Instructions for Radiation Safety at Karolinska Institutet

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Contents

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1. Introduction

1.1 Purpose

This document describes how work and research involving ionizing radiation should be carried out at Karolinska Institutet (KI). The instructions reflect national requirements for the handling of radioactive substances and X-ray equipment and, in combination with radiation safety training and annual radiation protection meetings, form the basis for a radiation-safe working procedure at KI.

1.2 Legal requirements

KI's instructions for radiation safety are in line with the Swedish radiation protection act (Strålskyddslagen), the Swedish radiation protection ordinance (Strålskyddsförordningen) and the regulations of the Swedish Radiation Safety Authority (Strålsäkerhetsmyndigheten, SSM).

- Radiation Protection Act 2018:396
- Radiation Protection Ordinance 2018:506
- SSM's regulations on license required work with ionizing radiation SSMFS 2018:1
- SSM's regulations on work subject to notification SSMFS 2018:2
- SSMs regulations on exemptions and on clearance of materials, building structures and areas SSMFS 2018:3

1.3 Internal Audit

KI's radiation protection expert should audit KI's radiation safety instructions every fifth years or earlier if it is crucial for radiation safety or when audit is required.

1.4 Exemptions from these instructions

1.4.1 Karolinska University Hospital premises

KI research groups and core facilities located on the Karolinska University Hospital (K) premises shall primarily follow radiation safety instructions provided by K. Collaboration in radiation safety between KI and K is regulated by a general radiation safety agreement and a cyclotron and radiochemistry dedicated agreement respectively.

1.4.2 Human research and/or patient examinations

Research groups/core facilities/clinics involved in human research and/or X-ray examinations of patients are required to have either a separate license from SSM or a signed agreement to work under K's license. For agreements, a local radiation protection organization specifying roles and responsibilities is required.

1.4.3 Non-ionizing radiation

Non-ionizing radiation (e.g., radio waves, microwaves, laser light, ultraviolet light) is not included in these instructions.

1.4.4 Nuclear holding

Nuclear holding (e.g. substances containing Thorium or Uranium) is described in KI's steering documents for nuclear holding.

1.4.5 Request for exception due to other causes

Should any ionizing radiation-related task require an exception from these instructions, an exemption request shall be sent to KI's radiation protection expert (RPE) for assessment.

2. Radiation protection organization

2.1 Organization outline

KI's radiation protection organization describes accountability and roles for radiation safety related matters at KI, hence providing adequate conditions for a radiation safe environment for staff and students at KI, and the public.

KI's radiation protection organisation (see Figure 1) consists of roles described in steering documents for the President's decision-making procedures and delegation rules. Contact information is listed on KI's staff portal. Three roles are described by separate chapters:

- radiation protection expert (henceforth referred to as the RPE)
- radiation protection representative (henceforth referred to as the representative)
- radiation protection assistant (henceforth referred to as the assistant).

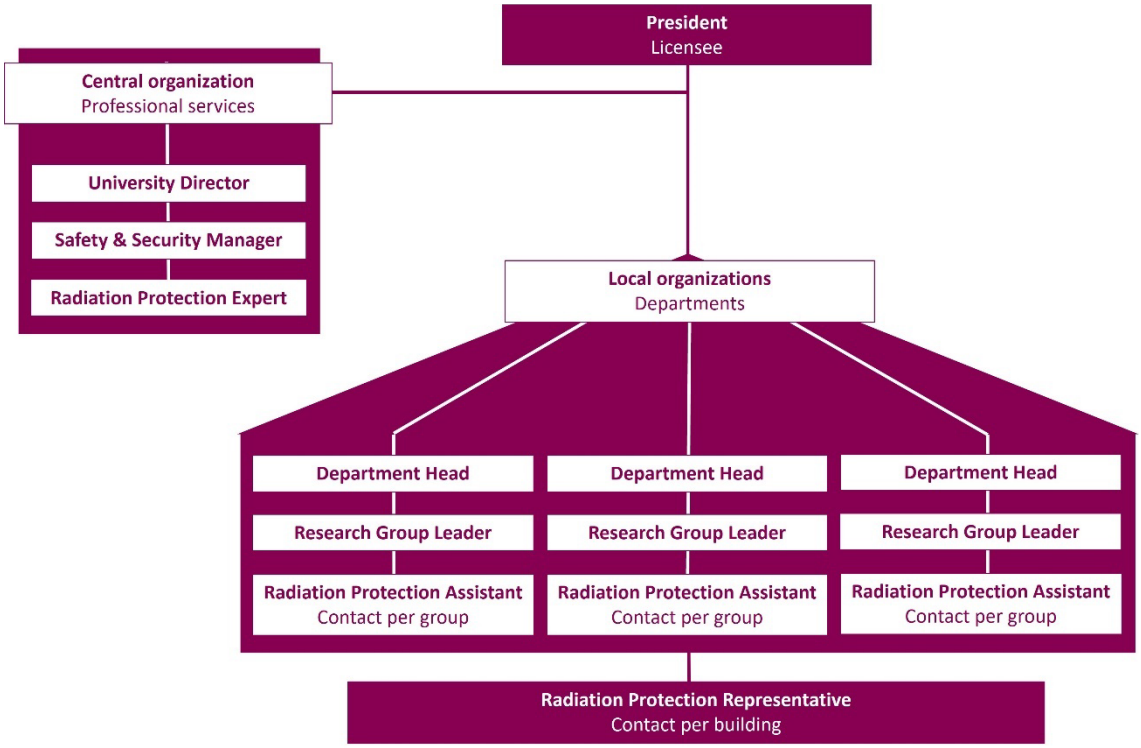

Figure 1 KI's radiation protection organization

2.2 Role descriptions

2.2.1 Radiation protection expert

KI's radiation protection expert is the licence holder's expert in radiation protection matters and has a mandate governed by the SSM (SSMFS 2018:1 Appendix 5). Furthermore, KI's radiation protection expert

- reports at the licensee's annual review of radiation safety
- monitors and renews radiation safety agreements/licenses regarding ionizing radiation
- reviews and grants local licences to research groups/core facilities involved in ionizing radiation.

2.2.2 Radiation protection representative

For each department (involved in ionizing radiation), a radiation protection representative must be appointed by the head of department. Where appropriate for practical reasons, the tasks of the radiation protection representative may be further allocated to several staff members if the institution is geographically divided (e.g. for KM-A, KM-B and KM-F) or to an institution-wide resource if institutions are co-located (e.g. for ANA Futura, Biomedicum and Neo).

The radiation protection representative shall have adequate competence in radiation safety adequate for the tasks in consultation with the head of department. The tasks should generally be defined as listed below.

