THE UNIVERSITY of EDINBURGH
Health & Safety Department

Radiation Risk Assessment Guidance

Unsealed Sources

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Function:	**Name:**
Author & lead assessor:	Mark Green (UoE, Radiation Protection Unit)
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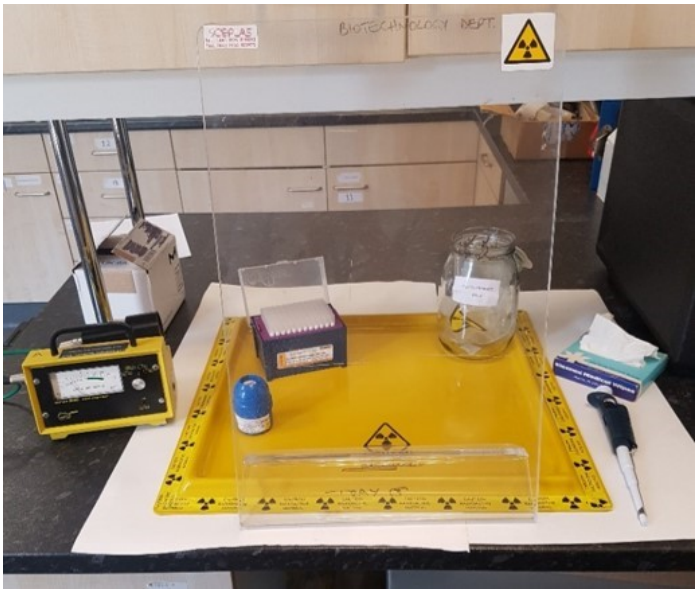
Summary of key Changes		
Version	*Date*	*Changes/Justification*
01	01/12/20	First version of the document
02	16/12/21	Clarifying that not ALL the possible accident scenarios listed in Section 4 need to have a dose estimate; only *reasonably foreseeable* accidents.

Contents

1 Introduction

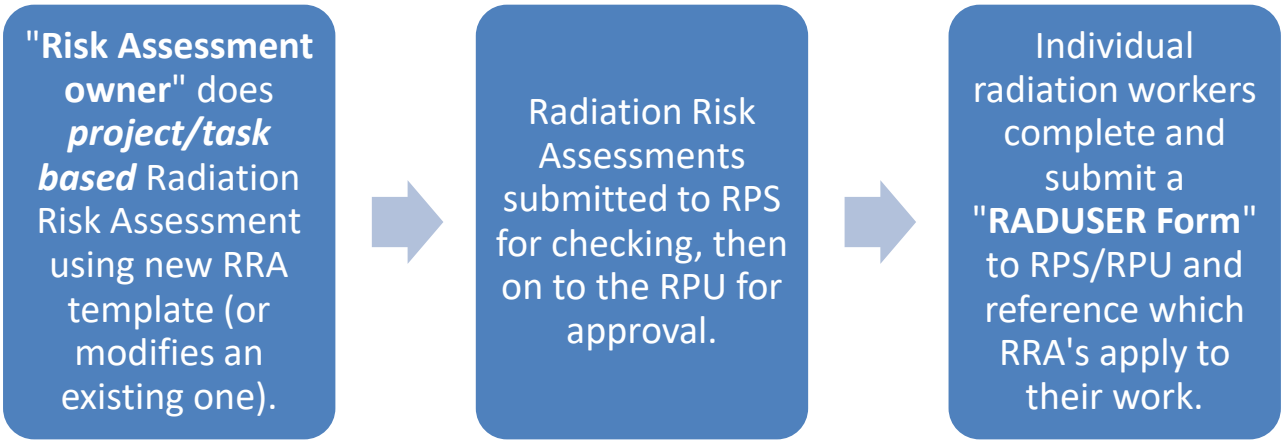


This Radiation Risk Assessment Guidance Note has been prepared to give staff and students a general appreciation of the kind of hazards and risks that should be considered when working with unsealed radioactive substances and to assist them in writing Radiation Risk Assessments (RRA) for their work with **unsealed (*open*) *sources of radioactive material.***

The Ionising Radiations Regulations 2017 (IRR17) and associated Approved Code of Practice (ACoP) [1] are enforced by the Health and Safety Executive (HSE). Regulation 8 of IRR17 requires employers to carry out a 'suitable and sufficient' assessment of the risks, for both routine and reasonably foreseeable accident situations, when working with ionising radiation. In order to be considered 'suitable and sufficient', the HSE expects all IRR17 ACoP Paragraph 70 (a) to (m) matters to have been considered, where they are relevant, and for the employer to decide on the appropriate next steps/decisions based on the matters in IRR17 ACoP Paragraph 71 (a) to (p), where they are relevant.

In order to meet the HSE's expectations of carrying out 'suitable and sufficient' risk assessments for its work with ionising radiation, the University has adopted a two-tier approach to Risk Assessment. This comprises of:

1. *A Project/task-based Radiation Risk Assessment (RRA); AND*
2. *A Signed individual 'Radiation User Registration (RADUSER) Form'*



1.1 Project/task-based Radiation Risk Assessments

The aim of this Radiation Risk Assessment Guide is to provide staff and students with a reference document containing useful information on how to complete a project/task based Radiation Risk Assessment using the Radiation Protection Unit (RPU) RRA template. The RRA template can be found on the Radiation Protection Unit (RPU) website under Risk Assessments at:
https://www.ed.ac.uk/health-safety/radiation-protection/radiation-protection-management

By completing the Risk Assessment in this way, the significant findings of the risk assessment are recorded to demonstrate that it is suitable and sufficient. If applicable, e.g. for unsealed sources, the RRA template also includes a section to record the estimates of radioactive waste disposed of to each of the permitted disposal routes.

Project/task-based Risk Assessments must be reviewed every two years.

1.2 Radiation User Registration (RADUSER) Form

Each use of radioactive material must be justified therefore the radiation user must record on their individual RADiation USEr Registration (RADUSER) Form *why* they need to use and work with the radioactive material covered by the Radiation Risk Assessment. This ensures *each use* of radioactive material is justified; as required by IRR17 and the Environmental Authorisation (Scotland) Regulations 2018 (EASR).

The RADUSER form is also used to:

- Record details about the individual working with the radioactive material;
- Ensure persons have had the required training to carry out the work;
- Ensure that the RPSs are aware of the work;
- Ensure the University RPU is aware of the work and has advised on any personal dosimetry requirements or any other control measures;
- Ensure the University has notified, registered or had consent from the HSE about the work being carried out;
- Ensure the work will not exceed any of the limits or conditions in its authorisations issued by the SEPA;
- Record any additional *task-specific* control measures that have been taken to further reduce the risk; these additional controls, if applicable, supplement the project/task-based risk assessment;
- Ensure any especial risks have been accounted for where they are necessary (for example, a pregnancy review section is included on the form);

2 Justification of work with ionising radiation

Three basic principles apply when working with, or planning to work with, ionising radiation:

1. Justification (benefit must outweigh risk)
2. Optimisation (keep doses as low as reasonably practicable – ALARP)
3. Limitation (keep doses below legal limits)

The University must apply these basic principles in its work with ionising radiation. Justification is a fundamental requirement of radiation protection and a balance must be struck between the potential benefits of the work with radiation against the potential harm from it. Justification can be thought of as a two-stage process:
STEP 1: Justify the *class* or *type* of practice involving ionising radiation; and
STEP 2: Justify each individual *use* of ionising radiation.

STEP 1:
This process of justification is the process of ensuring that before any new class or type of practice involving ionising radiation can be introduced in the UK, the Government must first assess it to determine whether the individual or societal benefit outweighs the health detriment it may cause. A good recent example of this is the use of x-rays in sports medicine to monitor athlete's performance. The current list of *justified practices* can be found on the .gov.uk website and the relevant regulations are the *Justification of Practices Involving Ionising Radiation Regulations 2004*, as amended, 'JPIIRR' 2004.

All current work at the University is expected to be justified in accordance with the above regulations but it is possible, that due to research, new practices may be planned. A list of justified practices, relevant to the University's work with ionising radiation, is shown in 2.1 below and is reproduced in the Radiation Risk Assessment template. The box relevant to the work covered by the risk assessment must be ticked by the Risk Assessor. If the work proposed to be carried out under the risk assessment is not listed, then users are directed to contact the Radiation Protection Unit radiation@ed.ac.uk in the first instance.

STEP 2:
This is the process of ensuring that risks are optimised and no radioactive waste is unnecessarily generated; i.e. the process of deciding 'Do you actually need to do the work?'. As this is an individual decision, determined for each individual working with ionising radiation on a case-by-case basis, it cannot be recorded on the project/task-based Radiation Risk Assessment. Individuals must therefore record a statement of justification on their RADUSER Form. A space to make this statement of why they need to use radioactivity is included in the template.

2.1 List of justified practices relevant to University work

The table below contains an abridged list of existing classes or types of practice that are relevant to the University's work with ionising radiation.

#	Area	Class or type of practice
5.	Production of radioisotopes	Manufacture of radioisotopes using nuclear reactors & accelerators.
6.	Production of radioactive products	Manufacture of radioactive sources, substances & radiopharmaceuticals.
7.	Non-destructive testing	Use of radioactive sources, substances & radiation generators for radiography.
9.	Radiation processing of products	Use of gamma, x-ray or electron beam radiation sources to reduce bacterial levels, sterilise, disinfect or modify materials.
11.	Detection & analysis	Use of sealed sources & x-ray generators for analysis.
15.	Safety Devices	Use of ionising radiation in smoke and fire detectors and other safety instruments.
17.	Equipment producing ionising radiation incidentally	Use of electron beam welders, electron microscopes, radar, thermionic valves, cathode ray tubes, ion implantation machines & high voltage switchgear.
18.	Radioactive tracers	Use of radioactive tracers for medical or biological techniques.
23.	Medical & biomedical research	Use of ionising radiation in radiography, fluoroscopy, interventional radiography, computed tomography, in-vivo nuclear medicine, in-vitro nuclear medicine, teletherapy, brachytherapy & neutron activation analysis.
25.	Diagnosis & therapy - Veterinary	Use of ionising radiation in radiography, fluoroscopy, computed tomography, in-vivo nuclear medicine, in-vitro nuclear medicine, teletherapy & brachytherapy.
26.	Teaching, including further & higher education & training	Use of radioactive sources, substances & radiation generators.
28.	Ionising radiation metrology	Use of calibration sources in the testing of equipment.
29.	Transport of radioactive material	Transport of radioactive material by road in accordance with ADR
30.	Use of Uranium and Thorium (other than for its fertile, fissile or radioactive properties)	Use of Uranium and Thorium compounds as laboratory reagents. Other uses of Uranium and Thorium other than for their fertile, fissile or radioactive properties.

Notes:

1. *# is the number of the justified practice from Annex 2 in the JPIIR Regulations 2004.*
2. *Practices involving medical diagnosis and treatment are deliberately excluded from this list as the University must involve a medial radiation protection professional. Contact radiation@ed.ac.uk for more information.*

3 Risk Assessment – Approved Code of Practice Paragraph 70

3.1 (a) The nature of the sources of ionising radiation to be used, or likely to be present, including accumulation of Radon in the working environment

What the HSE expects	Further Guidance
• List all of the radionuclides being used and give a description of their physical form.	• Consider all of the radionuclides that will be used and whether any changes in phase occur during the work covered by the Risk Assessment. • Is there any heating of solutions that creates gas/vapour? Any grinding of solids? Any solid waste generated? Any scintillation fluid waste generated?
• Maximum energies and emissions	• Consider the maximum energy, emission (e.g. Alpha, Beta, Gamma, etc), physical and biological half-life, target organs, range in air, etc. • It may be useful to include a datasheet of the radionuclides used in an Appendix to the RRA like the ones found in 'The Radionuclide and Radiation Protection Handbook 2002'. A copy of the Handbook can be downloaded for those in academia at the link here: https://academic.oup.com/rpd/article/98/1/1/1679556
• Typical and maximum activities and activity concentrations likely to be used	• Consider the quantities that are used on a regular basis and, where relevant, any stock quantities worked with. The RRA should consider the maximum activity and maximum activity concentrations likely to be handled/worked with at any one time as well as those activities that might regularly be used. • Consider whether work is required to take place out of normal working hours under this Risk Assessment. The higher the activity used, the greater the risk of spreading significant contamination around. In general, access to RPA advice may not be available out of hours and so an upper limit is applied to work with radioactive substances out of hours as per below (NOTE, these activities apply to the max. activity handled at any one time): ○ P-32: 1 MBq; ○ All other radionuclides: 10 MBq

What the HSE expects	Further Guidance
• Radon assessment (if required)	• Check whether the work is being done in a Radon affected area here → www.ukradon.org. • If the building/lab/etc. is NOT in a Radon affected area, and the work is not in a basement, no further Radon measurement is required. State this in the RRA. • If the building/lab/etc. is NOT in a Radon affected area, and the work is in a basement, a Radon measurement is recommended. The University carried out Radon measurements in all its basements in 2019 and all results were found to be below the Action Level (300 Bq/m^3). ○ Contact the RPU to confirm if your building was included in the RPU check. If it was, include this in your Radiation Risk Assessment. • If the work IS in a Radon affected area, then it may be necessary to further check the Radon levels within the immediate working area. See: https://www.ukradon.org/services/address_search

3.2 (b) Estimated radiation dose rates to which anyone can be exposed

What the HSE expects	Further Guidance
• Estimate dose rates and doses to which anyone can be exposed.	• Estimate whole body doses, doses to extremities (e.g. hands), eyes (if applicable), internal doses, etc. at ALL stages of the work. • Also consider ALL persons that could be exposed from the work. An example list is given in the RRA template of the type of persons that could be exposed but this is not intended to be exhaustive. • In order to comply with IRR Reg 12(3), each RRA must include an estimate of the dose to members of the public from the proposed work. • **Include estimated doses from ALL tasks; from receiving the material to its eventual disposal; including storage and all reasonably foreseeable accidents.**

What the HSE expects	Further Guidance

• Consider both routine and accident situations.	• As this part of the RRA can involve a number of different steps/stages, estimated doses and dose rates should be recorded in Appendix 1 of the RRA Template.
	  ○ Part 1 should be used to record the estimated doses to all persons affected by the work from *routine tasks*.
	  ○ Part 2 should be used to record the estimated doses to all persons affected by the work from *reasonably foreseeable accident situations*.
	• Consider the activities handled at each stage of the process, the length of time spent doing each task, the distance from the source and whether there is any shielding in place (*and how effective that shielding is*).
	  ○ For example, a radioactive stock may be dispensed for a short time, giving a high initial risk for that part of the work, but a lower estimated dose than for the situation where a lower activity aliquot is handled and worked with for a longer period of time.
	• Further guidance on how to estimate doses from various tasks is given in Appendix 1 of this document.

