooms on the site Utrecht Science Parc Bilthoven (USPB) and for the facility room administrator of PSP.
On the site are rooms where work is done with, or storage is carried out of, hazardous substances: chemical, (micro)biological (whether or not genetically modified) and/or radioactive and nuclear (CBRN) substances. These are so-called at risk rooms.

Because of the diversity of activities and organizations on the site, terms are kept as general as possible and included in the list of abbreviations and terms at the end of this document. A further note on the criteria, instructions for access and routing of reporting is described in the Appendices mentioned below:

Appendix 1: Marking materials
In order to give an indication of the risk present at the entrance to a room, the room must be given a colour mark. The symbols are described in this Appendix.

Appendix 2: Criteria for room marking
This describes the criteria on the basis of which a colour mark is determined for a room. For this the guidelines from the document 'Marking laboratory rooms for fire service action (reference 1) is chosen as a starting point. This KAM-rule does not however only determine the access for fire service personnel in a certain risk area, but also applies for third parties where there is no employer-employee relationship such as contractors, cleaning staff, security, emergency services and visitors.
If the nature of the hazardous substance does not fit within the criteria of this KAM-rule, based on a risk assessment a colour mark is determined or chosen for another management measure. This is done in consultation with the relevant (legal) expert of the own organization.
Colour marking of rooms may not be used improperly for example for keeping out unwanted visitors. Alternatives are available for this such as key procedures or pass reader.
The access restriction based on a colour mark may (temporarily) lapse if a room is released on the basis of a risk declaration (see KAM-rule 16).

Appendix 3: Instructions for access by third parties to at risk rooms and for laboratory-/room-administrators of the organization , informants and line administrators
On all at risk rooms a current colour mark must be present. The colour mark of a room indicates whether and under what conditions a room may be entered by third parties.

Appendix 4: Form for reporting/changing status of an at risk room on site

Purpose

The purpose of this KAM-rule is that the risk level of a room with hazardous substances is clear, and that risks for third parties, such as emergency services, are avoided or managed.

Responsibilities

Per organization on site:

The **line management** is responsible for:

- A current marking of the rooms according to the criteria of this KAM-rule (see Appendix 1), within his/her part of the organization;
- The timely indication of change of a room colour mark and of corresponding vaccination requirements (see Appendix 4);
- The designation of at least two **informants** per yellow or red room and the registering of the contact information of these informants or having this registered;
- The assessment of whether the vaccination status of third parties complies with vaccination requirements or having this assessed. (N.B. Vaccination status assessment does not of course apply for external emergency services, given the urgency of their action.);
- Keeping informed or being kept informed of this regulation and/or supervision of third parties such as security staff, cleaning staff, contractors, emergency services but also visitors and guest workers;
- The authorisation of third parties for access to a red room in consultation with the (legal) expert involved of the organization, with the exception of the red rooms with a (micro)biological risk. Access to these rooms is authorised by the Biologische VeiligheidsFunctionaris (BVF)/ BioSafety Officer (BSO) in consultation with the line management.
- Access of technical and cleaning staff to at risk rooms only in consultation with the relavant **room-/laboratory administrator**.
- Outside working hours, in the absence of the informants of yellow rooms, being available themselves and having a private telephone number for the informant(s).

The **room-/laboratory administrator** is responsible for:

- Being aware of the work in relevant rooms and having sufficient knowledge and experience to be able to estimate the risk in the room.
- If an order to carry out work in or on an at risk room is given directly outside PSP to an external party, to provide information on this KAM-rule and supervising and checking the vaccination status for this external party.
  N.B. In case of an order via PSP to a third (external) party, this responsibility does however lie with the facility room administrator of PSP (see KAM-rule 16 'Risk declaration').

The **production and laboratory staff** are responsible for:

- Leaving the workstation in an at risk room tidy and safe after working hours, so that the risk of – and during – any emergency is as low as possible.

The **informant** of a room marked yellow  or red  is responsible for:

- Being informed of the work and of the risk present in the yellow or red room.
- Assessment of whether and under what conditions access to the yellow room is granted to a third party.
- Support for line management in assessing whether, and under what condition(s), access is granted to third parties for the red room.
- Informing third parties of the risk of the relevant yellow room and what precautions must be taken to avoid exposure to and/or spread of hazardous substances.
- Mutually agreeing that at least one of the informants of the yellow room is available during working hours and is present on site. For emergencies outside working hours: See for a yellow room the responsibilities for the line management. For a red room the informant *as well as* the BVF/BSO (microbiological/GMO) or ACD (radiological/nuclear substances) is available, if necessary via the line management.

The **expert** for CBRN substances (e.g. occupational hygienist/safety officer, BVF/BSO or ACD) is responsible for:

- Estimating biological/GMO, radiological/nuclear or chemical risk.
- Checking the request of the line management to indicate or change the colour mark of a specific room based on criteria laid down.