- Act as the contact person and link between the building/department and KI's radiation protection expert.
- In consultation with KI's radiation protection expert, collaborate on local work regulations and instructions regarding radiation safety, such as routine for handling and storing radioactive substances and handling radioactive waste.
- Within each building/ department, provide rules and procedures for how radiation-related work is to be conducted.
- In consultation with the radiation protection expert and radiation protection assistant, provide access to the premises concerned.
- Report reported radiation-related incidents or deviations from routines regarding radiation safety to KI's radiation protection expert.

- Attend annual radiation safety meetings and possible follow-up meetings with radiation protection expert (convenor) and radiation protection assistants.
- Attend courses and meetings related to radiation safety at KI.
- In accordance with the delegation, notify in writing when the assignment as radiation protection representative ends.
- Immediately return the delegation if there are no prerequisites for the assignment.

2.2.3 Radiation protection assistant

For each research group/core facility (involving ionizing radiation), a radiation protection assistant shall be appointed by the research group leader/head of the core facility. Where appropriate for practical reasons, the radiation protection assistant may support several research groups/core facilities, e.g. research groups using a core facility may rely on the radiation protection assistant of the core facility.

The radiation protection assistant shall have adequate competence in radiation safety for his or her assignment in consultation with the research group leader/head of the core facility. The tasks should generally be defined as listed below.

- Act as the contact person and link between the radiation protection representative and the research group/core facility, between the radiation protection expert and the research group leader/core facility manager.
- Ensure that the research group/core facility has a valid local license and that licensing requirements (mandatory radiation safety training, requirements for radiation protection measures, etc.) are met.
- Manage possible personal dosimeters and dose reports, and report personnel radiation doses to KI's radiation protection expert, if applicable.
- Maintain list of group/facility members having completed mandatory radiation safety training and therefore entitled access to the radiation source.
- Provide introductory training to staff members who will be working with the radiation source.

- Manage logbook of the radiation source usage.
- If work involves open radioactive sources,
    - manage logbook for isotope work,
    - manage logbook of possible sink outlet and/or waste disposal,
    - record isotope holding in KLARA radiation.
- Report reported radiation-related incidents or deviations from routines regarding radiation safety to research group leader/core facility manager, radiation protection representative and radiation protection expert.
- Attend annual radiation safety meetings and possible follow-up meetings with radiation protection expert (convenor) and radiation protection representative.
- Attend radiation safety courses and meetings organized by the radiation protection expert.
- In accordance with the delegation template, notify in writing when the assignment as radiation protection assistant ends.
- Immediately return the delegation if there are no prerequisites for the assignment.

3. Start-up/changes/decommissioning

3.1 Start-up

Research groups/core facilities are required to send an application to KI's RPE before the start-up of any new operation involving ionizing radiation at KI for an assessment of the prerequisites for adequate radiation protection.

3.1.1 Application for open/sealed radioactive sources

Applications for open radioactive sources (i.e. liquid or solid radioactive substances) or sealed radioactive sources (i.e. radioactive substances permanently sealed in a solid container) shall specify the following:

- department, research group/core facility and group leader/core facility manager
- building, floor, room
- radiation protection assistant
- list of staff members involved in the isotope work
- list of radioactive isotopes
    - for an open source, estimation of
        - max activity holding
        - max activity per experiment
        - max amount of experiments per month
        - possible sink disposals (max disposal at a time, max amount of disposals per month)
    - for a sealed source
        - supplier, purchase date
        - manufacturer, model, serial number
        - reference activity, reference date.

An approved application qualifies for a local license that is reviewed annually by the RPE.

3.1.2 Application for X-ray systems

KI's RPE shall be informed well ahead of an X-ray system purchase. The information shall specify but not be limited to the following:

- department, research group/core facility, research group leader/core facility manager

- radiation protection assistant
- building, floor, room
- X-ray source
    - supplier, purchase date
    - manufacturer, type, serial number
    - max tube voltage (kV), max tube current (mA).

The RPE shall assess the required radiation protection and provide advice for purchase.

3.2 Operational changes

The RPE shall be contacted in the event of any operational change that could affect radiation safety to ensure that KI implements the required measurements, calculations, and assessments of any possible radiation-related consequences for staff, public and/or environment.

3.3 Decommissioning

The RPE shall be informed before any decommissioning of the premises and/or equipment involving ionizing radiation. The RPE assesses the clearance requirements and ensures that possible clearance application for premises and/or deregistration of X-ray sources will be sent to SSM. The assistant should coordinate the required measures and possible disposal of radiation sources and/or potentially contaminated material in consultation with the RPE. For open radioactive sources, there is a dedicated decommissioning plan (see Appendix 1).

4. General radiation safety requirements

4.1 Access to radiation sources

The assistant shall ensure, in consultation with the manager and representative, that only authorized staff are given access to a radiation source.

4.2 Competence

Only authorized staff is allowed to work with ionizing radiation. The staff shall have knowledge not only about these instructions but also the instructions specified in the mandatory radiation safety courses and during the practical on-site introduction. Research group leaders shall assess the competence of their staff in consultation with the assistant. The RPE shall be contacted if any doubts exist. The general competence matrix is listed in Table 1.

Role	Competence	Education	Frequency
President incl. central organization	Knowledge of KI's radiation protection organization, the Radiation Protection Act, the Radiation Protection Ordinance, and applicable regulations in radiation safety	Course provided by radiation protection expert	Every fifth year
Head of department	Knowledge of KI's radiation protection organization and applicable regulations in radiation safety	Course provided by radiation protection expert	Every fifth year
Radiation protection expert	Competence according to SSMFS 2018:1 Appendix 5 Approval by SSM	Continuous monitoring, and external course provider when required	Continuously
Radiation protection respresentative	Knowledge of KI's radiation protection organization and local radiation safety instructions	Course provided by radiation protection expert	Every fifth year
Radiation protection assistant	Knowledge of KI's radiation protection organization and local radiation safety instructions	Course provided by radiation protection expert	Every fifth year
Staff	Knowledge of KI's radiation protection organization and KI's radiation safety instructions and local radiation safety methods	Courses provided by radiation protection expert, radiation protection representative, radiation protection assistant, and external course provider when required	Every fifth year

Table 1 Competence required for each role in KI's radiation protection organization.

4.2.1 Course requirements for open/sealed radioactive sources

At least three courses are required for working with open/sealed radioactive sources. Access to web courses is provided after login with KI credentials at KI's staff portal. The mandatory courses are

- web course Introduction to radiation protection
- teacher-led course on Open radioactive sources
- on-site introduction with the assistant
- possible extra courses depending on the complexity of the isotope work (for example in hot lab)
- refresher course within five years.