3.3 (c) The likelihood of contamination arising and being spread

What the HSE expects	Further Guidance
• Consider how contamination can arise.	• The physical form of the material will have a significant effect on the likelihood of contamination arising and being spread. • In unsealed/open source laboratories using liquid sources of radioactive material, contamination events are to be expected, albeit infrequently, at various stages of the work. • If aqueous wastes are disposed of via a designated sink in the laboratory, pipework can become contaminated, requiring controls to be in place, or checks to be carried out, before maintenance staff access the pipework.

What the HSE expects	Further Guidance
• Consider how contamination could be spread outside the working area.	• Regular area contamination monitoring being carried out with suitable instrumentation. • Frequent contamination monitoring of hands and immediate working area being carried out during high risk work (e.g. dispensing from stock vials/containers). • Hand washing facilities provided at the exit to the area and maintained with hot & cold running water, soap & paper towels, nail brush, etc. • Provisions for allowing personnel to monitor themselves, and any items or equipment, when exiting from the area (e.g. contamination monitor). • Poor safety culture, e.g. staff choosing not to monitor themselves or wash their hands upon exit from the lab, can lead to contamination being spread outside the working area.

3.4 (d) The results of any previous personal dosimetry or area monitoring relevant to the proposed work

What the HSE expects	Further Guidance
• Is there any results from previous dosimetry that could support the estimates in this risk assessment?	• If a similar task or operation to the one being assessed has been carried out in the past, and those carrying out that task had been subject to personal dose monitoring, then those results might help to estimate the doses for this new risk assessment. • Consider any previous results from whole body dosemeters, extremity dosemeters, biological monitoring and from any Electronic Personal Dosemeter (EPD) campaigns carried out. • One of the duties of an RPS is to collate the dose information for work in their area; it may be worth asking your RPS about any dose results from persons in your area doing similar work. • If personal dosimetry results are available for similar work in your area, record the average and highest results for each year from the last 3-5 years in the RRA.

What the HSE expects	Further Guidance
• Results from any previous area monitoring	• Where there is a risk of gamma radiation from the proposed work, record the results from any monitoring of the environment (for example, dosimetry results from TLDs placed outside the controlled area OR Radiation Protection Unit surveys). • Review any area contamination monitoring results from the area. Is there evidence of contamination regularly being spread? Are all contamination monitoring results within twice the instrument's background count rate indicating that contamination is not arising from similar work? • If there is a risk of airborne contamination, are there any previous activity-in-air results or measurements that can be referenced?

3.5 (e) Advice from the manufacturer or supplier of equipment about its safe use and maintenance

What the HSE expects	Further Guidance
• Radioactive Stock vials	• Unsealed sources of radioactive material will likely come in glass or plastic vials and will generally have opening procedures to ensure safe opening. These should be considered in any risk assessment. • For example, opening and dispensing guidance for the NENSure Packing System by Perkin Elmer can be found here: https://www.perkinelmer.com/content/technicalinfo/tch_nensurepackagingsystem.pdf • Opening and dispensing guidance for the Hartmann Analytic system can be found here: https://www.youtube.com/watch?v=TmBAFRg1Zok&feature=youtu.be • No opening and dispensing guidance is supplied for the American Radiolabeled Chemicals (ARC inc.) range of products.

What the HSE expects	Further Guidance
• Other laboratory equipment which may come with manufacturer's advice on its safe use/maintenance.	• There may be other equipment in the laboratory that you need to consider in the Radiation Risk Assessment about its safe use and maintenance. For example, hot cells will need regular maintenance to ensure they remain effective and Liquid Scintillation Counters will need regular servicing. • A list of equipment you may wish to consider regarding safe use and maintenance is provided below (note, the list is intended to be a guide; you do not have to consider the safe use and maintenance of all the equipment in this list if it isn't relevant to the radiation risk assessment): • Macerators • Centrifuges • Liquid Scintillation Counters • Magnetic Stirrers • Gel Docs • Hybridisation Ovens • Contamination monitors • Electrophoresis kits • Heat blocks • Hot cells • Sonic Baths • Scales

3.6 (f) Engineering control measures and design features already in place, or planned

What the HSE expects	Further Guidance
• What engineering controls are in place, or planned, to ensure exposure of persons are kept as low as is reasonably practicable (ALARP).	• General Health and Safety legislation, as well as IRR17, requires the adoption of a hierarchy of control measures when carrying out risk assessments. • Once a decision has been made to work with radioactive material or work with radiation, the primary control measure for reducing exposures to ionising radiation is *engineering controls and design features* (e.g. shielding and containment) supplemented by appropriate *safety features and warning devices* (e.g. interlocks, pre exposure signals). • Engineering controls and design features are those that are normally *built-in* control measures such that the facility, device or work cannot proceed if they are not in place. Example engineering controls for work with unsealed radioactive material could include:

What the HSE expects	Further Guidance
	○ Local shielding to reduce external radiation (e.g. vials, transport lead pots, shielded source stores) ○ Local containment (e.g. stock arrives in vials, shielded waste bins) ○ Laboratory design features that consider the likelihood of contamination arising and being spread (e.g. easily decontaminable surfaces, separating radioactive work from non-radioactive work, smooth impervious floors, arrangements that allow area or equipment to be safely decommissioned at the end of its life, etc.). ▪ Further guidance on the design of radiochemical laboratories can be found in RP CoP014. ○ Adequate ventilation if there is a risk that airborne contamination could arise. Fume cupboards, filtration units, etc should be designed and constructed specifically to consider radioactive contaminants from the work. Filters should be able to be removed with minimal dose to individuals. ○ Equipment used in labs where unsealed radioactive material is used must be designed and constructed to make it easy to maintain, clean and decontaminate.

3.7 (g) Any planned systems of work

What the HSE expects	Further Guidance
• After engineering controls have been considered and implemented where practicable, systems of work, normally incorporated into the Local Rules, should be followed.	• Engineering controls are controls that are built-in and intrinsic to the work. Any control measure that can be by-passed, e.g. a person can choose not to use it or follow it, is a procedural control. • Systems of work are essentially a list of instructions or *procedural controls* to be followed by employees to restrict their exposure to ionising radiation. • It is expected that in work with unsealed radioactive material, the list of procedural controls will be considerably longer than the engineering controls due to the type of work being carried out. Some examples of typical procedural controls in unsealed work are listed below:

What the HSE expects	Further Guidance
	○ Use of drip trays at workstations, benchkote®, bench-top plastic shields for beta work, pipette shields, shielded waste containers, etc ○ Personal and area contamination monitoring ○ Written arrangements for non-classified persons working in Controlled or Supervised Areas ○ Procedures for cleaning up minor spillages during normal work ○ Minimising time spent with patients containing radioactive material ○ Appointment of a Radiation Protection Supervisor to supervise the work • More procedural controls relevant to work with unsealed radioactive material are listed in 5.1 and 5.2 covering IRR17 ACoP 71(a) and 71(b).
• Are any 'Permit-to-Work' arrangements required?	• 'Permit-to-work' (PTW) arrangements are a strict set of management controls on how a certain work task will proceed, how it will be done and how it will be supervised to ensure persons exposure to radiation and radioactive material is kept as low as is reasonably practicable. • Examples where 'Permit-to-Work' arrangements may need to be considered might be: ○ In labs with designated disposal sinks, a PTW may be needed by maintenance staff who fix or maintain the plumbing to record that a check is made of the pipework for contamination before they work on it. This check may not always necessarily include the designated sink as other pipework in the lab, up until the point at which the pipework meets the main flow, may also need checked for contamination. ○ Where maintenance staff access ventilation systems to replace filters from labs with fume cupboards where radioactive material is used and where airborne contamination has been identified as a risk. ○ Access to rooftop areas by maintenance staff where elevated dose rates from x-ray generating equipment pass through a false ceiling ○ The setting up and alignment of x-ray optics equipment

3.8 (h) Estimated levels of airborne and surface contamination likely to be encountered

<table>
<tr><th>What the HSE expects</th><th>Further Guidance</th></tr>
<tr><td>• If there is an airborne risk, what levels might be found?</td><td>
• If there is radioactive material present in liquid form, is there any risk of it evaporating? What would the airborne contamination levels be if it did?
• Is there any heating of liquid radioactive material done as part of the work? Heating of any liquid radioactive material could give rise to an airborne hazard.
• Is any part of the system under pressure which might increase the airborne risk if there was a loss of containment?
• Would there be an airborne risk if the product was dropped in an accident scenario? The table below gives some published data for airborne release fractions[1] for some reasonably foreseeable scenarios:
<table>
<tr><th>Scenario</th><th>Airborne Release Fraction (ARF)</th></tr>
<tr><td>Release of gas/vapour</td><td>1.0</td></tr>
<tr><td>Aqueous Liquid – thermal stress (e.g. heating)</td><td>3×10^{-5}</td></tr>
<tr><td>Aqueous Liquid – thermal stress (e.g. boiling)</td><td>2×10^{-3}</td></tr>
<tr><td>Venting of pressurised liquids (e.g. vials under pressure)</td><td>1×10^{-4}</td></tr>
<tr><td>Free-fall spill 3m - a dropped vial of liquid</td><td>4×10^{-5}</td></tr>
<tr><td>Free-fall spill 3m - a dropped powder</td><td>3×10^{-4}</td></tr>
</table>
</td></tr>
</table>

[1] For discrete events, the Airborne Release Fraction (ARF) is the fraction of the material affected that could be released as an aerosol and thus available for inhalation. Data taken from “DOE Handbook: Airborne Release Fractions/Rates and Respirable Fractions for Nonreactor Nuclear Facilities” DOE-HDBK-3010-94; 1994.

What the HSE expects	Further Guidance
	• In some cases, for example work with compounds of iodine in liquid form, there might be a small quantity of gas or vapour released when the container is opened. It is often difficult to avoid this but nevertheless, the risk must be assessed; for example, if the RRA covered work with Iodine-125, it might say that any stock vials or samples must be opened inside a fume cupboard. • Consider the size of the room, the ventilation (e.g. No. of air changes that occur in the lab), the laminar flow of the fume cupboard, the volume and activity concentration of air discharged to the environment from fume cupboards. • Is any Respiratory Protective Equipment (RPE) required to protect against the hazard? If so, then persons must undergo a Face-Fit test to ensure they are adequately protected.

• If there is a risk of surface contamination, what levels could be found?	• If stock material is worked with, what maximum activity concentration could a surface or person become contaminated with if it was spilled in an accident?
	• If the stock material is diluted at one or more stages during the process, what activity concentration could a person or surface become contaminated with in the event of an accident at each stage of the process?
	• Consider what contamination monitoring is routinely carried out in the area and the minimum detectable activities that might be on a surface.
	  ○ For example, the typical background of a Mini 900 type EP15 probe is 0.5-2 cps and therefore a twice background action level of 4 cps could equate to a minimum detectable activity for surface contamination of 3 Bq/cm^2 on the surface if C-14 or 1 Bq/cm^2 on the surface if P-32
	• Remember, direct surface contamination monitoring cannot be done for Tritium. A Risk Assessment for tritium work should therefore consider the additional risk from the delay of finding out the surface contamination results after they have been counted in the LS counter.
	  ○ Typically, the ‘rule-of-thumb’ is that only 10% of the surface activity is removed and counted on the wipe so users need to factor this in when determining action levels for Tritium swabs.

3.9 (i) The effectiveness and the suitability of PPE to be provided

What the HSE expects	Further Guidance
• When engineering controls and Systems-of-work, e.g. procedural controls, have been implemented, is Personal Protective Equipment (PPE) required to further reduce the risk?	• PPE should always be considered as a 'last resort'. • PPE only provides protection to the wearer and not anyone else; for example, it does not protect other persons who may be working in the area from your work. • PPE should be 'personal' if being re-used • Typical PPE used in unsealed laboratories might be disposable gloves, disposable aprons, laboratory coats, overshoes, protective eyewear, etc. • Laboratory coats used in Controlled Areas for unsealed sources work must be dedicated to that area; i.e. they should remain in the Controlled Area and not be taken out (unless for laundering) to reduce the risk of spreading contamination out of the Controlled Area.
• How effective is the PPE in protecting against the hazard?	• For high energy gamma emitters like Iodine-131, the effectiveness of wearing lead aprons may not be beneficial. For example, a typical 0.35mm lead apron may reduce the external dose by 10% but, by wearing the lead apron, the time spent in the controlled area could be longer, making the task more cumbersome, and cause musculoskeletal issues. If a decision has been made not to wear PPE, this should be stated in the RRA. • Tritium is a very mobile substance and can penetrate through gloves depending on the compound used. In some cases, two pairs of gloves are worn with the outer gloves changed regularly to reduce the risk of the tritium passing through the inner gloves. • Taping of gloves to the lab coat cuffs can help to reduce the risk of contamination getting on to the skin.
• Maintenance of PPE	• Where PPE is supplied to protect against the hazard, it must be checked and maintained to ensure it remains fit for purpose. For unsealed laboratories this might include: o The regular checking of lab coats for contamination, o The regular laundering of laboratory coats,

What the HSE expects	Further Guidance
	○ Visually inspecting lab coats regularly to ensure there are no missing buttons which might prevent them being buttoned up properly, ○ Checking protective eyewear is not cracked or broken, ○ Inspecting overshoes for signs of damage before use; particularly in areas where overshoes are reused, ○ Inspecting reusable RPE on a regular basis and replacing filters when needed, • Disposable PPE, such as gloves, do not need to be examined if they are not being re-used.