Site wide:

The **room administrator PSP** is responsible for:

- Processing the information in the room administration system (Planon) and affixing the colour mark on the room.
- Informing externally hired staff of this KAM-rule upon starting maintenance and/or an order and checking the vaccination status.
  Note: If an external person is called in directly via the organization (outside PSP) then this responsibility lies with the relevant organization on site. No access is granted without sufficient security.

Procedure

Green room

For green rooms no informants are designated. However each green room has a laboratory-/room administrator. The health and environmental risks resulting from the substances present in a green room are low. In case of escalation of an incident the maximum expected health impact is low, even if no personal protection equipment is used. Third parties may only enter the room after consultation with the room-/laboratory administrator of relevant organization. Outside working hours in the absence of the room-/laboratory administrator it is permitted to enter the room on the conditions mentioned in Appendix 3.

Yellow room

For each room marked yellow at least two informants are appointed (these may also be the room-/laboratory administrator s). The health and environmental risks resulting from the substances or equipment present in a yellow room are medium. In case of incorrect action due to unfamiliarity with the work or hazardous substances present, this may lead to unwanted exposure and/or spread of unwanted health damage due to equipment present. The use of personal protection equipment and or restrictive measures may be necessary, in particular after an incident or emergency. During working hours access is granted by informants, whose name and telephone number is indicated by the entrance door. The informant assesses whether it is reasonable after giving instruction or taking protective and/or restrictive measures, to allow third parties to enter the yellow room. Outside working hours the responsible line management is approached first. They have the private telephone number of the informant(s).

Red room

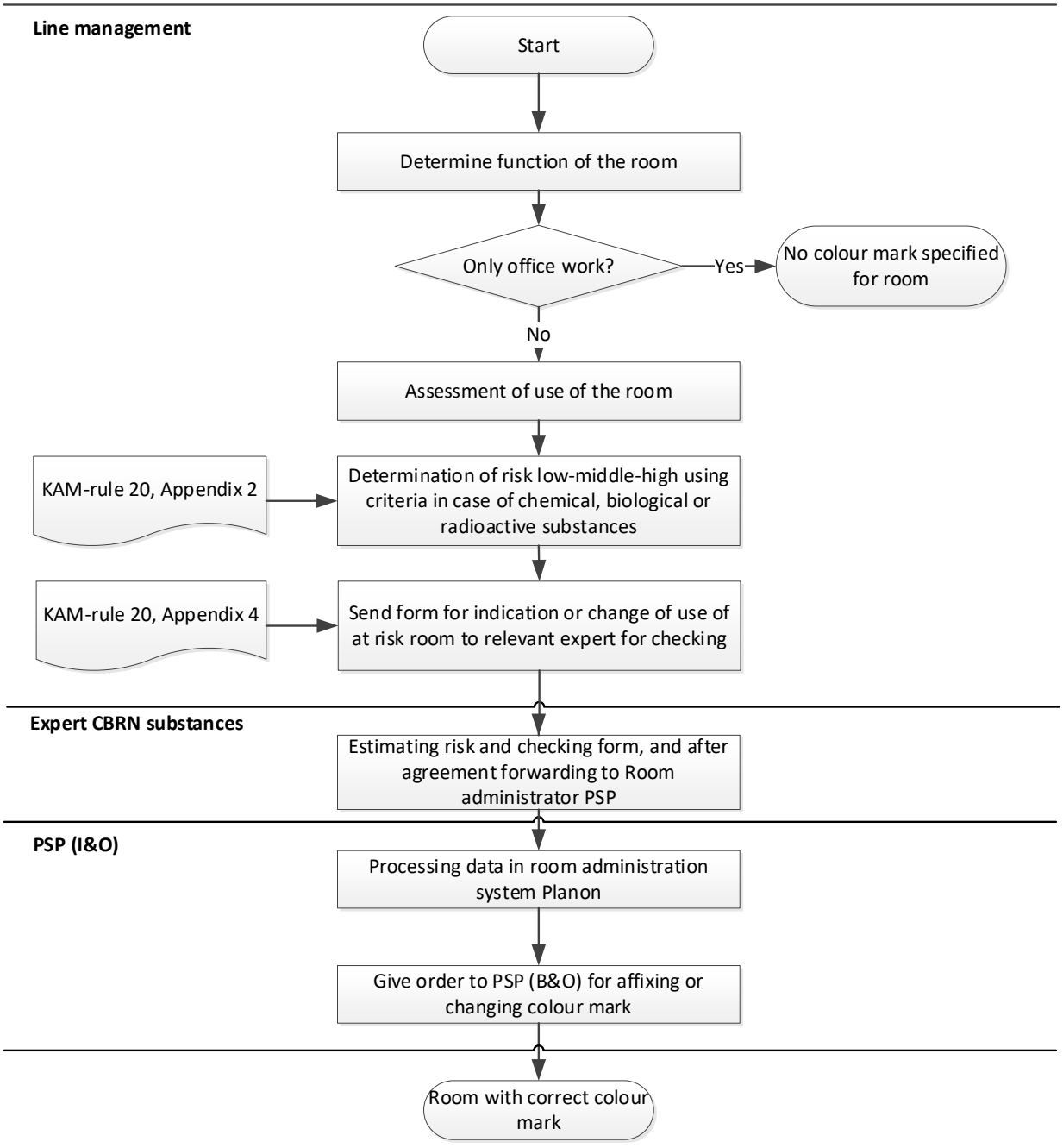
For each room marked red at least two informants are appointed (these may also be the room administrators). The health and environmental risks resulting from the substances or equipment present in a red room are high. In case of incorrect action due to unfamiliarity with the work or the hazardous substances present, this may lead to unwanted exposure and/or spread, or unwanted health damage due to equipment present. The use of personal protection equipment is necessary, in particular after an incident or disaster.