4.2.2 Course requirements for X-ray sources

Three mandatory course subjects are required for working with X-ray sources. Course access is provided after login with KI credentials at KI's staff portal. The mandatory course subjects are

- web course Introduction to radiation protection
- web course for the specific X-ray source
- on-site introduction with the assistant
- possible extra courses depending on the complexity of the X-ray system (for example PET/CT)
- refresher course within five years.

4.3 Registration of radiation sources

4.3.1 KLARA radiation

KLARA radiation is KI's central register for radiation sources. KI's RPE is the administrator of KLARA radiation. The assistant shall register a radiation source (X-ray, open/sealed radioactive source) in KLARA radiation without delay upon purchasing and deregister sources upon decommissioning. For radioactive isotopes, registration in KLARA radiation is only required if half-life is at least 14 days. The RPE shall assess whether the registration/deregistration is required to SSM.

4.3.2 Local licenses

KI's RPE shall keep a register of the local licenses involving work with radiation sources at KI. At a minimum this register shall specify (but not be limited to) the following:

- local license number
- building, floor, room (excl. design of premises, which is documented by KI's premises department)
- department and research group/core facility

- manager/principal investigator, representative and assistant
- type of radiation source and extent of work
- date for annual check-ups incl. possible measures required
- staff categorization and premises classification.

The RPE shall review local licenses annually. Risk categories shall be assessed according to Appendix 2.

4.3.3 Fundamental radiation protection

There are different types of ionizing radiation. The characteristics of each type of radiation will require specific radiation protection measures assessed by the RPE. However, three fundamental radiation protection concepts are always valid regardless of radiation source: time, distance and shielding.

4.3.4 Minimize time

Radiation exposure is directly proportional to exposure time, which in practice means that half exposure time results in a half radiation dose. Hence, staff shall always

- practice new and difficult procedures in advance without radiation source
- work quickly, safely, and methodically.

4.3.5 Maximize distance

The decrease in the intensity of radiation is inversely proportional to the square of the distance (inverse square law) which in practice means that the radiation decreases very quickly when the distance to the radiation source increases. Hence, staff shall as far as possible and reasonably

- work at the greatest possible distance from the radiation source
- use distance tools when handling high-energy radiation sources of high activity
- step outside the room when imaging with X-ray systems.

4.3.6 Use adequate shielding

The intensity of the radiation can easily be reduced by adequate shielding. Shielding includes different types of radiation protection, for example

screens, glasses, and aprons. The material and thickness of the shielding should be assessed by the RPE.

4.3.7 Radiation risk assessment

All research groups/core facilities shall do a radiation risk assessment (RADRA, form available at KI's staff portal) before introducing work involving ionizing radiation. The RADRA shall be updated whenever there is a method change having a possible impact on radiation protection. All staff working within the facility must have knowledge about the RADRA, which furthermore shall be kept in an easily accessible location in the laboratory.

4.4 Radiation-related incident

4.4.1 Registration of incident

A radiation-related incident is an unintentional exposure of the staff, public or environment, including cases in which a possible incident is identified as a "could have happened" even though no incident has occurred. Staff shall always contact the assistant without delay in the event of a radiation safety-related incident. Staff shall thereafter record the incident in KI's incident reporting system, preferably together with the assistant.

4.4.2 Severity assessment

The severity of a radiation-related incident differs between incident categories. Depending on the severity level of an incident/near incident (see **Table 2**) different roles should be informed without delay in addition to reporting in KI's incident reporting system. The direct information may only await the annual radiation safety meeting, if the assistant assesses severity level as low.

Severity level	Incident description	To be informed without delay in addition to reporting in KI's incident reporting system
Low	Minor spillage of open radioactive sources, e.g., a drop on gloves or bench paper. Purchase of radioactive isotopes not registered upon delivery. Error message on X-ray irradiator.	Assistant
Mid	Extensive spillage of open radioactive sources, e.g., floor/wall in isotope premises. X-ray equipment accidently crashed into wall/door.	Assistant & Representative
High	Spillage involving staff contamination, e.g., contaminated face/hand. Spillage involving the public, e.g., spillage during transport.	Assistant & Representative & RPE
Radiological Emergency Situation	Staff/public has been, or risks being exposed to radiation doses motivating the implementation of immediate measures to avoid serious health effects.	Assistant & Representative & RPE & Head of Safety and security

Table 2 *The severity differs between radiation-related incident categories.*

4.4.3 Radiation dose estimates

The RPE reviews reported radiation-related incidents and assesses whether a radiation dose estimate is required. If so, the RPE ensures that the radiation dose is estimated and sent to the research group leader/core facility manager with a copy to the head of department.

4.5 Radiation dose monitoring

4.5.1 Radiation dose concepts

In monitoring the staff's radiation dose, the two most common dose terms are "equivalent dose" and "effective dose". Equivalent dose and effective dose represent two completely different dose concepts, although they share the same unit (Sievert, Sv).

4.5.1.1 Equivalent dose

Equivalent dose to an organ/tissue is the average value of absorbed energy (from ionizing radiation) per mass unit weighted with the biological effect for the specific radiation type of the radiation source. Equivalent dose enables comparison of radiation dose to organs/tissues regardless of radiation source, for example comparing radiation dose to eye lens for two different radioactive isotopes.

4.5.1.2 Effective dose
Effective dose is the sum of all equivalent doses to exposed organs and/or tissues, weighted with the radiosensitivity of each organ/tissue. Effective dose enables comparison of risk for different radiation exposure scenarios regardless of radiation source and exposed body part.

4.5.2 Radiation dose limits
Radiation dose limits differ between staff categories and risk groups. Staff shall inform the RPE of possible sub-operational changes that could have an impact on radiation dose and require certain categorization. Staff categorization shall be assessed by the RPE.

4.5.2.1 Staff in category A
Staff shall be categorized A if the risk is not negligible that they annually can exceed an

- effective dose of 6 mSv
- equivalent dose of 15 mSv to eye lens
- equivalent dose of 150 mSv to extremities (e.g. fingers)
- equivalent dose of 150 mSv/cm^2 to skin.

Category A staff is required to wear a dosimeter. The radiation dose reports shall be reviewed by the RPE. The RPE initiate an investigation if a monthly dose exceeds an

- effective dose of 0.5 mSv (0.15 mSv for pregnant staff)
- equivalent dose of 0.5 mSv to eye lens
- equivalent dose of 5.0 mSv to extremities
- equivalent dose of 5.0 mSv/cm^2 to skin.

Staff in category A require an approved annual health declaration according to KI¨s Anvisning för tjänstbarhetsbedömning av personal tillhörande kategori A.