3.10 (j) The extent of unrestricted access to working areas where dose rates or contamination levels are likely to be significant

What the HSE expects	Further Guidance
• Employers must be able to demonstrate how they control access to areas where work with radiation or radioactive material is being carried out.	• Although the regulations say 'significant', this effectively means access must be controlled to <u>any</u> Controlled or Supervised Area. • Person's required to enter a Controlled or Supervised Area need to have had sufficient information, instruction and training on the arrangements to be followed in that area to restrict their exposure to ionising radiation; this means access has to be controlled. • Physical barriers, e.g. doors and chain-link barriers, and warning signs are part of the measures to restrict access to Controlled and Supervised Areas. • However, other measures to ensure access is restricted might include: ○ Swipe-card access allowing only selected individuals to enter the area. How is swipe-card access managed? ○ Key-control access; If access to the area is key-controlled, who has access to the keys? Is there a list of all key holders kept?

What the HSE expects	Further Guidance
	○ If access to the area is by a PIN code, when was this last changed? Is there a list of person's who have been given the PIN code? • For all the managed access types above, consider who is responsible for 'approving' persons to the list? How are they checked to ensure they have had the appropriate information, instruction and training? Is the list regularly reviewed to remove staff who have left and to add newly trained staff?
• Do people not employed by the University of Edinburgh need to enter or work in the area?	• This could be service personnel, visitors, NHS workers, specialist consultants, etc.; essentially anyone not employed by the University of Edinburgh. • If there are persons from other employers entering your Controlled or Supervised Area then they are referred to as 'Outside Workers' under the regulations. • Their access to Controlled or Supervised Areas needs to be managed as the regulations require the employer in control of the area (i.e. the University) to check various bits of information before they can access the area. This is further discussed in ACoP 71 (k).
• Is the area 'handed over' to a contractor or service engineer?	• In some cases, particularly where equipment is concerned (e.g. an x-ray set or an irradiator), the area is 'handed over' to a contractor or service engineer. • When an area is 'handed over', that employer is then responsible for controlling access to his/her controlled area and this should be stated in their Local Rules. • If an area is handed over to a contractor or service engineer then this must be recorded. A 'Controlled Area and Equipment Handover form' is provided on the 'forms' area of the RPU website: https://www.ed.ac.uk/health-safety/radiation-protection/radiation-protection-management
• Entry to areas by members of the public and those who do not normally work with ionising radiation.	• For the risk assessment, consider how members of the public, or those who do not normally work with ionising radiation (for example other students/office staff) could access the working area. Remember, many of the University's buildings are open-access. • Arrangements must be put in place to restrict the doses of these persons; further information is given in ACoP 71 (m).

3.11 (k) Possible accident situations, their likelihood and potential severity

See Section 4 below.

3.12 (l) The consequences of possible failures of control measures – such as electrical interlocks, ventilation systems and warning devices – or systems of work

See Section 4 below.

3.13 (m) Steps to prevent identified accidents, or limit their consequences

See Section 4 below.

4 Possible accident situations, consequences and steps taken to prevent/limit them

4.1 Risk Rating (Likelihood x Severity)

When working with unsealed radioactive material, it is reasonably foreseeable that accidents could occur. In order for the risk assessment to be considered 'suitable and sufficient', all reasonably foreseeable accidents should be identified, the consequences of those accidents addressed, and the control measures taken to prevent, or limit the consequences of, those accidents occurring.

The Radiation Risk Assessment template aims to record these possible and reasonably foreseeable accidents in a table format so that a record is made of who might be affected by the accidents, what the consequences might be if the control measures failed, the Risk Rating assigned to those accidents (based on the likelihood and severity of those accidents occurring), the steps taken to prevent or limit them and the residual risk from those accidents with the steps/control measures in place. An example snip of the pro-forma table from the RRA is shown below:

#	Reasonably foreseeable accident situation(s)	Who is affected	Effect of failure of control measures	Likelihood	Severity	Unmitigated Risk (H/M/L)	Steps to prevent accident or limit its consequences	Mitigated Risk (H/M/L)	Comments / Notes / Recommendations / Actions
		•	•				•		

Some reasonably foreseeable accidents that could occur when working with unsealed sources, their possible effects, and examples of steps that could be adopted to reduce the likelihood and severity of those accidents are given in 4.2 below. Note, this list is not intended to be exhaustive and risk assessors should adapt it to suit their individual circumstances.

Each *reasonably foreseeable accident* should have its potential dose estimated as part of the Risk Assessment. The estimated doses from each of the reasonably foreseeable accidents should be recorded in Appendix 1 of the RRA template under section 8.2.

Assigning a risk rating is a good way of assessing and comparing risk from different tasks/scenarios. The risk rating is the likelihood or probability of that accident happening, multiplied by the severity of the consequences if that event occurred. For example, it might be quite likely (4) that a small spillage could occur during work with unsealed radioactive material, but the severity might only be minor (2) if the concentration was low and only a small radiation dose could be received which was below a local investigation level.

The Radiation Risk Assessment template includes a matrix, like the one shown here on the right, which should assist you in deciding what the likelihood is, and what is the severity of, any particular accident or incident from your work.

In most cases, the steps taken to prevent the accident, or limit its consequences, should reduce the likelihood and/or severity such that the probability of the accident occurring, after control measures are implemented, are low. However, this may not always be the case. A 'comments and recommendations' column is provided on the RRA template to record any actions taken, or recommendations made, to further reduce the overall risk.

Risk Rating	**Severity**				
Likelihood	**(1) Negligible** *Slight chance injury / background radiation dose*	**(2) Minor** *Minor injury/ dose below investigation levels*	**(3) Moderate** *Three-day injury / dose less than legal limits*	**(4) Major** *Major Injury/ dose > legal limits*	**(5) Extreme** *Fatal / dose > deterministic threshold*
(5) Very Likely *Very likely to occur / regular occurrence*	**(Medium)**	**(Medium)**	**(High)**	**(High)**	**(High)**
(4) Likely *Probable / Frequent Occurrence*	**(Medium)**	**(Medium)**	**(Medium)**	**(High)**	**(High)**
(3) Possible *Possible Occasional Occurrence*	**(Low)**	**(Medium)**	**(Medium)**	**(Medium)**	**(High)**
(2) Unlikely *Remote Rare Occurrence*	**(Low)**	**(Low)**	**(Medium)**	**(Medium)**	**(Medium)**
(1) Very Unlikely *Improbable Remote Occurrence*	**(Low)**	**(Low)**	**(Low)**	**(Medium)**	**(Medium)**

4.2 Examples of typical accidents from working with unsealed radioactive material

Note the table shown below is for guidance only and is not intended to be copied verbatim. Risk assessors must consider each individual circumstance relevant to their application.

Reasonably foreseeable accident situation(s)	Effect of failure of control measures	Steps to prevent accident or limit its consequences
• Loss or theft of radioactive material/waste	• Persons, including other staff and members of the public, could receive internal and/or external doses above dose investigation levels set out in the Local Rules or above public dose limits.	• Use of University approved couriers to transport radioactive material / waste; • Delivery, storage and acceptance instructions written into Local Rules and communicated to relevant staff; • Chain-of-custody established for handover of radioactive material delivered to the premises; • Radioactive material received on to the premises is transferred immediately to a secure store; • Only authorised personnel have access to radioactive stores; • Radioactive substances stores (including waste stores) are labelled appropriately to warn persons of their contents; • Swipe-card access controls are in place for rooms where radioactive materials or waste are stored such that only authorised personnel may enter.
• Minor spillage of radioactive material / waste contained within the controlled area	• Persons could receive internal and/or external doses above background levels but likely below the dose investigation level set out in the Local Rules.	• Use of spill trays and Benchkote® (or other absorbent liner) to contain small spillages during the work; • Lids kept on stock containers and samples when not in use to reduce risk of spillages; • Surfaces in the working area are designed so that they can be easily decontaminated;

Reasonably foreseeable accident situation(s)	Effect of failure of control measures	Steps to prevent accident or limit its consequences
		• Regular monitoring of surfaces within the working area before and after the work using a suitable contamination meter; • Practical training for staff at local level on how to deal with small spillages involving radioactive material; • 'Spills procedure' in Local Rules; • Spill kits available in working areas where large volumes are used to assist in the clean-up of minor spills; • Consideration given to whether radioactive decay could be used to reduce potential doses from clean up;
• Spillage of radioactive material / waste outside of controlled area during transfer between rooms or laboratories / buildings	• Persons, including other staff, undergraduates and members of the public, could receive internal and/or external doses above dose investigation levels set out in the Local Rules or above public dose limits.	• Radioactive substances are carried in suitable containers over long distances (e.g. between labs) such that the contents are unlikely to be released if they are dropped (e.g. screw topped lids); • Secondary containment is used when carrying liquid samples;
• Release of radioactive substances to the atmosphere	• Persons, including other staff and members of the public, could receive internal and/or external doses above dose investigation levels set out in the Local Rules or above public dose limits.	• Any work that could give rise to an airborne hazard is carried out in a Fume Cupboard with at least a -0.5m/s laminar flow at the sash; • All fume Cupboards used for radioactive material work are maintained and serviced at regular intervals; • Radioactive substances are carried in suitable containers over long distances (e.g. between labs) such that the contents are unlikely to be released if they are dropped (e.g. screw topped lids);

Reasonably foreseeable accident situation(s)	Effect of failure of control measures	Steps to prevent accident or limit its consequences
• Spread of radioactive contamination outside the Controlled or Supervised Area	• Persons, including other staff and members of the public, could receive internal and/or external doses above dose investigation levels set out in the Local Rules or above public dose limits.	• Only authorised staff enter controlled areas where contamination could be present; • Staff only enter controlled areas when necessary; • Surfaces in the room are designed so they can be easily decontaminated if required; • Persons carry out a contamination check of their workstation before and after their work to assist in the identifying of contamination events; • Persons carry out personal and area contamination monitoring regularly during the work (e.g. checking gloves after manipulations or checking vial lids before handling); • Personal Protective Equipment is worn during the work as described in the Local Rules and is not removed from the area; • Persons carry out personal contamination monitoring before leaving the working area; • Items that are removed from the working area are checked for contamination; • A routine area contamination monitoring programme is carried out as outlined in the Local Rules; • Persons adopt good contamination control procedures when working with unsealed radioactive material; • If contamination is identified outside the Controlled or Supervised area, contingency plans direct the user/reader to cordon off the immediate area and restrict access to the area to only those assisting with the clean-up.

Reasonably foreseeable accident situation(s)	Effect of failure of control measures	Steps to prevent accident or limit its consequences
• Workstation contaminated by previous user	• Persons could receive internal and/or external doses above background levels but likely below the dose investigation level set out in the Local Rules.	• Local Rules instruct persons to carry out a contamination check of their workstation before and after their work to minimise the risk of leaving contamination for the next user; • Persons carry out personal and area contamination monitoring regularly during their work (e.g. checking gloves after manipulations or checking vial lids before handling); • Workstations are included in routine contamination monitoring programmes due to them being a high risk for contamination;
• Personal contamination (staff)	• Persons could receive internal and/or external doses above background levels but likely below the dose investigation level set out in the Local Rules.	• Cuts/breaks in the skin are covered with a waterproof dressing; • Personal Protective Equipment is worn during the work as described in the Local Rules and is not removed from the area; • Persons check hands etc. after manipulating radioactive substances to minimise the length of time that contamination could be present on the skin/glove/lab coat etc.; • Persons carry out personal contamination monitoring, including hand-washing, whenever leaving the Controlled Area;
• Skin or puncture wounds	• Persons could receive internal and/or external doses above background levels but likely below the dose investigation level set out in the Local Rules.	• No re-capping of sharps is carried out and used sharps are placed straight into a sharps container adjacent to the workstation; • Sharps are not carried across laboratories or between labs; • Staff cover wounds with suitable waterproof dressings before entering the area when working with unsealed radioactive material;

Reasonably foreseeable accident situation(s)	Effect of failure of control measures	Steps to prevent accident or limit its consequences
		• Contingency Plan in Local Rules to advise staff on the actions to be taken in the event of a puncture wound; • Wounds are irrigated with plenty of running water with care taken to limit the spread of contamination to other parts of the body (wet wipes or similar could be used to remove the bulk of the any activity prior to washing); • Advice of the RPA is usually sought after skin or puncture wounds involving radioactive substances.
• Fire in the vicinity of the Controlled Area	• Persons, including other staff and members of the public, could receive internal and/or external doses above dose investigation levels set out in the Local Rules or above public dose limits.	• Persons follow normal University fire evacuation procedures; • Stock material and samples are returned, where possible, to secure fireproof stores when not in use to minimise the risk of dispersal; • Staff monitor themselves upon exit from the Controlled Area or, in the case of an emergency, take a contamination meter with them and monitor themselves for contamination when safely away from the building.

5 Risk Assessment – Approved Code of Practice Paragraph 71

5.1 (a) The action needed to make sure the radiation exposure of all people is kept as low as is reasonably practicable

What the HSE expects	Further Guidance

• What control measures are in place to reduce the exposure to all persons from EXTERNAL radiation to levels that are as low as reasonably practicable?	**EXTERNAL RADIATION**
	In addition to the control measures referred to elsewhere in this guidance note, the following control measures should be considered to restrict persons from external radiation exposure.
	• Selecting the lowest amount of radioactivity to achieve the desired purpose;
	• Radioactive stock stored in suitable stores, where external dose rates are below 2.5µSv/h when not in use;
	• Acrylic/polycarbonate screens and pipette shields to eliminate external radiation to the torso and the fingertips respectively;
	  ○ For high-energy betas like P-32, torso screens and pipette shields of 10mm are sufficient;
	  ○ For low-energy betas like H-3, C-14, and S-35, torso screens and pipette shields are not required to protect against the external hazard (but see contamination control measures below);
	• Lead castles or lead-loaded screens to reduce the dose rate to the torso from gamma radiation;
	  ○ Where the measured dose rate at the torso is greater than 2.5 µSv/h, shielded screens or lead castles must be used to protect the worker;
	  ○ See Appendix 1 for tenth-value layers (TVLs) for some commonly used radionuclides;
	  ○ Lead-loaded acrylic/polycarbonate screens, which can be distinguished from normal ones by their brown hue, are typically 12mm thick (0.5mm Pb equivalence) and will reduce the dose rate from I-125 to less than 1% of the incident dose rate;
	• Keeping parts of the body behind protective screens where possible when not working or manipulating material;

What the HSE expects	Further Guidance

	• Local Rules instruct persons not to handle radioactive material/sources with bare hands and encourage the use of handling equipment such as tweezers/tongs/etc.;
	• Additional control measures when using high-energy beta emitters such as P-32:
	  ○ Use of shielded racks; for example, placing racks of Eppendorf tubes containing radioactive material inside polycarbonate tip boxes when not in use;
	  ○ Use of shielded waste containers; for example, placing waste in 10mm thick polycarbonate boxes to eliminate beta radiation. This applies to both bench-top waste containers and larger, under-bench waste containers.