A red room is only accessible for authorised persons. Authorisation is carried out by:

- The line management in consultation with the ACD (radiological/nuclear substances);
- On the basis of for example GMO legislation: The BVF/BSO in consultation with the line management (BSL3/ML-III/BSL3).

Third parties who have been given access are always accompanied by one of the informants. Outside working hours one of the informants, the responsible line management or relevant (legal) expert for CBRN substances is available.

Routing for reporting/changing status of an at risk room



References/additional documents

1. 'Marking laboratory rooms for the fire service action', Repressief zakboek Veiligheidsregio Utrecht (Fire Service Region of Utrecht Land), interne procedure BRUL: 2-08 BIO-hazard-laboratorium
2. Vaccination policy for people employed on site (to be requested from the relevant organization or client)
3. Work description form (WOF) (to be requested from the relevant organization or client)
4. Application form vaccination/control, ETD (External Technical Services), HHD (Housekeeping Service), BEV (Security) (to be requested from the relevant organization or client)
5. Appendices 1 to 4 (see Introduction)

Abbreviations and terms

Abbreviations	
ACD	Algemeen coördinerend stralingsdeskundige (General coordinating radiation protection expert)
BBio	Bilthoven Biologicals
BVF/BSO	Biologisch veiligheidsfunctionaris / BioSafety officer
CBRN	Chemical, (micro)Biological, Radiological and Nuclear
GMO	Genetically Modified Organisms
GHS	Global Harmonized System
KAM-rules	Quality, Heath, Safety and Environmental rules
PSP **- B&O or I&O**	Poonawalla Science Park B.V. - Afdeling Beheer en Onderhoud (Dep. Administration & Maintenance) or Afdeling Infrastructuur en Ontwikkeling (Dep. Infrastructure and Development)
RIVM	Rijks Instituut voor Volksgezondheid en Milieu (Dutch National Institute for Public Health and Environment)
SIE	Snel inzetbare groep EHBO (First aid rapid response group)
USP(B)	Utrecht Science Park (Bilthoven site)

Terms	
Third parties	Persons with whom in general there is no employer-employee relationship. 'Third parties' includes as a minimum: security staff, cleaning staff, contractors, emergency services (BHV (in-house emergency), SIE (First aid rapid response group), fire service, etc.) but also visitors and guest workers. 'Third parties' have an inadequate awareness of the work/substances present and corresponding risk in a specific room on site. The Dutch Working Conditions Act (Arbowet) obliges every employer to protect 'third parties'.
Expert	Expert of the own organization in the field of CBRN substances. For example: biologisch veiligheidsfunctionaris (BVF) / BioSafety Officer (BSO), algemeen coördinerend stralingsdeskundige (ACS) (general coordinating radiation protection expert) or occupational hygienist / safety expert.
room administrator PSP	Room administrator of PSP, who administrates rooms in Planon for the whole site and who facilitates the delivery of colour marks. Contact via: ruimten@stichting-alt.nl

Room-/Laboratory administrator	Employee of the relevant organization, entrusted with the daily administration of the relevant at risk room.
Hazardous substances	Chemical, microbiological (whether or not genetically modified) and/or radioactive substances.
Informant	Designated employee in the department who is fully aware of the work that is carried out in a specific, at risk room and who has sufficient knowledge and experience to assess the risk in the relevant room. He/she acts as a contact person or information provider. The name and telephone number of the informant are posted up by the entrance to the room. The informant may also be the room-/laboratory administrator.
Laboratory manager	The part of the department that carries out the logistical and financial management tasks. Laboratory management may be combined with functional room administration.
Line management	Responsible manager of the organization with at risk room(s). For BBio and InTraVacc: department head; for RIVM: centre head.
Risk	Chemical, (micro)biological, GMO, radiological or nuclear risk.
Room	Laboratory room, (vaccine) production room, experimental animal house and storage room.
Site	Site on Antonie van Leeuwenhoeklaan 9-13, also called Utrecht Science Parc Bilthoven (USPB)