4.5.2.2 Staff in category B

Staff shall be categorized B if the risk is not negligible that they annually can exceed an

- effective dose of 1 mSv (but less than 6 mSv)
- equivalent dose of 50 mSv to extremities (but less than 150 mSv)
- equivalent dose of 50 mSv/cm^2 to skin (but less than 150 mSv/cm^2).

The RPE shall assess if category B staff shall be required to wear dosimeters during a limited period to ensure they are in the correct category.

4.5.2.3 Non-categorized staff

No categorization of staff is required if the risk of exceeding the radiation dose limits for category B is negligible. This applies, for example, to staff working with X-ray irradiators (X-ray cabinets).

4.5.2.4 Pregnant staff

Pregnant staff shall contact the RPE without delay as soon as pregnancy is established for a risk assessment. The foetus is not only extra sensitive to radiation, but also legally interpreted as being part of the public, for which a lower dose limit applies. Pregnant staff always has the right to be reassigned to work not involving more exposure than what is allowed for the public. However, they are allowed to continue their work involving ionizing radiation as long as the equivalent dose to the uterus does not risk exceeding 1 mSv (for the remainder of the pregnancy).

4.5.2.5 Breastfeeding staff

Breastfeeding staff involved in work with open radioactive sources shall contact the RPE without delay for advice and risk assessment. There shall not be any risk for a breastfed child to ingest radioactive substances during breastfeeding.

4.5.2.6 Medical examinations

No dose restrictions apply for patients exposed to ionizing radiation during medical examinations, but the radiation dose shall be kept As Low As Reasonably Achievable (ALARA). The possible risk (with each exposure) shall be weighed against the medical benefit, and the benefit-to-risk ratio shall be kept As High As Reasonably Achievable (AHARA).

4.5.2.7 Human/animal studies
Special dose restrictions apply for test subjects exposed to ionizing radiation within research, due to test subjects not being expected to receive any medical benefit from the exposure. Dose restrictions for animal studies are set the regional animal experimentation ethics committee and for human studies by the Swedish Ethical Review Authority (Etikprövningsmyndigheten).

5. X-ray requirements

5.1 Signage

Entrances shall be marked with a sign indicating the appropriate classification (see Figure 2). The RPE shall assess which classification is required. The assistant shall ensure, in consultation with the manager and representative, that only authorized staff is given access to controlled areas.

Figure 2 Sign for a supervised area (left) and a controlled area (right) respectively.

5.2 Personal protective equipment

Radiation protection requirements differ between X-ray systems and their usage. A radiation protection apron shall generally be worn when standing next to X-ray equipment during exposure, except for X-ray cabinets which are completely shielded. Other requirements shall be clarified in system-specific courses.

5.3 Quality assurance requirements

5.3.1 X-ray system

X-ray systems shall always undergo a quality assurance (QA) check upon delivery. QA check shall include (but not be limited to) performance and

function control and checks for possible leakage radiation. The assessment shall be made by the RPE. The assistant shall ensure that regular preventive maintenance (PM) is carried out according to the manufacturer's recommendations. The assistant shall inform the RPE without delay regarding any intervention that might have an impact on the properties of the radiation source. The RPE shall assess whether a QA check is required.

At least once per year, the RPE shall assess the parameters and procedures of importance in terms of radiation protection for each X-ray source intended for exposure. This QA check shall include but not be limited to

- the premises
- radiation protection equipment
- safety systems
- signage and labeling
- dosimetry.

5.3.2 Dosimetry devices

The RPE shall monitor the annual functional checks (description in Appendix 3) and five-year calibrations (description in Appendix 4) of the dosimetry devices.

5.3.3 Personal protective equipment

Functional checks of lead-equivalent radiation protection aprons and other personal protective equipment shall be done annually by the assistant. Checks shall include but not be limited to

- ensuring that labels (incl. individual marking) are correct
- checking for visible damages
- taking an X-ray image of radiation protection aprons (to check for cracks etc.)
- recording the check-up.

6. Radioactive sources requirements

6.1 Signage

6.1.1 Entrance to isotope laboratory

Premises for work with radioactive isotopes shall be classified as supervised or controlled areas depending on the risk category (see Appendix 2). Signage (see Figure 3) is required at all entrances to the premises. The assistant shall ensure, in consultation with the research group leader/core facility manager, that only authorized staff is given access to controlled areas.

Figure 3 Mandatory entrance signs for supervised (left) and controlled areas (right).

6.1.2 Open radioactive sources

Radioactive substances shall be labelled with the

- radioactive isotope
- reference activity
- time of reference activity, and
- research group/core facility.

The substances shall be kept in a separate box (or on a tray) to minimize risk for contamination of the locker/fridge/freezer. All holding shall be recorded by the assistant (see chapter on Mandatory registration). All holding shall be adequately shielded.

Furthermore, signage is required for all storage locations for radioactive substances. Doors to cupboards, freezers or fridges shall be labelled with the sign in Figure 4.

Figure 4 Storage sign for radioactive substances. Please note that the name of the assistant shall be specified.

6.1.3 Sealed radioactive sources

The assistant shall annually check that all sealed radiation sources intended for exposure are in their registered storage area, in good condition and marked with the

- manufacturer name, product name, identification number
- radioactive isotope, reference activity, reference date,
- research group/core facility
- warning symbol for ionizing radiation.

6.2 Minimizing risk of contamination

6.2.1 Ventilation

Separate ventilation systems shall be used when there is a risk for airborne radioactive substances. Special ventilation requirements apply when for example

- labelling with volatile I-125
- working with volatile PET isotopes (e.g., C-11, O-15 and F-18)
- performing work that might cause airborne radioactivity (e.g., incubating or mixing chemical substances)
- exceeding isotope specific activity levels (assessment by the RPE).

Control of ventilation shall be booked by the assistant at start-up and regularly thereafter according to KI practices.

6.2.2 Cleanliness and tidiness

All surfaces shall be kept clean and tidy. Radioactive substances shall be returned to dedicated storage areas between work sessions. Absorbent paper with a plasticized underside shall be used on workbenches dedicated to work with open radioactive sources. The protective paper shall be changed regularly (depending on workload) and whenever there is any splash/spill.

Cleaning staff is only allowed to

- clean floors (not move anything except chairs)
- empty paper towel trash bins (never any laboratory waste bins)

provided clear and concise radiation safety instructions (use gloves, wash hands afterwards, etc.). Any radioactive spillage shall always be cleaned by laboratory staff (instructions in Appendix 7).

6.2.3 Contamination check

6.2.3.1 Check frequency

Contamination checks (method description in Appendix 6) shall be carried out regularly according to the isotope laboratory risk category (see Table 3). Staff shall always check for contamination whenever there is a non-negligible risk of contamination, e.g. when a computer or mobile phone has been used in the isotope laboratory. Documentation of contamination checks shall be available in the isotope laboratory.