• What control measures are in place to reduce the exposure to all persons from INTERNAL radiation to levels that are as low as reasonably practicable?	**INTERNAL RADIATION** **In addition to the control measures referred to elsewhere in this guidance note, the following control measures should be considered in the risk assessment, where appropriate, to minimise the risk of contamination arising and being spread and to restrict internal radiation exposure.** • Only carrying out work with radioactive material in designated areas; • Acrylic or polycarbonate screens to reduce the likelihood of material being splashed onto the skin/lab coat; • Surfaces of the laboratory must be designed to minimise the risk of contamination (e.g. non porous surfaces) and to allow easy decontamination; • Following good contamination control procedures as outlined in RP CoP006 "*Work with Unsealed Radioactive Material*". • Provision of waste disposal sinks, with suitable signage, in areas where unsealed/open sources of radioactive material are used; it is not acceptable to have to walk between laboratories to have to dispose of waste; • Sink traps and pipework marked to identify presence of potential contamination at waste disposal sinks; ○ RP Guidance Note 010 provides further information on pipe-marking;

What the HSE expects	Further Guidance

	• Separate hand-basin in area (for Controlled Areas) or adjacent to working area (Supervised and non-designated areas). Washing areas must have:
	  ○ Hot and cold running water;
	  ○ Plentiful supplies of disposable towels, soap, etc.
	• Fume cupboards where there is a risk of airborne contamination arising. The fume cupboard or cabinet must:
	  ○ Have a laminar flow at the sash of at least -0.5 m/s;
	  ○ Be designed and constructed to allow ease of decontamination of surfaces;
	• Use of PPE where deemed necessary;
	• Adequate storage areas for PPE, including the storage of personally issued PPE (e.g. dedicated lab coats for controlled areas);
	• Suitable storage areas for storing radioactive material and radioactive waste which are marked with the appropriate signs in accordance with the Health and Safety (Safety Signs and Signals) regulations;
	• Radioactive material must be stored in suitable containers and with screw-top lid where possible when not in use;
	• Areas which are designated as Controlled or Supervised Areas must be adequately marked to warn persons of the hazard. Signs must be in accordance with the Health and Safety (Safety Signs and Signals) regulations;
	• Provision of suitable contamination monitoring equipment provided in areas where unsealed/open sources of radioactive material are used that:
	  ○ Are tested and calibrated annually;
	  ○ Are kept free of contamination;

What the HSE expects	Further Guidance
	○ Are checked before each use that they respond to a known source of radiation, have sufficient battery and are not damaged. • Work with radioactivity is planned before any radioactive material is used; i.e. all the equipment needed to carry out the task is laid out and checked before stock containers or aliquots are opened. • Consider carrying out rehearsals with non-radioactive samples where new procedures or handling techniques are employed to familiarise yourself with the task; • Prohibition of eating/chewing, drinking, smoking and applying cosmetics (and other similar acts) in Controlled or Supervised Areas; • Avoiding touching of the face, hair or other exposed body parts when in the Controlled or Supervised Area; • Covering of cuts/abrasions with waterproof dressings to minimise the risk of radioactive material bypassing the body's natural defences and getting into the body; • Restricting pregnant and breast feeding workers to only carry out certain tasks; • Restricting access to the working area to only those persons who are authorised workers;

5.2 (b) The steps necessary to achieve this control of exposure by the use of engineering controls, design features, safety devices and warning devices and, in addition, to develop systems of work

What the HSE expects	Further Guidance
• Engineering Controls, design features and safety/warning devices	• Regulation 9(2) of IRR17 sets out a hierarchy of control measures for restricting exposure. • Consider in your Risk Assessment what engineering controls you can put in place to reduce the likelihood of both external and internal radiation exposures.

What the HSE expects	Further Guidance

	• For example, shielding radioactive substances at source during work will minimise external exposures. This could be ensuring vials, sample holders, screens, waste containers, etc. provide adequate shielding to reduce external doses to workers as far as reasonably practicable.
	• Ensuring unsealed radioactive substances are contained at various stages of the work helps to minimise the risk of contamination arising and being spread. Consider in your risk assessment what additional steps you could take to improve the containment of the substance/waste and reduce the likelihood of contamination arising.
	• Design features, for example vial opening procedures, are designed to reduce dose rates and minimise the risk of contamination to users from opening vials containing radioactive substances. Are long-reach tools available to assist with vial opening that could reduce dose rates to the dominant hand?
	• Design features would extend to consider how labs are designed to make sure surfaces are easy to clean and decontaminate.
	  ○ For existing labs, consider how modifications or upgrades to the lab are managed; how do you ensure that equipment/facilities are replaced like-for-like and continue to be adequate?
	  ○ Further information on laboratory design is given in Radiation Protection Code of Practice RP CoP014 "*The Design of Radiochemical Laboratories*".
	• Consider the airborne hazard and ensure fume cupboards/cabinets are designed and constructed specifically for radioactive atmospheres.
	• Safety features and warning devices, such as interlocked enclosures (e.g. hot cells) and external gamma/activity-in-air alarms are examples of typical safety features and warning devices for areas where high activities are expected.
	• For routine unsealed radioactive material work, safety features and warning devices are unlikely to be present.

• Systems of work	• Systems of work are essentially the *procedural controls* to be followed by staff to further restrict their exposure to ionising radiation once all the engineering controls have been exhausted.

What the HSE expects	Further Guidance

	• For work with unsealed radioactive material, much of these controls are listed in the Local Rules. Examples of the types of procedural controls to reduce external and internal radiation exposures are given in 5.1.
	• Procedural controls relevant to work with unsealed radioactive material must be included in the local rules. The University RPU have created model local rules for unsealed work to capture much of the procedural controls designed to reduce exposures to ionising radiation. These model local rules can be found here:
	  ○ https://www.ed.ac.uk/health-safety/radiation-protection/radiation-protection-management/local-rules
	• To assist the systems of work, a Permit to Work may be required in situations where strict management controls are required over the conditions in which work will proceed, how it will be done, and how it will be supervised. For example a Permit-to-Work might be required for:
	  ○ Plumbers fixing pipes etc. in Controlled or Supervised Areas;
	  ○ Person's working in areas normally unoccupied or low occupancy areas where the high dose rates are found (for example roof spaces or void spaces above hot cells or CT scanners);
	  ○ Where interlocks or other engineered safety devices are by-passed or over-ridden.

5.3 (c) Whether it is appropriate to provide PPE and if so, what type is adequate and suitable

What the HSE expects	Further Guidance
• What PPE is still required to protect persons from the hazard after engineering & procedural controls have been exhausted.	• After engineering controls and safe systems of work have been taken into account, it may still be appropriate to provide persons with Personal Protective Equipment (PPE). • In the case of work with unsealed sources, PPE is almost always going to be required as an additional control measure to further reduce the risk to persons. This is because protection against the contamination hazard is by far the biggest risk when working with unsealed radioactive material.

What the HSE expects	Further Guidance

	• Routine PPE for unsealed work that might be required could be:
	  ○ A dedicated lab coat which remains in the Controlled Area. The lab coat, to provide adequate protection, must be buttoned up and come with elasticated cuffs;
	  ○ Laboratory gloves;
	  ○ Protective eyewear to minimise risk of splashes getting to the eyes;
	• There may also be a need to consider and wear additional (or different) PPE due to the specific task, location of the work or the radionuclide being worked with. For example:
	  ○ Double gloves during tasks where splashes from material are higher risk or where inadvertent contact during glove removal would cause a significant skin dose in a short time;
	  ○ Dedicated footwear;
	  ○ Longer-style lab gloves to further protect the wrists and forearms;
	  ○ Disposable overshoes;
	  ○ Disposable aprons;
	  ○ Full body suit, e.g. a disposable Tyvek suit;
	  ○ Lead aprons with a lead thickness of no less than 0.35mm;

• Where reliance is placed on the use of PPE, ensure that it is checked and maintained so that it remains fit for purpose.	• Many items of PPE used in unsealed laboratories are disposable and single use; e.g. gloves, overshoes. However, if gloves or overshoes are to be re-used, they must be checked prior to their use; for example they may be contaminated or have holes in them which would reduce their effectiveness. • Lab coats, whether dedicated to the area or not, will need laundered occasionally. Provided they are checked for contamination with a suitable monitor before being removed from the area for laundering, then the risk from handling and laundering the item is very low. A suitable contamination monitor should be able to detect contamination down to a few Bq/cm^2 for most radionuclides used at the University.

What the HSE expects	Further Guidance
	• Lead aprons and other lead protective PPE must be checked visually once a month and also be subject to an annual radiograph to ensure the lead protection remains adequate.
• Changing areas next to Controlled or Supervised Areas	• An area must be made available next to or close to the entrance of the Controlled or Supervised Area to store PPE and it must be kept topped up and ready to be used.

5.4 (d) Whether it is appropriate to establish any dose constraints for planning or design purposes and if so, what values will be used

What the HSE expects	Further Guidance
• Dose constraints for occupational exposures.	• In most cases, dose constraints are not normally appropriate for routine work in the non-nuclear sector as doses tend to be low. They are not intended to be used as investigation levels once work is planned and underway; they are replaced by Dose Investigation Levels (DILs) in Local Rules. • Therefore, for routine unsealed work, dose constraints are not normally required.
• Dose constraints for members of the public should not exceed 0.3mSv.	• In order to comply with Regulation 12(3) of IRR17, an assessment of the potential dose to a member of the public from the work must be included in each Risk Assessment. • It is unlikely that work with unsealed material could give rise to a public dose in excess of 0.3mSv. However, some gamma emitting waste could be stored in an outside waste store where the public could access. This may require shielding on the store if the dose estimate indicated doses >0.3mSv were possible to persons approaching the store.
• Dose constraints for ‘new’ work	• Dose constraints are often considered when planning new facilities or new procedures using radiation or radioactive material. For example, it is quite common to specify a dose constraint when designing and planning a new x-ray room/suite in a building.

What the HSE expects	Further Guidance
	• It may be useful to specify a dose constraint for unsealed work if the technique or experiment is 'novel' and doses may be different to other work being done. • Dose constraints for new work help to filter out options for radiation protection that could lead to unreasonably high doses; e.g. if the dose constraint is exceeded, consider other options and control measures to try and reduce the potential dose down further. • If applicable, a common dose constraint selected for workers is around 1mSv and 0.3mSv for all other persons. However, a dose constraint must be selected which is specific to the task.

5.5 (e) The need to alter the working conditions of any employee who declares they are pregnant or breastfeeding

What the HSE expects	Further Guidance
• Employers must make female workers aware of the increased risk to the foetus from work with ionising radiation.	• Include in the risk assessment the arrangements that have been put in place to make female workers aware of the arrangements for pregnant and breast-feeding workers; • Ensure the arrangements in the Risk Assessment (and Local Rules) include *how* and *who* female workers should contact when declaring their pregnancy; ○ Their Line Manager should be their main contact; they are NOT legally required to inform the RPS but it may be easier or more helpful for them to do so. • Further guidance on working with radiation when pregnant or breast-feeding can be found in Radiation Protection Code of Practice RP CoP013 "*Working with Radiation when Pregnant or Breastfeeding*".
• Employers must ensure the dose to the foetus does not exceed 1mSv following the declaration of pregnancy.	• Once informed about an employee's pregnancy, the employer must ensure the dose to the foetus doesn't exceed 1mSv for the remainder of the pregnancy; • This often means that the Risk Assessment for the employee should be reviewed once pregnancy has been declared. A section is included on the RADUSER Form to record this risk assessment review;

What the HSE expects	Further Guidance
	• Radiation Protection Code of Practice RP CoP013 gives more guidance on the type of things that should be reviewed as part of the risk assessment; • The Risk Assessment review should be led by the RPS (if they have been informed) or the employee's Line Manager with input from the University Radiation Protection Unit; • Pregnant workers need not be completely excluded from working with ionising radiation; however, due to the increased risk from internal contamination, pregnant or breastfeeding workers should not be involved in riskier tasks such as: o Cleaning up contamination following spillages; o Injecting radioactive material to patients; o Activities involving the use of syringes if they contain radioactive material; o Working with unsealed quantities of radioactive material above the levels outlined in RP CoP013.

5.6 (f) An appropriate investigation level to check that exposures are being restricted as far as is reasonably practicable

What the HSE expects	Further Guidance
• Employers must include in their Risk Assessment (and Local Rules) an appropriate dose investigation level.	• The Dose Investigation Level (DIL) chosen must be set at a level whereby it allows the employer to monitor whether radiation exposures are being managed As Low As Reasonably Practicable (ALARP). • The level chosen should be set such that the dose is unlikely to be exceeded by persons following appropriate controls to minimise their external and internal radiation dose. • In most cases, persons working with unsealed radioactive material should not receive significant radiation doses. • **It is therefore advised that, unless the work involves Classified Persons, the Dose Investigation Level (DIL) for anyone working with unsealed radioactive material at the University must not be greater than the levels below in any calendar year:**

What the HSE expects	Further Guidance
	○ **1mSv effective (whole body) dose; or** ○ **50mSv to the skin and extremities; or** ○ **15mSv to the lens of the eye.** • Where work with unsealed radioactive material is taking place that involves Classified Persons, higher DILs may be appropriate. • Departments may choose to set lower 'action levels'; for example, based on dosemeter wearing periods, so that they can monitor radiation doses throughout the year to ensure a DIL isn't going to be exceeded. These Action Levels can be managed locally by RPSs and within the Local Rules.
• Carry out an investigation if the DIL is exceeded.	• The purpose of the investigation is to trigger a review of the group's, or individual's, working arrangements to consider if doses are being managed as low as is reasonably practicable. • Any dose investigation involving an employee who has exceeded, or who is likely to exceed, a DIL must involve the University Radiation Protection Unit. • A formal report, under IRR Reg 9(8), is required which will include: ○ Details of the person's routine before and after the incident including any colleagues who worked closely with them over the investigation period; ○ Whether the person had been involved in any other known incidents in which they may have received an unusual exposure; ○ Details of the person's estimated dose over the period being investigated compared with estimated doses of other persons carrying out similar work; ○ Results of any special radiation or contamination surveys carried out in the area after or before the incident to determine if there had been any deterioration in physical control measures; ○ Evidence from the RPS, the individual concerned and from other work colleagues on adherence to local rules or any deficiencies in those Local Rules in light of the incident.

5.7 (g) The maintenance and testing schedules required for the control measures selected

What the HSE expects	Further Guidance
• Instruments and equipment designed to assist and help with ensuring radiation protection measures are controlled must be subject to regular maintenance and testing.	• Some of the control measure employed in the Risk Assessment to reduce radiation exposures may rely on equipment, instruments, safety features, warning devices, engineering controls, etc. being maintained and/or tested to ensure they are measuring or functioning correctly. Such instruments/equipment might include: • Liquid scintillation counters; • Contamination monitoring equipment; • Fume cupboards; • Dose calibrators; • Activity in air monitors; • Checks of PPE (e.g. lead aprons) • Irradiators; • X-ray generators; • Automatic warning lights at Controlled Areas; • Interlocks; • Emergency stop buttons; • If the work carried out as part of your Risk Assessment relies on any of the things above then you should consider, as part of the risk assessment: o Who carries out the maintenance? Do they require access to a Controlled or Supervised Area? o Who is responsible for organising the maintenance/testing and how is it organised? o Is the maintenance carried out as part of a regular maintenance or service contract? o The appropriate interval between maintenance and/or testing to ensure that the control measures relying on it remain adequate. For example this interval may be a manufacturer's recommended interval or an interval stated in the regulations; o Who is responsible for ensuring it is carried out on time?

What the HSE expects	Further Guidance
	• Radiation and contamination monitoring instruments must be subject to an annual periodic check which includes a check of the overall instrument condition and a calibration check. Annual periodic checks are normally arranged by the RPS.
• A record must be kept of the examination and tests carried out.	• Ensure the risk assessment includes what records are kept, for example, warning light checks, service reports, instrument test certificates, tests of emergency stops, etc.

5.8 (h) What contingency plans are necessary to address reasonably foreseeable accidents

What the HSE expects	Further Guidance

• If a radiation accident is considered to be reasonably foreseeable then a Contingency Plan is required.	• The aim of a Contingency Plan is to restrict exposures that arise from a 'radiation accident' as far as reasonably practicable. The level of detail within the plan should reflect the circumstances anticipated.
	• A 'radiation accident' is defined as an accident where immediate action is required to prevent or reduce the exposure to ionising radiation of employees or any other person.
	  ○ The intention is that the action should be 'immediate' and should prevent or reduce 'exposures of concern'. Whilst no value is assigned to this, an 'exposure of concern' is an exposure which significantly exceeds, or could significantly exceed, normal planned exposures.
	  ○ As doses at the University are low, an 'exposure of concern' is taken to be an exposure greater than 1mSv per year; **i.e. Contingency Plans should be written where immediate action is required to prevent or reduce doses below 1mSv.**
	• Note, small contained spillages, i.e. spillages that have not spread outside the immediate spill tray and have not contaminated any persons, are not likely to result in exposures of concern. They can be dealt with via a 'Spills Procedure' in the Local Rules. An example spills procedure can be found on the guidance notes pages of the RPU website.

What the HSE expects	Further Guidance
	• Some plans might be generic across the Schools/Institutes etc. as the same 'types' of operations are carried out but in different places. Because of this, some example Contingency Plans for typical radiation accidents in Unsealed Sources work are included in Appendix 2. • Remember, Contingency Plans and Spills Procedures must be specific to the area covered by the Local Rules.
• Consideration must be given to accident scenarios that could lead to offsite emergencies.	• A Radiation Risk Assessment (RRA) has been carried out by the University RPU against the requirements of the Radiation (Emergency Preparedness and Public Information) Regulations 2019 "REPPIR". This Risk Assessment is managed centrally by the RPU and available on request. • The assessment concluded that the quantity and type of sources held by the University would not lead to an effective dose greater than 1mSv to a member of the public following a radiation emergency.
• If circumstances arise where it is necessary for all, or part of, arrangements in a contingency plan to be used then a report must be written and kept for two years.	• As a report is required to be written and kept, the University RPA must be informed of any incidents where all, or part of, a contingency plan is enacted. • Contacting the University RPA should therefore feature in all Contingency Plans so they can advise on the content of any report. Although the report does not need to be sent to the HSE, they can ask to see it, or be sent it, if they request to do so. • Note, small contained spillages are dealt with via a Spills Procedure so do not automatically require a report to be written and sent to the RPA (although the RPS may wish to make a report and keep it locally).
• Where appropriate, rehearsals of the arrangements within Contingency Plans must be carried out at suitable intervals.	• Where appropriate, rehearsals of the arrangements in Contingency Plans must be carried out at suitable intervals. Desktop rehearsals may be appropriate in cases where contingency arrangements are simple and doses from reasonably foreseeable accidents are low. • RPSs should arrange for Contingency Plan rehearsals to take place as part of their local training. • Records of rehearsals (e.g. what parts of the Contingency Plans were tested, who attended and on what date) must be kept in case they are required during an audit or inspection.

5.9 (i) The training needs of classified and non-classified employees

What the HSE expects	Further Guidance

• Employers engaged in work with ionising radiation need to demonstrate that their employees have been given sufficient information, instruction and training.	• All workers who wish to work unsupervised with ionising radiation must be given appropriate information, instruction and training to ensure that they know;
	  ○ The risks to their health from exposure to ionising radiation (*i.e. having the background knowledge in ionising radiation*);
	  ○ The precautions that need to be taken to ensure their radiation exposures are managed As Low As is Reasonably Practicable (ALARP) when working with the radionuclides (*i.e. local instruction or induction from the RPS or manufacturer's training on the equipment*); and
	  ○ The importance of complying with the regulations (*i.e. having the appropriate legislative knowledge from IRR17 on what arrangements are in place to comply with the law*).
	• The above instruction and training requirements are normally met by:
	  ○ Attending one of the University's Basic Courses in Radiation Protection (e.g. The Basic Course Research & Teaching or the Basic Course in Veterinary Diagnostic Imaging & Therapy); and,
	  ○ Completing and passing the relevant competence assessment(s) on LEARN, the University's Virtual Learning Environment, linked to the training course modules being sat; and,
	  ○ Receiving practical instruction from the RPS or Deputy RPS on the *local arrangements* within the area for working with ionising radiation.
	• Line managers and academic supervisors should ensure that arrangements are made for staff to receive the appropriate training. This can be done in conjunction with the RPS.
	• Further guidance on training can be found in Radiation Protection Code of Practice RP CoP008 "*Information, Instruction & Training in work with radiation sources*".

What the HSE expects	Further Guidance

• Adequate information is given to other persons who may be involved in the work with ionising radiation either directly or indirectly.	• Other persons may need to be given information or instruction or training to ensure they can work safely and reduce risks to their health. Other persons that may need information, instruction or training might be:
	• Domestic (cleaning) staff:
	  ○ Access arrangements;
	  ○ What can and cannot be cleaned;
	  ○ What can and cannot be taken out of the area (e.g. emptying of bins);
	  ○ Basic principles of time, distance and shielding to reduce external radiation hazard;
	  ○ Basic principles of good hygiene control to minimise the internal hazard;
	• Service/maintenance engineers;
	  ○ Service or maintenance engineers may need to be given information or instruction, particularly if they are entering a Controlled or Supervised Area;
	  ○ Normally, service engineers take control of the area, and therefore are responsible for managing their own risks. A 'handover' form is provided on the RPU website and should be included in the Local Rules for the area, see:
	  ▪ https://www.ed.ac.uk/health-safety/radiation-protection/radiation-protection-management
	• Other persons in the building (e.g. other research staff or office staff);
	  ○ Other lab workers may work in a shared space with unsealed/open source users;
	  ○ These workers should receive some instruction on the hazards in the area and any actions they are required to take; particularly in an accident situation;
	• Visitors may not need any formal training provided they are closely supervised when in a Controlled or Supervised Area and do not work with the radioactive material;

What the HSE expects	Further Guidance
• Training records to be kept	• All training, and even local instruction, must be recorded and those records maintained. • Line managers and academic supervisors should notify the RPS when refresher training is required.
• Persons working with ionising radiation must repeat their training at regular intervals	• In order to maintain the competence levels of staff and other persons working with ionising radiation, refresher training must be scheduled at regular intervals; • There is no definite time interval for refresher training but the RPU advise that the interval between refresher training should not normally exceed 5 years.

5.10 (j) The need to designate specific areas as Controlled or Supervised areas and to specify local rules

What the HSE expects	Further Guidance
• Areas to be designated as Controlled or Supervised areas if there is a need to control who can enter or work in the area to reduce radiation exposures.	• If there is a need to control who can enter or work in an area, to reduce their potential radiation exposure, then it is likely to be necessary to designate a Controlled or Supervised Area. The purpose of designated areas is to manage radiation risk by separating higher risk activities from lower risk activities. • Risk assessors must consider 'others' that may need to work in the area. For example, persons working with low activities of Tritium, which may only require a non-designated area, should not need to subject themselves to a greater risk by working alongside someone working with P-32, which may require a Controlled Area designation. • In the majority of cases, unsealed/open sources work will require a Controlled or a Supervised Area. • Further guidance on the designation of Controlled and Supervised Areas, including a step-by-step guide on how to determine the area designation, can be found in RP CoP011 "*Controlled and Supervised Areas*".

What the HSE expects	Further Guidance
• Adequate demarcation of the designated area must be provided.	• Once the designated area has been established, it needs to be demarcated and segregated from areas which are not designated to restrict unauthorised access. • For Controlled Areas, it is advised to use physical boundaries, such as walls and doors, to signify the extent of the Controlled Area; a line across the floor is not normally sufficient. For unsealed/open sources, this is therefore normally the whole of the room in which the work is being carried out. • For Supervised Areas, a physical boundary is not always required. The boundary must still be demarcated but could be demarcated by a retractable belt barrier, or be a bay within a larger laboratory. There are poor examples and good examples of Supervised Area demarcation in RP CoP011 to guide you. • Whatever demarcation is chosen, it must be referred to in the local rules (e.g. a picture or drawing of the area).
• Persons must be warned of the presence of the designated area.	• If an area is designated as a Controlled or Supervised area then it needs to be accompanied by a sign, **at the entrance to the designated area**, informing persons of the hazard within the area. In most cases this will be the door to the lab **but not always!** • This is done via Controlled or Supervised area notices. Examples of these notices can be found at the back of RP CoP011. • Copies of the signs can be downloaded from the RPU website at the link below. It is important that signs across the University are consistent; **do not use your own version!** • Controlled Area notices must have a yellow background and Supervised Areas a white background. • https://www.ed.ac.uk/health-safety/radiation-protection/radiation-protection-management/signs
• Local Rules are required for all Controlled areas and some Supervised Areas taking into	• In almost all cases where work with unsealed radioactive material is carried out, Local Rules will be required to ensure procedures are followed to reduce the likelihood of significant exposures. • Local Rules for work with unsealed radioactive material must contain:

What the HSE expects	Further Guidance
account the work being carried out.	○ The Dose Investigation Level (DIL) set in 6.6(f) above; ○ A summary of the contingency arrangements set out in 6.8(h) above; ○ The name of the appointed RPS; ○ A description and identification of the area covered by the Local Rules; ○ A summary of the key working instructions for restricting access to the area; ○ The written arrangements for non-classified workers (i.e. the steps they need to follow to keep their radiation exposures as low as reasonably practicable when in the area). • It is also advised that the Local Rules also provide information on the following: ○ A summary of the arrangements for pregnant and breast-feeding staff set out in 6.5(e); ○ A link to the Risk Assessment carried out for the work; ○ Arrangements for the information, instruction and training of staff and other persons who wish to work in the area or who are affected by the work in the area (as set out in 6.9 (i)); ○ Personal dosimetry arrangements as set out in 6.13 (m); ○ A spillage procedure on the arrangements for dealing with small contained spillages; ○ Arrangements for the PPE required for the area as set out in 6.3 (c); ○ Arrangements for radiation and contamination monitoring of the area to ensure that contamination is not arising and being spread (see RP CoP003); ○ Arrangements for managing service engineers and others who may need to enter the area to carry out work; • For traditional unsealed sources work in science laboratories (e.g. tracer work), the University RPU has written *Model* Local Rules. These must be added to and completed to suit each particular circumstance. They can be found on the RPU website at: • https://www.ed.ac.uk/health-safety/radiation-protection/radiation-protection-management/local-rules

What the HSE expects	Further Guidance
• The appointment of an RPS to supervise the arrangements set out in the Local Rules.	• In almost all cases, a Radiation Protection Supervisor (RPS) will need to be appointed to oversee the arrangements set out in the Local Rules; i.e. an RPS is almost always required where there is work with unsealed radioactive material. • As mentioned above, the RPS must be named, along with their contact details, in the Local Rules for the area. • Further information on the typical duties that an RPS may carry out are given in RP CoP001 "*Radiation Protection Supervisors*": https://www.ed.ac.uk/health-safety/radiation-protection/codes-of-practice-and-guidance/codes-of-practice

5.11 (k) The actions needed to make sure access is restricted and other specific measures are put in place in Controlled or Supervised areas

What the HSE expects	Further Guidance

• Employers who have designated a Controlled Area must not permit any person to enter or remain in that area unless they meet various criteria.	• Consider in your Risk Assessment who needs to access the area where you are working and how they, and others, might access the area.
	  ○ Is the building open access to members of the public and visitors? (i.e. can anyone walk in?)
	  ○ Is there a swipe card entry system to the building/floor/laboratory? Who manages access requests for that system and how are persons granted access to laboratory spaces where work with radioactive materials is taking place?
	  ○ Is there a key-code or PIN to enter the laboratory or room? If so, when was the code last changed?
	• Consider how access is to be managed such that only fully trained and authorised persons are able to enter and work in the area.