Risk category	Contamination check of work surfaces	Contamination check of hands	Required documentation
1	Recommended both before and after work	Before and after work	Always for work surfaces. For other checks when a non-negligible risk of contamination exists
2	Controlled areas: recommended both before and after work Supervised areas: after work	After work	At least four times per year and when a non-negligible risk of contamination exists
3	Not regularly, only when a non-negligible risk of contamination exists.	Not regularly, only when a non-negligible risk of contamination exists	At least annually and when a non-negligible risk of contamination exists

Table 3 Contamination check frequency differ between risk categories.

6.2.3.2 Annual measure points

The assistant shall annually do a more thorough contamination check of the isotope laboratory. Measure points for the annual check shall at a minimum include but not be limited to

- door & cabinet handles
- door surfaces
- knobs, handles/etc on equipment (for example beta counters)
- mouse, keyboard, and/or touch displays
- work surfaces (e.g., tables, shelves)
- work chairs and/or trollies
- sink and/or basin.

6.2.3.3 GM tube

A Geiger Müller tube (radiation protection instrument or radiation monitor, left in Figure 5) shall be used to measure possible contamination of gamma and/or high-energy beta emitters. Functional check shall be done before each use by staff (instructions in Appendix 3). The RPE shall monitor annual calibration (instructions in Appendix 4).

6.2.3.4 Liquid scintillation counter

A liquid scintillation counter (to the right in Figure 5) shall be used to measure possible contamination of low-energy beta emitters (ex. H-3, C-14 and S-35). There is also a certain type of liquid scintillation counter for low-energy gamma emitters. Samples shall be taken by wipe tests (instructions in Appendix 5) that are analysed in the scintillation counter. Functional check and calibration of a scintillation counter shall be arranged by the assistant in accordance with manufacturer recommendations.

Figure 5 Radiation protection instrument to the left and liquid scintillation counter to the right.

6.2.4 Food and drink prohibited

It is forbidden to eat, drink, or use chewing gum/snuff in premises where open radiation sources are handled. It is also forbidden to store/bring drinks, food, chewing gum or snuff into such premises. Violating these rules will increase the risk of internal contamination.

6.2.5 Personal protective equipment

6.2.5.1 Lab coat

Always wear a lab coat when working in the isotope facility. The assistant shall ensure that lab coats are changed regularly.

6.2.5.2 Eye and hair protection

Eye and hair protection shall be worn if there is a risk of splashes. The RPE shall assess if radiation protection glasses are required.

6.2.5.3 Gloves

Always use gloves. Used gloves shall be treated as radioactive waste. Always wash hands afterwards.

Use double gloves when cleaning contaminated surfaces. Change gloves immediately if a radioactive spillage (see Appendix 7). So called lead gloves should not be used.

6.2.5.4 Standalone shielding

Staff shall always use adequate shielding for radioactive preparations. Shielding dimensions shall be assessed by the RPE (for example 10 mm plastic shield for P-32, 10 mm lead equivalent shield for Cr-51). Working behind an adequate screen also protects against splashes.

6.2.5.5 Pliers or tweezers

Pliers/tweezers (see Figure 6) shall preferably be used when working with gamma or high-energy beta emitters. Syringe shields shall be used at syringe withdrawing or injecting with gamma emitters.

Figure 6 Pliers/tweezers shall be used when handling gamma or high-energy beta radiation.

6.3 Radioactive waste

6.3.1 Waste containers

Green waste containers shall as far as possible and reasonable be used for all radioactive waste. In case of combinations of waste, such as contagious radioactive waste, the measures in Table 4 shall be carried out.

The RPE shall assess if radioactive waste of gamma or high-energy beta emitters requires extra shielding, e.g. plexiglass is required P-32 (see Figure 7), whereas adequate lead equivalent shielding is required for gamma emitters. Different isotopes should preferably not be mixed, and the RPE shall be contacted if research work requires isotope mixtures.

Figure 7 Green containers might require extra shielding, e.g. plexiglass for high-energy beta emitters (ex. P-32) or lead (ex. Cr-51).

Type of radioactive waste	***Bin colour***	***Instruction***
Only radioactive waste incl. more than one radioactive isotope	*Green*	*Generally, only one isotope per waste box. The RPE shall be contacted if research generates isotope mixtures. The formula for how to estimate total activity of a mix of more than one isotope is described in Appendix 8. The waste box should be labelled according to Figure 8.*
Radioactive chemical waste	*Green*	*Waste containers that, in addition to radioactive waste, also contain chemical waste shall be labelled both according to Figure 8 and with a label according to the chemical compound (for example scintillation solution). Radioactive chemical waste requires storage in the radioactive waste room until decayed to radioactivity below limit for incineration. Then it shall be treated as chemical waste.*
Radioactive contagious/stingy waste	*Yellow*	*Waste containers that, in addition to radioactive waste, also contain infectious/stingy waste shall be labelled according to Figure 8 and with a label according to the contagious/stingy waste. Radioactive contagious/stingy waste requires storage in the radioactive waste room until decayed to radioactivity below limits for incineration. Then it shall be treated as infectious/stingy waste.*
Radioactive biological waste	*Black*	*Radioactive organs/tissues shall be disposed in black plastic boxes labelled as both radioactive (see Figure 8) and biological waste. The freezer shall be labelled as storage for radioactive substances (see Figure 4). The RPE shall be contacted if waste involves gamma-emitting nuclides, as extra shielding might be relevant. Radioactive biological waste requires storage in freezer waste room until decayed to radioactivity below limit for incineration. Then it shall be treated as biological waste.*

Table 4 Different mixtures of radioactive waste require certain measures listed in this table.

6.3.2 Radioactive waste labels

The assistant shall label radioactive waste with the label to the left in Figure 8 upon transport to the radioactive waste room. The outside of the radioactive waste container shall be kept clean (checked for contamination before transport) and with the lid properly closed.

The representative shall label decayed radioactive waste with the etiquette to the right in Figure 8 before ordering the transport to an external waste facility.

Figure 8 Label for radioactive waste containers (left), label for decayed radioactive waste containers (right).

6.3.3 Empty canisters and packaging material

Empty plastic/glass/lead canisters that have contained radioactive substances should – after being checked for contamination – have their radioactivity labels removed. The canisters should be treated according to general waste regulations. Same is valid for packaging materials.

6.3.4 Logbook at radioactive waste bin

The assistant shall keep a logbook for each radioactive waste container to estimate total activity per container (instructions in Appendix 8). The assistant shall order internal transport of radioactive waste containers to the buildings radioactive waste room when the container is either full or has reached its allowed activity limit, crucial for some isotopes (see Table 5).