What the HSE expects	Further Guidance
	○ How do you ensure persons working in the area have had the necessary training? ○ How do you ensure they have had local information and instruction to allow them to work safely? ○ How do you ensure they have read the Local Rules? • For Supervised Areas, access must still be managed (e.g. by signage) but access restrictions are not as stringent as those for Controlled Areas.
• It is the responsibility of the employer in control of the area to restrict access.	• In some cases, service engineer's visit premises to carry out "work" in a Controlled or Supervised Area. "Work" could include such things as installation, routine service/repair, adjustment, part replacement, software upgrades, hardware upgrades, reactive visits, etc. • Whenever ionising radiation equipment, e.g. an Irradiator, is handed over to a service engineer or other person, then they must take ownership of the Controlled or Supervised Area and therefore work under their own company's Local Rules and procedures.
• Consider the arrangements for the different types of person who may access the area.	• Most of the University's workers working with unsealed sources of ionising radiation are non-classified workers entering and working in the area under *written arrangements*. ○ These written arrangements must be included in the Local Rules and outline the steps that the non-classified person must take to restrict their exposure. ○ Things to consider include their supervision in the area, what PPE is required to be used and restrictions on the type of work they are allowed to carry out. ○ Consider other persons who may access the area too (e.g. cleaners, estates personnel, etc) • Classified Persons: ○ How will you check their medical surveillance is up to date? ○ How will you ensure they are subject to personal dose monitoring? • Classified outside workers (i.e. Classified Persons who have NOT been classified by the University of Edinburgh; e.g. other employers Classified Persons):

What the HSE expects	Further Guidance
	○ How will you check their radiation passbook is up to date? ○ How will you ensure they have received the necessary training to enter and work in the area? ○ How will you check that they have been passed fit-to-work by an appointed doctor? ○ How will you ensure that they are subject to routine dose assessment by an Approved Dosimetry Service? • Non-classified outside workers are persons, who are not classified persons, but who carry out 'services' in a Controlled or Supervised area which has not been designated by their own employer. For example, a service engineer coming to fix a piece of equipment where the background dose rate in the area exceeds 7.5 microSv/h. ○ Access arrangements for these types of workers should be included in the written arrangements if they are required.

5.12 (I) The need to designate certain employees as Classified Persons

What the HSE expects	Further Guidance
• Employers must designate employees who are *likely* to receive an effective dose greater than 6mSv in a year or an equivalent dose greater than 15mSv to the lens of the eye or 150mSv to the skin or extremities. • The employer should take into account not only routine work	• Under normal circumstances, *routine* work with unsealed sources is unlikely to result in effective doses in excess of 6mSv or equivalent doses in excess of those mentioned in Column 1. • However, the IRR17 require employers to also consider classifying persons on the basis of *potential* exposure from any reasonably foreseeable radiation accident. • When working with unsealed radioactive material, it is reasonably foreseeable that persons could receive a splash/droplet of contamination on to the skin or glove which could lead to a significant skin dose. Even a droplet of radioactive material on a lab coat could lead to a significant skin dose if it is allowed to soak through.

What the HSE expects	Further Guidance

but the possibility of accidents *likely* to occur.	• The University doesn't expect to have to designate Classified Persons for the majority of its work with unsealed radioactive material however, careful consideration of the control measures needed to reduce the risk of skin doses from working with stock materials (which generally have a high activity concentration) needs to be considered.
	• Based on data published by the nuclear industry, and the typical contamination monitoring carried out by those working with unsealed radioactive material, an exposure time of 30 minutes is a conservative exposure time between a contamination event and completion of decontamination.
	• However, dose rates for skin contamination when working with stock containers can easily be >1000 mSv/h in some cases and doses for 30 minutes exposure can be greater than three-tenths of the relevant dose limits.
	• In these scenarios**, additional control measures must be included in the Local Rules** to demonstrate that Classification of Persons is not required. For example:
	  ○ Ensuring a contamination monitor is present and switched on during dispensing operations from stock containers to identify any unusual occurrences; and
	  ○ Ensure persons check their hands for contamination immediately after dispensing from stock containers thereby reducing the time that contamination could remain on the skin from 30 minutes to <1 min.
	  ○ Typically these additional control measures are required in cases where P-32 and PET radioisotopes are used and worked with.
	• Examples of how to carry out a skin contamination dose assessment are shown in Appendix 1.

5.13 (m) The content of a suitable programme of dose assessment for employees designated as Classified Persons and for others who enter Controlled Areas

What the HSE expects	Further Guidance
• Dose assessment for Classified Persons	• If work with unsealed sources *does* require the person to be designated as a Classified Person, it is likely to be down to the risk of a significant skin exposure from an accidental spill (i.e. greater than 3/10ths of the dose limit) rather than from a whole body dose in excess of 6mSv being exceeded or expected. • Guidance on a suitable programme for dose assessment for Classified Workers is given in Radiation Protection Code of Practice RP CoP015 "*Classified Radiation Workers*".
• Dose assessment for non-classified persons	• In most cases, work at the University of Edinburgh with unsealed sources shouldn't require persons to be designated as Classified Persons however, a programme of dose assessment will still need to be considered for unsealed work as the majority of the work will be in Controlled Areas. • Whole Body dosemeters: o For low-energy beta emitters like P-33, S-35, C-14, H-3, etc., whole-body dosemeters are not required as the range of the beta particles in air is generally quite short and the betas are unlikely to penetrate through the outer packaging of the dosemeters to register a dose. o For high-energy beta emitters like P-32, where protection against whole body doses is afforded by suitable Perspex screens for the majority of the work, whole body dosimetry would not normally be required. It is expected that this would be the normal position for working with unsealed sources of P-32. o If suitable shielded screens cannot be used, whole body TLDs should be worn by ALL persons working with P-32 for prolonged periods; regardless of the activity. o It may be worthwhile carrying out a whole-body dose monitoring programme for P-32 workers to demonstrate that significant doses are not being received; for example carrying out dose monitoring for a year and then reviewed after this time.

What the HSE expects	Further Guidance
	○ Obviously some short-duration tasks like moving waste bins or carrying stock vials to/from fridges etc. are unlikely to have shielded screens in place; these tasks would not normally require the person to wear a whole-body dosemeter due to their short duration. A dose assessment could be included in the Risk Assessment to demonstrate this for such routine tasks. ○ For photon emitters, whole body dosemeters should normally be worn (with the exception of low activity I-125 RIA kits). • Internal dose monitoring (i.e. biological monitoring): ○ Regular contamination monitoring and persons following good contamination control procedures indicates that contamination does not arise from the University's work with unsealed radioactive material, nor is it being spread. ○ Inhalation doses are not expected in wet chemistry applications and therefore the only likely route of intake for internal doses would be through ingestion following contamination (or by direction injection following a sharps accident). ○ Therefore internal dose monitoring is not generally required for work with unsealed radioactive material at the University. ○ Some high activity work, for example > 200 MBq H-3, may require a pre- and post-work urine sample. This must be discussed with the University RPA. • Extremity dose monitoring: ○ Extremity dosemeters should be worn where there may be significant dose rates present at the fingertips/hands such that assessment of the doses received is required to demonstrate compliance with the dose limits and that doses are being managed ALARP. ○ Extremity dosemeters are advised where the activities below are routinely handled in unsealed work:

<table>
<tr><th>What the HSE expects</th><th>Further Guidance</th></tr>
<tr><td></td><td>
<table>
<tr><th>Radionuclide or group</th><th colspan="2">Extremity dosemeters advised if persons routinely handle above the activities below:</th></tr>
<tr><th></th><th>If <u>NOT</u> using pipette/syringe shield</th><th>If using pipette/syringe shield</th></tr>
<tr><td>H-3, C-14, S-35, P-33</td><td>Not required</td><td>Not required</td></tr>
<tr><td>P-32, Na-24</td><td>> 5 MBq</td><td>> 50 MBq</td></tr>
<tr><td>I-131, F-18</td><td>> 10 MBq</td><td>> 50 MBq</td></tr>
<tr><td>Tc-99m, Cl-36</td><td>> 30 MBq</td><td>> 100 MBq</td></tr>
<tr><td>DepU</td><td>> 1Kg</td><td>> 1Kg</td></tr>
<tr><td>Others</td><td>Contact RPU</td><td>Contact RPU</td></tr>
</table>

Extremity dosemeters may need to be worn on one or more hands depending on the task. This should be considered as part of the risk assessment. If the user is likely to handle the substance with both hands, or place the fingertips of both hands in close proximity to the source, then an extremity dose meter should be worn on both hands.
Extremity dosemeters must be worn underneath any disposable glove to avoid a dose getting onto the dosemeter through contamination.
It would be considered good practice for new workers to wear extremity dosemeters for a limited period to confirm good isotope handling procedures.

</td></tr>
<tr><td>• Other persons who may enter Controlled Areas</td><td>• The written arrangements to allow non-classified persons entry to Controlled Areas also applies to visitors and other persons who may enter the area.
• The IRR17 state that the employer must demonstrate, by personal dose monitoring or other suitable measurements, that dose limits are not being exceeded for those categories of person.</td></tr>
</table>

What the HSE expects	Further Guidance
	• IRR17 suggests that an easy way to demonstrate this is to issue a personal dosemeter to the visitor or other person entering the controlled area. • If your risk assessment requires ***workers*** to wear whole-body dosemeters then visitors and other persons entering the Controlled Area may need some form of dosimetry to show that significant doses are not being received; especially where gamma emitting radioisotopes are used. ○ The easiest way to do this is through a smart dosemeter (i.e. an electronic personal dosemeter, EPD, or a smart dosemeter like Instadose®) • No extremity dose monitoring is expected to be needed for visitors and other persons as they are unlikely to be handling/working with activities in excess of those outlined in the table above. • No dose monitoring is required to demonstrate that internal doses are not being received by visitors. If workers are not receiving internal doses then it can be assumed that visitors and other persons are not receiving internal doses either.

5.14 (n) The requirements for the leak testing of radioactive sources

What the HSE expects	Further Guidance
• Employers to carry out leakage tests on all their closed sources to ensure the mechanisms preventing dispersal remain adequate and effective.	• Closed sources includes sealed sources and also unsealed/open sources which have been ‘sealed’; for example a liquid ‘open’ source may have had its lid permanently closed such that it behaves more like a ‘closed’ source than an ‘open’ source. • In most cases, for unsealed/open source work, leakage tests are not required. • Further information on leakage tests and Closed/Sealed Sources can be found in RP CoP020 “*Working with Sealed (Closed) Sources*”

5.15 (o) The responsibilities of managers and workers (including outside workers) for ensuring compliance with these regulations

What the HSE expects	Further Guidance
• Assigning of responsibilities and duties to ensure compliance with the regulations	• This part of the Risk Assessment is essentially looking for what appointments and arrangements are in place to ensure compliance with the regulations. • The University has appointed an internal *Radiation Protection Adviser* (RPA) to provide advice, when consulted, on compliance with the requirements of the Ionising Radiations Regulations 2017 (IRR17); specifically those matters specified in Schedule 4 of the regulations. • Heads of School and other equivalent roles are responsible for the management of health and safety matters within the areas under their control, including ionising radiation. ○ This responsibility extends to ensuring risk assessments are prepared for all work with ionising radiation although the authority to carry out risk assessments can be delegated to others; such as Principal Investigators, Group Leaders, etc. • Most work with unsealed radioactive sources will require the appointment of a *Radiation Protection Supervisor (RPS)*, by the Head of School or other equivalent role, to supervise the arrangements set out in the Local Rules. • The number of RPSs or assistant/deputy RPSs required to be appointed will depend on the extent of the work undertaken. The Head of School may wish to seek the advice of the University RPA on the appropriate number of RPSs. • Typical duties of an RPS are outlined in Radiation Protection Code of Practice RP CoP001 "*Radiation Protection Supervisors".*
• Responsibilities of workers (including outside workers)	• All workers, to some extent, have their own responsibilities under health and safety law and there are duties placed on all workers under the Ionising Radiations Regulations. • All persons have to take reasonable care of themselves and others who may be affected by their actions, therefore anyone working with ionising radiation must:

What the HSE expects	Further Guidance
	○ Not knowingly expose themselves, or any other person, to ionising radiation to an extent greater than is reasonably necessary for the purposes of their work (i.e. to work safely); ○ Correctly use any PPE provided to them, take care of it and store it correctly; ○ Recognise that they should not continue with a particular task if they feel that they are exposed to a risk to their health and safety that is not being appropriately controlled; ○ Report any accidents, near-misses or other incidents relating to work with ionising radiation; ○ Be aware of the importance of notifying their line manager as soon as possible if they are pregnant or breastfeeding; ○ Attend and complete any training for which they have been nominated/advised to attend; ○ Comply with any local rules, written arrangements or other procedures relating to ionising radiation to which they are working under; ○ Take care of any dosimetry they are provided with and ensure its timely return to allow dose measurements to be made. • Outside workers, i.e. those who carry out 'services' in another employers Controlled Area, may be at particular risk as they may be unfamiliar with the hazards and controls in the other employers Controlled Area; • Consider whether outside workers may enter and work under your risk assessment and what additional measures or controls need to be put in place to ensure they comply with the regulations and Local Rules.

5.16 (p) An appropriate programme of monitoring or auditing of arrangements to check the requirements of these regulations are being met

What the HSE expects	Further Guidance
• Radiation Protection Unit auditing	• The University Radiation Protection Unit undertake a rolling programme of lab/room inspections and audits of departments/schools using radioactive substances. • Audits focus more on the *arrangements* for radiation protection management within the schools whereas lab/room inspections focus on the actual control measures implemented down at local level in individual areas. • For unsealed risk assessments, risk assessors should include when the last RPU audit was carried out and also include when the next audit is scheduled for. It may also be worth including any open or incomplete actions from the audit if they relate to this risk assessment. • Further information on RPU auditing and inspection, including the rolling programme dates, can be found on the RPU webpage at: o https://www.ed.ac.uk/health-safety/radiation-protection/radiation-protection-management
• Departmental inspections and reviews	• The audits carried out by the RPU include an element of inspection of various areas/labs. • The RPU strongly encourage departments to carry out their own inspections and the RPU inspection templates are available for all Schools and departments to use for their own internal inspections. • If departmental inspections are carried out in the area, list these on the Risk Assessment (i.e. the previous inspection and the next inspection). It may also be worth including any open or incomplete actions from the departmental inspection if they relate to this risk assessment.

6 Summary of actions & recommendations

What the HSE expects	Further Guidance
• N/A	• If there are any recommended actions that were noted during the review of or creation of the Risk Assessment, record them in the summary section along with the person responsible for taking ownership of the action and an expected date of completion.

7 References

[1] Health and Safety Executive, “Work with Ionising Radiation - Ionising Radiations Regulations 2017 and Approved Code of Practice - 2nd Edition,” The Stationary Office (TSO), 2018.