Radioactive isotope	Half-life		Max activity per waste container (MBq)	Max activity concentration (MBq/kg)
H-3	12.3	years	1000	1000
C-14	5730	years	10	10
P-32	14.3	days	0.1	1
P-33	25.6	days	100	100
S-35	87.5	days	100	100
Cr-51	27.7	days	10	1
Se-75	119.8	days	1	0.1
Rb-86	18.6	days	0.1	0.1
Zr-89	78.4	hours	1	0.01
In-111	2.8	days	1	0.1
I-125	59.9	days	1	1
Lu-177	6.7	days	10	1

Table 5 Maximum activity levels for radioactive waste listed as activity per container and activity concentration. Please note: 1 MBq = 0.027 mCi = 27 µCi. The RPE shall be contacted for radioactive isotopes not listed in this table.

6.3.5 Registration in RadWaste

The representative shall register the radioactive waste on the website RadWaste upon transport to the radioactive waste room. RadWaste will confirm when waste has decayed below the isotope-specific threshold values (listed in Table 5).

6.3.6 Sink disposal

Possible request of disposing liquid radioactive waste shall be assessed by the RPE. Each disposal site shall have a sign according to Figure 9. Both before and after release, the drain must be generously flushed with water to avoid radioactivity remaining nearby in e.g. water trap.

The assistant should keep a logbook for releases at each disposal site. Registration shall be done for all isotopes with half-lives longer than 10 hours. The assistant shall report to the RPE if a local license's maximum activity per month is exceeded. KI's total average monthly disposals shall be annually assessed by the RPE.

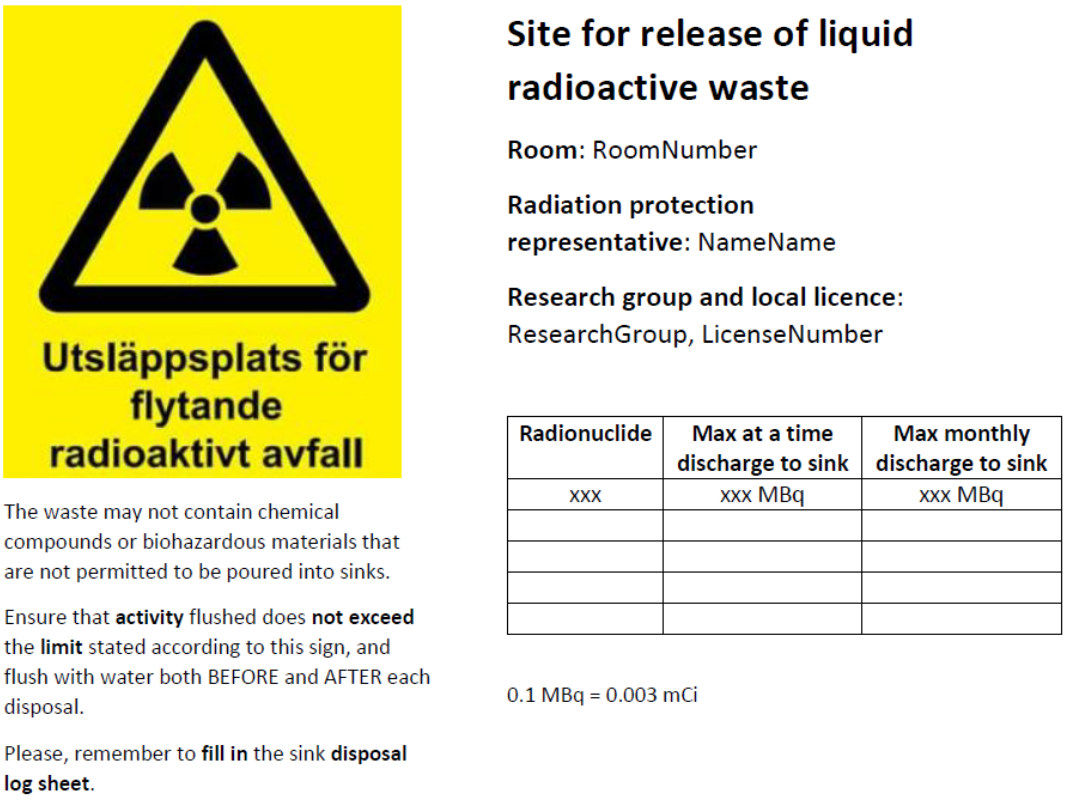

Figure 9 Sign for release of liquid radioactive waste shall be posted at each disposal site.

6.3.7 Radioactive waste rooms

There are three permanent radioactive waste rooms on the KI premises (listed below). Temporary waste rooms (e.g., freezer rooms) shall be arranged in consultation with the RPE. The representative shall perform an annual contamination check of the radioactive waste room (equal to contamination checks for isotope laboratories; see chapter on Contamination check).

- ANA8, floor 3, room 31301
- Biomedicum, floor 2, room C0218
- Neo, floor 3, lattice cage

Doors to radioactive waste rooms shall be labelled with the sign in Figure 10.

Figure 10 Sign for radioactive waste room, where the name of the representative shall be specified.

6.4 Transport

6.4.1 Internal transport

Internal transport of radioactive substances within KI's and K's geographical areas shall be included in the risk assessment of each research group/core facility. Generally, staff shall

- ensure that the transport package is adequately sealed and shielded (instructions in Appendix 9)
- preferably use culverts (with roller cart/kick-bike if required, assessment by the RPE) and avoid public areas
- carry a phone in case of an incident
- establish a transport routine in writing.

6.4.2 External transport

External transport of radioactive substances is regulated by the Swedish Civil Contingencies Agency's (Myndigheten för samhällsskydd och beredskap, MSB) regulation on the transport of dangerous goods (ADR-S). Radioactive substances can only be transported between KI Solna/North and KI South with an authorized transport company (see KI's staff portal).

Appendix 1
Decommissioning plan for open radioactive sources at KI

Introduction
KI's decommissioning plan shall be applied to future actions required for clearance of premises used for open radiation sources at KI.

Open radioactive sources at KI
The system of local licenses ensures that knowledge exists of the extent of open radioactive sources at KI. Table A1 lists the total amount of possible max holding of open radioactive sources at KI as registered in 2024.