[2] Delacroix et al., “Radionuclide and Radiation Protection Data Handbook,” Radiation Protection Dosimetry, ISBN: 1870965876, 2002.

8 Appendix 1: Estimating radiation doses and dose rates to which anyone can be exposed

In order to be suitable and sufficient, the Risk Assessment needs to include ALL the exposure pathways from routine tasks and from *reasonably foreseeable* accidents. Examples of routine and accident exposure pathways when working with unsealed radioactive material are shown below. Note, this list is not intended to be exhaustive, and each individual use at the University will have its own routine and reasonably foreseeable accident situations that require dose estimates to be made.

Note, only consider dose estimates from *reasonably foreseeable* accidents. For example, it might be possible for a radioactive substance to be lost and then ingested by another person but is that reasonably foreseeable? The 'loss' may be reasonably foreseeable but not the subsequent ingestion. Similarly, is it *reasonably foreseeable* for an entire stock vial or aliquot to be ingested? What is more reasonably foreseeable is the inadvertent ingestion of a small quantity of the stock/solution based on the volume being manipulated.

Possible Routine tasks	Possible reasonably foreseeable accidents
• Receipt of Stock Material and transfer to secure store/fridge • Checking of package as part of receiving procedure • Opening of packages containing radioactive stock/material • External dose rate in room from stock/samples in their storage location • Dispensing or working with high activity radioactive stock • Dispensing or working with lower activity radioactive aliquots /samples • Waste disposal tasks (e.g. disposing of sharps to sharps bin, sluice of aqueous waste to drains, etc.) • Potential doses to members of the public from waste disposed to various disposal routes	• Receiving more activity than ordered • Loss/theft of radioactive material • Spillage or release of radioactive stock solution • Spillage or release of radioactive aliquots/samples/other media • Spread of contamination out with the designated area (e.g. outside the room) • Sample dropped during transfer across lab or to another room • Personal unintended external exposure • Skin contamination / puncture wounds • Fire involving, or having the potential to involve, radioactive material • Breakdown in controls (e.g. persons not following Local Rules)

8.1 Useful data for selected isotopes

The following table gives relevant dose rate and dose information for selected radioisotopes[2] [2]. Those carrying out Risk Assessments can use this information, or other information if they wish, to estimate doses and dose rates from routine and reasonably foreseeable accident situations:

Isotope	Main Emissions[3]	Physical Half-life	Range[4] (approx.)		Tenth Value Layer in lead (mm)	External Dose Rate @ 10cm from an unshielded point source of 1MBq[5] (μSv/h)	External Dose Rate @ 10cm from a glass vial containing 1MBq (μSv/h)	Skin Dose from 50μL droplet on skin (mSv/h/kBq)	Committed Effective Dose per unit intake (ingestion) (Sv per Bq)
			Air (cm)	Plastic (mm)					
Tritium (H-3)	18.6 keV; β	12.3 y	0.5	< 0.1	--	760	<0.1	--	1.8×10^{-11}
Carbon-14 (C-14)	157 keV; β	5730 y	20	0.3	--	760	<0.1	2.7×10^{-3}	5.8×10^{-10}
Chromium-51 (Cr-51)	320 keV (10%) γ	27.7 d	metres	< 0.1	7	1	1	5.65×10^{-4}	3.8×10^{-11}
Fluorine-18 (F-18)	511 keV (200%) γ 634 keV β^+	1.83 h	metres	1.7 (β)	17	16	16	0.79	4.9×10^{-11}
Indium-111 (In-111)	171 & 245 keV γ	2.80 d	metres	0.5	3	7	7	6.48×10^{-2}	2.9×10^{-10}
Iodine-125 (I-125)	27keV γ	59.9 d	metres	--	< 1	1	1	6.30×10^{-3}	1.5×10^{-8}
Iodine-131 (I-131)	365 keV γ 606 keV β	8.0 d	metres	1.6 (β)	11	6	6	5.72×10^{-1}	2.2×10^{-8}

[2] The list of radionuclides is not intended to be exhaustive. The data is a summary of useful information which may be used as part of the Risk Assessment.

[3] The figures in brackets show the percentage of emissions where values are significantly different from 100%. For Beta energies, β_{max} is quoted. Not all emissions have been listed. Data taken from [2].

[4] The range is the approx. distance travelled in the material by the beta particle. Data taken from [2].

[5] Values are approximate using rules-of-thumb formula below. Likely to be an overestimate for beta energies < 1MeV.

Isotope	Main Emissions[3]	Physical Half-life	Range[4] (approx.) Air (cm)	Range[4] (approx.) Plastic (mm)	Tenth Value Layer in lead (mm)	External Dose Rate @ 10cm from an unshielded point source of 1MBq[5] (µSv/h)	External Dose Rate @ 10cm from a glass vial containing 1MBq (µSv/h)	Skin Dose from 50µL droplet on skin (mSv/h/kBq)	Committed Effective Dose per unit intake (ingestion) (Sv per Bq)
Phosphorus-32 (P-32)	1710 keV; β	14.3 d	800	6.3	--	760	0.55	1.33	2.4×10^{-9}
Phosphorus-33 (P-33)	249 keV; β	25.6 d	50	0.5	--	760	<0.1	0.14	2.4×10^{-10}
Sulphur-35 (S-35)	168 keV; β	87.5 d	24	0.3	--	760	<0.1	4.05×10^{-3}	7.7×10^{-10}
Technetium-99m (Tc-99m)	141 keV γ	6.0 h	metres	--	1	2	2	8.77×10^{-3}	2.2×10^{-11}

Uranium and Thorium data:

	Activity per g	Committed Effective dose per unit intake (ingestion)	ALI* (ingestion) [Bq]	ALI* (ingestion) [g]	Committed Effective dose per unit intake (inhalation**)	ALI* (inhalation) [Bq]	ALI* (inhalation) [g]
Natural Uranium:	26 kBq/g	4.64×10^{-8}	0.43 MBq	16.6 g	6.22×10^{-6}	3.22 kBq	0.12 g
Depleted Uranium:	15 kBq/g	4.47×10^{-8}	0.45 MBq	29.8 g	5.85×10^{-6}	3.42 kBq	0.23 g
Natural Thorium***	8 kBq/g	2.2×10^{-7}	0.09 MBq	11.3 g	2.9×10^{-5}	0.69 kBq	0.09 g

* 1 ALI = 20mSv. Remember, inhaling or ingesting 100% of compound used is unrealistic. Use values in 3.8(h) above.

** A default 5 micron Activity Median Aerodynamic Diameter (AMAD) has been used as recommended by ICRP 68 Page 3.

*** The specific activity of Natural Thorium (Th-232) is quoted here in secular equilibrium with its daughters. Whilst this is the case for Thorium sources of more than a few years old, it might not always be the case for NEWLY created Th sources/compounds.

8.2 Estimating external doses

8.2.1 Using proprietary Software

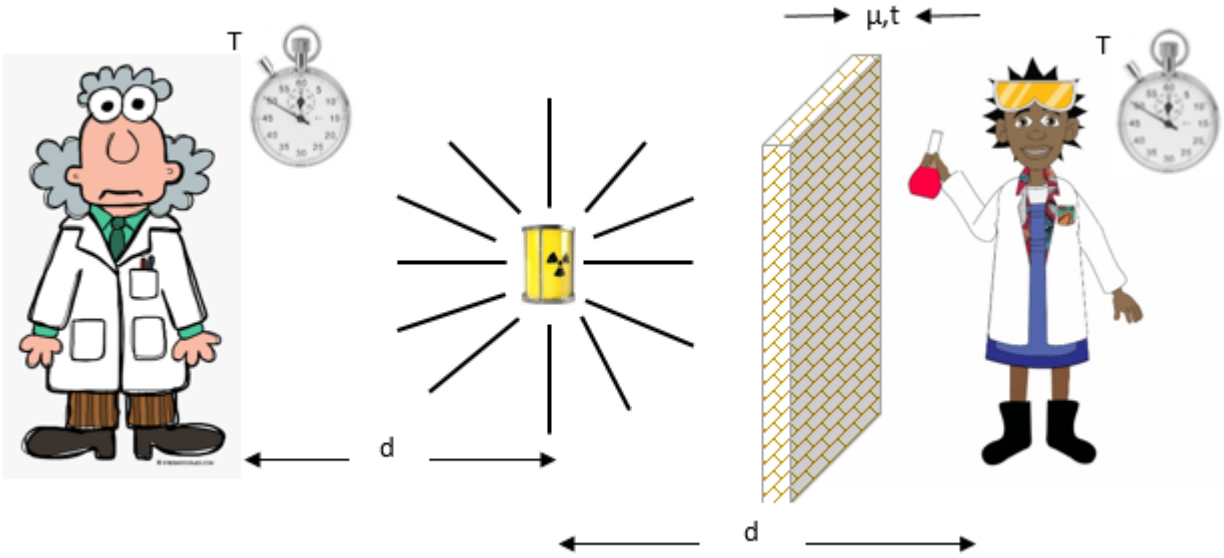
Dose rate and dose calculations can also be made using an on-line software programme - see http://www.radprocalculator.com/default.aspx .

This handy tool provides online calculators for Gamma Activity to dose rate from point sources and beta activity to dose rate from point and plane sources. Shielding can also be added if required however, be warned, the data you get out is only as good as the data you put in.

8.2.2 Using traditional hand calculations

Potential doses can be estimated if there is a knowledge of the:

- dose rates for each type of radiation from the source;
- typical distance of the source from the exposed person(s);
- time of exposure;
- time of emission (i.e. duration of use of the source); and
- any absorbing material in between the source and person.



Without attenuation:

Potential Dose (H) = Dose rate at distance d x Time of exposure (T) x [Time of emission (T)] [1]

Radiation protection is not exact, and doses should be calculated to the nearest part of the body to the source. This dose is normally taken as a "whole-body" dose, for comparison against the dose limits in IRR17. However, it is sometimes necessary to distinguish in between doses to the extremities, skin, eyes and the whole body, and assume distances that are appropriate to these parts of the body. Assume the minimum likely distance to the source when correcting dose rate for distance.

Care should be taken when applying factors for both time of emission ***and*** time of exposure, because there is often a correlation in between the two; for example a source might only be used one hour a day, so the ***USE*** factor is $1/8^{th}$ of an 8-hour working day (i.e. 12.5%) but the operator will always be there at this time, so the ***OCCUPANCY*** factor in this case would be 1 (i.e. 100%). The following time values are normally used for dose calculations:

Working Period	Assumed Time
Day	8 hours
Week	5 days; 40 hours
Year	50 weeks; 2000 hours

With attenuation:

Potential Dose (H) = Dose rate at distance d x T x attenuation factor [2]

The attenuation of radiation in material depends upon the type of radiation, the energy of the incident radiation, the beam size, and the composition, density and thickness of the material. Where there is already shielding, contact the University RPU for help on estimating attenuation.

Dose Estimate Calculations/methodology:

Radiation Type	*Further information*
Alpha radiation	Due to their high absorption in material, including air and dead skin, exposure to alpha radiation ***externally*** does not result in any dose, and there is no need to calculate dose rates.
Positrons	Because the path of a positron ends up with the production of penetrating gamma radiation, it is often unnecessary to estimate the external dose contribution from the charged particle at distances greater than a few mm (Ref: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4894854/. However, you may need to estimate a skin dose; see below.
Neutrons	Seek advice from the Radiation Protection Unit as estimating neutron doses can be complicated.
Gamma, x- and Beta radiation	In many cases, beta radiation doses may not need to be considered when estimating external doses. There is no need to calculate dose rates from beta radiation at distances greater than the maximum range for that beta energy in air, or other material as appropriate; see 8.1 for beta-range information. Generally, in work with unsealed radioactive material, the radionuclides are stored in glass bottles or absorbed into gels or samples which significantly attenuate the beta radiation that could reach the operator/user. Provided that the dimensions of the source are small compared to the distance to the observer/person, gamma, x- and beta radiation levels follow the Inverse Square Law (see below).

Distance: The Inverse Square law can be stated as: $DR_2 = (DR_1 \times d_1^2) / d_2^2$ [3]

where DR_1 is the dose rate at distance d_1, and DR_2 is the dose rate at distance d_2.

Using the dose-rate-per-unit-activity at a given distance information in 8.1, the dose rate for any particular activity at points of interest can then be estimated. *Note that this law will not apply at distances close in to the source.* It is usual to express dose rates in dose / hour; for example mSv/h or mSv h^{-1}.

Time:

Dose is linear with exposure time, so: *Dose = Dose rate x exposure (or emission) time* [4]

A time-averaged dose rate, i.e. averaged over an 8-hour period, can be calculated by multiplying the measured dose rate by the fraction of 8h working day when exposure occurs:

Time-averaged dose rate = Instantaneous Dose Rate x Period of Exposure (h) / 8 (h) [5]

Calculation of activity:

The activity of a radioisotope at any particular time can be calculated using the equation: $A_t = A_0 e^{-\lambda t}$ [6]

Where A_0 is the original activity, A_t is the activity after a decay time of t, and λ is the decay constant, which values are readily available on the internet. λ is equal to the 0.693 / half-life.

Calculation of activity (rapidly decaying radionuclides):

The dose arising from short half-life radioisotopes, i.e. those decaying significantly over the period of their use like F-18 or Tc-99m, cannot be accurately estimated from an instantaneous dose rate value. Failing to take decay into account would result in a significant dose overestimate.

The cumulative dose arising from exposure to a rapidly decaying radionuclide can be calculated using the following equation:

$$Dose = \frac{\Gamma \,.\, A_0}{\lambda} \left[e^{-\lambda t_0} - e^{-\lambda t}\right] \quad [7]$$

where Γ is the dose rate / unit activity, A_0 is the initial activity, λ is the decay constant, t_0 is the start of the time period of interest and t is the end of the time period.

If the time period starts at the beginning of exposure, the equation can be reduced to:

$$Dose = \frac{\Gamma \,.\, A_0}{\lambda} \left[1 - e^{-\lambda t}\right] \quad [8]$$

8.2.3 Useful rules of thumb

Estimating dose-rates from penetrating beta emitters:

$$D = 760\ A \qquad [9]$$

Where:

D = the dose rate in μSv h^{-1} at a distance of 10cm from a point source.

A = the source activity in MBq.