Radioactive isotope	Total amount of allowed holding
H-3	17 GBq
C-11	20 GBq
C-14	5 GBq
O-15	20 GBq
F-18	40 GBq
P-32	2 GBq
P-33	250 MBq
S-35	2 GBq
Ti-45	2 GBq
Cr-51	2 GBq
Mn-52	1 GBq
Co-55	2GBq
Cu-64	1 GBq
Ga-68	12 GBq
Se-75	100 MBq
Rb-86	100 MBq
Zr-89	5 GBq
Tc-99m	1 GBq
In-111	100 MBq
I-125	600 MBq
I-131	500 MBq
Tb-161	1 GBq
Lu-177	11 GBq
Ac-225	10 MBq

Table A1 *List of the total amount of possible max holding per radioactive isotope at KI as registered in 2024.*

Decommissioning plan
A radiological survey is required before premises/buildings (used for open radioactive sources) can be passed to other operations. The survey shall be based on the register of local licenses, including information on the premises, isotopes, amount of activity used, and disposal sites. The RPE

(radiation protection expert) shall assess the risk categorization according to KI's measurement program for the clearance of premises and buildings. The risk categorization shall determine whether measurements are required prior to applying for exemption/clearance from the Swedish Radiation Safety Authority (Strålsäkerhetsmyndigheten, SSM). Laboratory equipment and materials on the premises shall be treated accordingly.

Estimation of radioactive waste and associated cost

Possible quantities of generated radioactive waste (in case KI shall leave a major building, e.g. ANA Futura, Biomedicum or Neo) is estimated not to exceed national limits (SSMFS 2018:3 Appendix 1, third column). All possible generated radioactive waste is assumed to be sent for incineration at a waste facility, except for a small amount of long-lived radioactive waste (primarily C-14) that must be kept in KI's central radioactive waste room until there is a national body for long-lived radioactive waste.

Based on KI's previous clearance of premises (for example upon moving into Biomedicum, when no major clean-up measures were required, except for radioactive waste for disposal) the cost of clearance is estimated to be about 30 kSEK/room. An extra cost of about 10 kSEK/room is estimated for the disposal of sealed sources. Measures that may be required for cleaning/exchanging contaminated areas, drains and/or ventilation is not included in this cost estimation.

Appendix 2

Isotope laboratory risk categories

Research with open radioactive sources is divided into the four risk categories specified in Table A2. Each risk level corresponds to a risk assessment by the RPE (radiation protection expert) based on Table A3. Tabled data provided by Karolinska University Hospital.

Risk category	Supervision	Premises classification	Staff categorization	Assessment
1 Extensive work	Annual	Controlled area	A	Minimum activity values of Table A2 Column 1 or Column 2 are/might be exceeded.
2	Annual	Supervised area (Controlled area if risk of airborne radioactivity)	B	Max activity values of Table A2 Column 2 (but not Column 1) are/might be exceeded.
3 Low activity	Annual	Supervised area	Non-categorized	Max activity values of Table A2 Column 3 could not be exceeded.
4 Non-active license	Semi-annual	Supervised area	Non-categorized	Holding only, and not exceeding Table A2 Column 2.

Table A2 *Risk categories for radioactive isotope laboratories at KI.*

Radioactive isotope	Column 1 Minimum handled activity (MBq)	Column 2 Minimum holding (GBq)	Column 3 Maximum handled activity (MBq)
H-3	1000	50	1000
C-11	100	5	1
C-14	100	5	10
O-15	100	50	1000
F-18	100	5	1
P-32	25	5	0,1
P-33	250	50	100
S-35	100	50	100
Cr-51	1000	5	10
Cu-64	500	5	1
Ga-66	500	5	1
Ga-67	500	5	1
Ga-68	100	5	0,1
Y-90	25	5	0,1
Tc-99m	500	5	10
In-111	250	5	1
I-123	250	5	10
I-125	5	5	1
I-131	5	5	1
Ra-223	Regardless of quantity	Regardless of quantity	NA

Table A3 *Activity levels specified for gamma isotopes are based on an activity that at 1 m distance from a source does not exceed 20 µSv/h, which for a 1.5 h/day and 200 days/year would annually correspond to 6 mSv. Activity levels for alpha and beta irradiation are based on internal contamination (intake/inhale) where limits are set to 10 % of an activity that would correspond to 6 mSv for a single intake/inhalation. This same limit is applied to combinations of gamma and alpha/beta. A holding of isotopes not listed shall be assessed by the RPE.*

Appendix 3
Functional check instructions

Radiation protection instruments
Functional check-ups of radiation protection instruments shall be carried out before each experiment by the users.

- Check that the probe looks intact and that there are no visible holes or damages on the probe's entrance window. If damage is detected, contact the RPE (radiation protection expert) without delay.
- Switch to the BAT position to check that the batteries are charged. If the indicator shows less than 30%, the batteries shall be replaced with fully charged batteries (or recharged if rechargeable batteries) before the next step.
- Switch to ON position. There shall be an audible sound to indicate that the system is on. If no sound is heard when selecting the "on" mode or if no radiation is detected at all (when checking a known source), contact the RPE without delay.

Ionization chamber and electrometer
Functional check-ups of ion chambers and electrometers shall be carried out annually by the RPE. Check-ups shall be documented by the RPE.

- Check that ionization chamber is safely stored in a dedicated storage area.
- Check that there is no visible damage to either the chamber or contacts. Do a visual check of the electrometer. If any damage is detected, the instruments shall be calibrated.
- Connect the ion chamber to the electrometer. Turn on the electrometer. Select the correct ion chamber ID. Check that no error messages appear on the display. If any error message appears, a calibration shall be carried out.

Appendix 4
Calibration instructions

General calibration information

- Measured values shall be compared against the average value of the original and previous measurements, where the tolerance level is 20% and the action level is 50%.
- If the measured value exceeds tolerance the level, but is lower than the action level, the interval between checks must be reduced.
- If the measured value exceeds the action level or exceeds the tolerance level three times in a row, the instrument shall be taken out of service. The RPE (radiation protection expert) shall assess whether instruments should be sent for service, calibration (by a second standard dosimetry laboratory), or be decommissioned.
- Calibrations shall be documented by the RPE.

Radiation protection instruments

KI's radiation protection instruments shall be calibrated annually.

- The radiation protection instrument's probe window shall be placed facing the calibration radiation source (pen source, Eckert & Ziegler Nuclitec, type QCRB1282, s/n BC-7137). The distance between radiation source and probe shall be kept identical between measurements.
- Perform the measurement with and without the source's protective cap for 30 seconds. Record the measured values. Evaluate.

Ionization chamber and electrometer

One electrometer and ionization chamber pair shall be calibrated every five years by a second standard dosimetry laboratory and thereafter used for cross calibrating the remaining electrometer and ion chamber pairs.

- Connect all ion chambers to each electrometer respectively.
- Turn on all the electrometers (voltage and polarity: -400 V) and allow them to warm-up for at least 15 minutes before measurement.
- Place an ion chamber in the X-ray cabinet on FSD 60 cm.
- Irradiate (with 300 kV and 195 kV respectively, and filtration of interest) for 60 seconds and record the measured values. Evaluate.

Appendix 5

Wipe test instructions

Possible contamination from low-energy beta emitting isotopes (e.g., H-3) shall always be measured with wipe tests. Although some medium-energy beta emitters might be possible to detect with certain radiation protection instruments (e.g., C-14 and S-35), the measurement efficiency of these measurements are generally very low; hence possible contamination of medium-energy beta emitting isotopes shall also be measured with wipe tests.

- Use protective gloves. Change gloves if any contamination is suspected.
- Create a numbered list with a number for each area/object to be measured including a number for the background.
- Take scintillation tubes and label the lids with the respective numbers.
- Start with the background wipe test, which shall undoubtedly be free of contamination.
- Wet a filter paper (or other absorbent material) with alcohol or Count-Off.
- Drag the filter paper over the surface with one even stroke in one direction. If the sampling is done on a larger surface: wipe a 10 X 10 cm^2 area. If sampling smaller objects: wipe the actual area. Use disposable tweezers if high contamination is suspected.
- Place the filter paper in a labelled scintillation tube and fill with scintillation fluid. Check that labels match the numbered list.
- Shake thoroughly before analysing the wipe test samples in a liquid scintillation beta counter.

Appendix 6

Contamination check

Use the radiation protection instrument located in the lab for gamma and high-energy beta radiation. Use wipe test for low-energy beta radiation (instructions in Appendix 5).

- Measure the background (i.e. make sure there is no source/contamination nearby) and record the value.
- Measure work surfaces, hands, and lab coat, and record the values. In case of suspected floor contamination, measure shoe soles, as well.
- If contamination exceeds three times the background value, record the values and clean the contaminated surfaces with soap and water (or Count-Off). Paper towels/cleaning cloths shall be treated as radioactive waste. Repeat measurement and cleaning until measured values are less than three times background. If contamination persists, contact the RPE (radiation protection expert).
- If contamination exceeds ten times the background value, contact the RPE without delay. Cleaning shall be carried out in consultation with the RPE.
- Record all measurements and keep the documentation in a folder at the isotope laboratory.

Appendix 7
Measures to take after a radioactive spillage

General

- Staff not involved in the spillage shall leave the premises without delay if they are not suspected of being contaminated. The cleaning staff shall never be asked to clean until clearance is confirmed.
- The contaminated area shall be marked, including a notice on the door. Employees in adjacent spaces shall be informed of the incident.
- Protective clothing (coat, double protective gloves, and shoe covers) shall be worn and changed without delay in case of suspected contamination.
- Contamination shall generally be checked according to the instructions in Appendix 6.
- Cleaning materials and contaminated clothing shall generally be handled as radioactive waste. If an excess quantity arises, the contaminated material shall be placed in a well-sealed and marked (date, isotope, amount of activity, and contact person) plastic bag.
- All staff involved in the cleanup shall be checked for contamination.
- Record all measurements and keep the documentation in a folder at the isotope laboratory.

Surface contamination

- Spills on surfaces shall be absorbed with absorbent material. Wipe from the outer edge of the contaminated surface inwards. Never rub as this may spread contamination to a larger area.
- When as much as possible has been absorbed, the surface shall be cleaned and checked for contamination after cleaning. Continue cleaning (according to Appendix 6) until further washing shows no sign on contamination.
- If contamination persists, the surface must be covered with plastic paper and labelled (radionuclide, estimated amount of activity that has been spilled, the latest measured value after cleanup, and the name and telephone number of the radiation protection assistant). The area must be marked with warning tape and the door with a note

of the incident. The RPE (radiation protection expert) shall be informed.

Personal contamination

- Splashed clothing shall be removed without delay. Remember that shoes might be contaminated as well.
- Remaining clothes and skin shall be checked for contamination (method described in Appendix 6). At this moment, staff shall help each other.
- Contaminated skin shall be rinsed (never scrubbed) repeatedly (at least three times) with lukewarm water (mild soap can be used, but never solvents or cleaning agents containing alcohol, which reduce the skin's own protective function). If a large part of the body is contaminated, contaminated staff shall put on non-contaminated shoes and go to the nearest changing room to shower. Continue washing/rinsing contaminated skin until contamination free.
- In case of suspected splashing in the eyes, repeated eye washes shall be carried out without delay.
- If possible, allow contaminated wounds bleed for a while, then rinse thoroughly with water.
- In case of suspected internal contamination (oral/inhalation) or if contamination persists despite extensive rinsing, the assistant shall contact the RPE (office hours) and the health care advisory service on phone number 1177 (after office hours). Occupational health care shall be contacted regarding follow-up.

Appendix 8

Activity estimation for radioactive waste containers

The formula below shall be used to estimate the amount of activity A(t) at a certain time (t).

$$A(t) = A(t_0) \cdot e^{-(t-t_0)\cdot \ln(2)/T}$$

- $A(t_0)$ is total activity in the original stock solution at reference time t_0.
- T is the nuclide's half-life.

To estimate the amount of activity added to a radioactive waste container, use the original radioactivity of the stock solution to calculate the following:

- the amount (if any) remaining in the stock solution
- the amount (if any) that is lost as liquid waste
- the amount (if any) that is lost as scintillation liquid
- the amount (if any) that is lost as biological waste.

These amounts of radioactivity shall be subtracted from the original. The calculated activity shall be recorded on the logbook attached to the radioactive waste container. Rather overestimate than underestimate the amount of radioactivity.

If waste consists of more than one radioactive isotope, total activity shall be calculated using the formula below, where c_i is the amount of activity of radionuclide i, and $c_{FN,i}$, is the limit level for radionuclide i. The RPE (radiation protection expert) shall be contacted for advice.

$$\sum_{i=1}^{n} \frac{c_i}{c_{\mathrm{FN}i}} < 1$$

Appendix 9
Transport instructions for radioactive substances

Package requirements
Packages containing a radioactive isotope shall

- be properly marked (radionuclide, activity and time at specified activity, contact info)
- be properly shielded and sealed (must withstand being dropped from a standing height)
- not irradiate more than 5 µSv/h at the surface
- not be contaminated (i.e. gloves shall not be required).

Surface dose rate measurement
Surface dose measurements are required for gamma or high-energy beta isotopes. A radiation protection instrument adequate for gamma and/or high-energy beta shall be used.

- Determine the background radiation level by measuring with the radiation protection instrument in a nearby room.
- Measure the surface of the package by slowly moving the probe of the instrument close to the surface of the package without touching it.
- If any measured value exceeds 5 µSv/h, the radiation dose rate is too high. Either increase the shielding or divide the package into several packages with a smaller amount of activity in each package and measure again. The RPE (radiation protection expert) shall be contacted if the surface dose still exceeds 5 µSv/h.
- Record the measurement and keep the documentation in a folder at the isotope laboratory.