[Taken from AURPO Guidance Notes on Working with Ionising Radiation in Research and Teaching – March 2019 edition]

Estimating dose-rates from gamma emitters:

$$D = \frac{ME}{6r^2} \qquad [10]$$

Where:

D = dose rate in μSv h^{-1}

M = the Activity in MBq

E is the energy per disintegration in MeV

r = distance from the source in metres

[Taken from an Introduction to Radiation Protection by Martin and Harbison, page 78]

8.3 Estimating Skin doses from contamination (routine & accidents)

When working with unsealed sources of radioactive material, it is reasonably foreseeable that contamination could arise or a spill/splash could occur and be deposited on the skin (or glove) of a worker leading to a skin dose. The potential exposure to the skin can be estimated if we know:

Required information:	*Further details:*
A. The activity/activity concentration of the material coming into contact with the skin;	The activity and activity concentration of the material can be obtained from either the manufacturer's labels or data in the case of stock material that has been purchased OR from experimental protocols. In most cases, an estimate of the activity concentration of the material should be known.
B. The length of time the material might be in contact with the skin;	Based on data published by the nuclear industry, and the typical contamination monitoring carried out by those working with unsealed radioactive material, an exposure time of 30 minutes is a conservative estimate of the exposure time between a contamination event and completion of decontamination. It is possible to reduce this time, but additional local control procedures, e.g. checking hands after a stock manipulation, would need to be added to the Local Rules.
C. The contamination skin dose rate from the material; and,	Data for contact skin exposure due to external contamination are published in Delacroix et al. [2] for an extensive uniformly (infinitely thin) spread out deposit of contamination on the skin and also for a 50µL droplet residing on the skin. For simplicity, the dose rate data for contamination on the skin from a 50µL droplet is normally used even though, in most cases at the University, the potential volume that might be spilled on the skin, especially from stock volumes of ten of microlitres, is likely to be less than 50 µL.
D. The potential volume that might be splashed/spilled.	It is recognised that, in some cases where the activity handled is less than around 0.5ml (500µL), it is not deemed reasonably foreseeable that entire stock containers or samples could be spilled/splashed onto the skin for 30mins without the operator knowing. A value of 10% of the total stock/sample manipulated could therefore be assumed to estimate the potential activity spilled on to the skin in an accident. Where the volume handled is greater than 0.5ml, it is reasonably foreseeable to consider a 50µL droplet residing on the skin for 30 mins. Widespread bodily contamination is not thought to be reasonably foreseeable in most cases.

Method:

(1) Firstly, we need to work out the activity of the spilled quantity, in kBq, that is giving rise to the skin dose.

If ≤0.5ml handled then activity of spilled material = 10% of stock container activity/volume. ***Remember to convert to kBq.***

If >0.5ml handled then activity of spilled material = activity in a 50µL droplet at activity concentration. ***Remember to convert to kBq.***

(2) Based on the activity of the spilled material, the contamination skin dose rate and the length of time on the skin we can work out the skin dose using the following equation:

Skin Dose (mSv) = Activity of spilled material (kBq) x Contamination skin dose rate (mSv h^{-1} kBq^{-1}) x time on skin (h) [9]

Example 1:

Q: For the Risk Assessment, calculate the potential skin dose from the manipulation of an 18.5MBq (0.5mCi) P-32 stock sample (50µL).

Assessment:

The quantity of P-32 ordered from the supplier was supposed to be 18.5MBq on the calibration date but it normally arrives around a week early and so the arrival activity is around 26 MBq. The material was to be handled the same day so the activity handled during the experiment is around 26MBq. The activity concentration on the label from the vial states 370MBq/ml and so the delivered volume is around 50 µL.

As the total volume is less than 0.5ml, assume that around 10% of the total activity/volume could be 'spilled' in an accident/spillage scenario. Therefore, the activity that could be present in a spill scenario would be around 2.6 MBq. Due to the small volume in the potential spillage, in this case about 5µL, it is likely any contamination will be present as an infinitely thin film on the surface of the skin.

Potential Skin Dose (mSv) = Activity in spill (kBq) x skin dose rate for uniform contamination (mSv h^{-1} kBq^{-1}) x time on skin (h)
= 2600 x 1.33 x 0.5
= 1729 mSv

Even though workers would be wearing at least one pair of disposable gloves, the dose reduction afforded by the glove to P-32 is likely to be very low (<10%); in any case, it is reasonably foreseeable that contamination could get onto the skin between the glove and the labcoat cuff or onto the face of the person carrying out the work.

Due to the large potential dose to the skin from an accidental spillage, classification of the worker may have to be considered.

However, in the case of typical stock vial manipulations at the University, continuous radiation/contamination monitoring throughout the procedure and the vigilant use (and removal) of PPE would allow the rapid detection of any spills/splashes such that the hazard would be removed quickly. In many cases, these stock vial manipulations involve handling times of less than 2 minutes. Persons following good contamination control procedures would therefore likely detect, locate and remove contamination in around 2 minutes, as opposed to 30 minutes, thereby reducing the potential dose from an accident scenario to:

Skin Dose (mSv) = Activity in spill (kBq) x skin dose rate for uniform contam. (mSv h^{-1} kBq^{-1}) x time on skin with additional control measures (h)
= 2600 x 1.33 x (2/60)
= 115 mSv

In this case, due to the rapid detection and removal of contamination, it isn't likely an accident involving a P-32 stock vial, resulting in a brief contamination of the skin, would lead to an equivalent dose in excess of 150mSv. Classification of the person would therefore **NOT** be required.

Example 2:

Q: For the Risk Assessment, calculate the potential skin dose from a splash of radioactively contaminated urine from a feline I-131 patient given 450 MBq as an initial dose.

Assessment:

Measurements taken by the Radiation Protection Unit on the initial cohort of patients measured an average activity concentration of 40 kBq/ml in the first week post-administration of the I-131. The initial cohort were administered with around 92.5 MBq; around $1/5^{th}$ of the activity in this case. Assuming a linear relationship, the activity concentration of the urine in this example could be x5 the levels measured by the RPU on the initial cohort; e.g. approx. 200 kBq/ml. The urine is collected and sampled around 6 days post injection of the radioactive material to the patient so the activity concentration is likely to be less than this; however, 200 kBq/ml is a good conservative estimate.

As the volume being handled is almost always measured in ml, consider the scenario where a 50 µL droplet of the urine is present on the skin for around 30 minutes. At 200kBq/ml, a 50 µL droplet could contain approx. 10 kBq.

Potential Skin Dose (mSv) = Activity in spill (kBq) x skin dose rate for uniform contamination (mSv h^{-1} kBq^{-1}) x time on skin (h)
= 10 x 0.57 x 0.5
= 2.9 mSv

For larger-scale spillages, for example where larger volumes of urine may be spilled, it is likely that the potential dose would be from external radiation at distance X rather than from any contamination on the skin (as tweezers/tongs would be used to clean and bag the spill).

Example 3:

Q: For the Risk Assessment, calculate the potential skin dose from the routine handling of Quality Control samples from the Cyclotron facility.

Assessment:

The target activity concentration in the final ^{18}F-FDG product for injection into the patients is typically 500 MBq/ml @09:30am. However, handling of the QC samples could start earlier and therefore a higher activity concentration would be observed. It can be assumed, for the purposes of this risk assessment that the volume of the initial stock material handled doesn't exceed 2ml and that the QC work may start around 2 hours ahead of the 'injection time' i.e. 1 half-life earlier.

- Target activity concentration for patient injection = 500 MBq/ml (t=0hrs);
- Activity concentration at time of manipulation/handling (t=-2hrs) = 1000 MBq/ml;
- Assume skin contamination occurs as a result of a 50 µL droplet (approx. 2.5% of total volume being handled);
- Activity in a 50 µL droplet = 50MBq (@1000MBq/ml);
- From Ref [2], a 50µL droplet on the skin containing 1kBq would give a dose rate of = 0.788mSv/h;
- And therefore a 50µL droplet containing 50MBq would give a dose rate of approx. 39.4 Sv/h;
- Based upon nuclear industry published data and the frequent contamination monitoring that is carried out by the operator during all processes, a conservative exposure time of 30 minutes is assumed between the contamination event and completion of decontamination;
- Over 30 minutes, a dose of 19.7 Sv could be delivered to the skin from a 50MBq droplet.

Persons following good contamination control procedures could potentially detect, locate and remove contamination in 1-2 minutes, as opposed to 30 minutes, thereby reducing the potential dose from an accident scenario to 650 - 1300 mSv.

This is still clearly in excess of three-tenths of the skin dose and therefore this risk assessment would need to consider designation of these workers as Classified Persons.

9 Appendix 2: Example Contingency Plans

9.1 Content of Contingency Plans

The content of any Contingency Plan should identify the requirements set out in ACoP paragraph 244 of IRR17, namely:

a) Who is responsible for putting the plan into effect;
b) What immediate actions for assessing the seriousness of the situation are necessary, for the example the use of suitable radiation and contamination monitors;
c) What immediate mitigating actions are needed, for instance in clearing the accident area and establishing temporary means of preventing access to that area;
d) What emergency equipment is required to deal with identified accidents and where this can be found;
e) Other sources of information and guidance, such as equipment manufacturers and contact details;
f) What PPE is needed and where it can be found;
g) What personal dosimetry requirements there are for people involved in controlling the accident;
h) What training is required for employees;
i) How to obtain radiation protection expertise so that proper judgements can be made about the seriousness of the situation and the measures necessary to recover from it;
j) Under what circumstances to contact the emergency services and who is responsible for doing this;
k) What dosimetry follow-up is needed so that the people affected by the accident are identified and provision is made for their dose to be assessed.

Where appropriate, rehearsals of the arrangements in Contingency Plans must be carried out at suitable intervals. Desktop rehearsals may be appropriate in cases where contingency arrangements are simple and doses from reasonably foreseeable accidents are low. RPSs should arrange for Contingency Plan rehearsals to take place as part of their local training. Records of rehearsals (e.g. what parts of the Contingency Plans were tested, who attended and on what date) must be kept in case they are required during an audit or inspection.

9.2 Major Spillage or unauthorised release of radioactivity

A major spill or unauthorised release is one that has spread contamination out of the working area, cannot be quickly contained or has contaminated additional surfaces (e.g. a floor). Contact MUST be made with the RPS and the University RPA as the spill may be reportable to the HSE and/or SEPA. If the incident involves the contamination of a person, then decontamination of the person takes priority over everything else (see 9.3 below).

1. Cordon off the area immediately and restrict access it to only those persons authorised by the RPS or University RPA.
2. Carry out a short risk assessment on how to tackle the incident and the proposed method of decontamination. This should be completed by the RPS and/or University RPA and should include an assessment of the likely activity spilled. If radiation or contamination measurements are available from the initial incident, these can be used to help formulate the response. Where action is required immediately, a dynamic risk assessment may be carried out and recorded later.
3. Only suitably trained and competent persons must be involved in the clean-up operation, under advice from the RPS or University RPA.
4. For short-lived radionuclides, e.g. radionuclides with half-lives of around 2 weeks or less, decay should be used as the primary means of removal of the radioactive inventory of the spill.
5. Where decay is not possible, using disposable paper towels, long reach tongs/tweezers where possible and suitable cleaning solutions, the spill should be cleaned;
    a. Wear appropriate PPE (double gloves, overshoes, lab coat) and mark the extent of the spill using a marker if possible. Begin to wipe up the spilled material but do not spray cleaning solution directly onto the spilt material yet. If PPE is not available in the Lab/area where the spill occurred, seek assistance from the RPS or immediate helper.
    b. Clean from the outside of the spill towards the centre; this minimises the spread of contamination beyond the area of the spill itself.
    c. Once the spill has been absorbed, use a cleaning solution, for example decon-90® or similar, and cover the area in the solution. Clean the area, again starting from the outside of the spill towards the centre.
    d. Use an appropriate monitoring technique for the isotope in question (consult with RPS or University RPA for information) and conduct a survey of the area noting down the background and maximum readings.
    e. If contamination is found above twice the normal background level, use the cleaning solution again to clean the area and remove any remaining contamination.

f. Repeat the cleaning and monitoring stages until all residual contamination has been removed or contamination monitoring readings remain unchanged after a cleaning cycle.
g. If contamination persists after several cycles of cleaning, contact the RPS or University RPA for further guidance.
h. All materials used in the cleaning of the spill must be double bagged and disposed of as radioactive waste.

6. The RPS, with assistance from the University RPA, will investigate the cause of the incident and complete a report detailing the full incident. Any reporting to the authorities (e.g. SEPA/HSE) will be led by the University RPA if required.

9.3 Contamination of individuals (including skin/puncture wounds)

Any person that is, or is believed to be, contaminated must immediately notify a colleague that they may be contaminated. If practicable to do so, they must not travel throughout the building to prevent the spread of contamination. If a bare hand, or hands, are contaminated then it may be helpful to put on a pair of gloves until help arrives to minimise the spread of contamination. Contact MUST be made with the RPS and potentially the University RPA, as appropriate for advice.

Due to the potential need to remove items of clothing, a chaperone of the contaminated persons choosing MUST be present during any decontamination process.

1. A suitably trained person, using a suitable instrument, shall monitor the person to confirm extent of contamination. Ensure the chosen instrument is capable of detecting the radionuclide in question. Be sure to record:
    a. Background and maximum readings, location of contamination on the individual and approximate size of area(s) of contamination – use a permanent pen to mark out area(s).
    b. Remove any contaminated clothing and items of jewellery – place in plastic waste bag and leave in or near the affected area. Temporary clothing (coveralls) should be supplied in the area; if not, request these from the RPS and remain in the area until temporary clothing arrives. Removed clothing and accessories may be returned if possible, but may need to be destroyed if not able to be decontaminated.

2. Under direction from competent personnel (e.g RPS or University RPA):
    a. Wash the affected area thoroughly, but gently, with soap and cold water over a plastic bowl (or a sink if one is available in the room). This will help to contain waste water and reduce the spread of contamination. Wash from the edges of the contaminated area inwards to prevent spreading contamination to other parts of the body.
    b. Should large areas of clothing / skin be contaminated, this may necessitate the movement of the worker to an appropriate showering facility. This would be discussed and dealt with in conjunction with the University RPA due to the potential for intakes by the affected person as well as disposals of radionuclides to the environment.
    c. Washing should be gentle as vigorous rubbing may cause surface damage to the skin, permitting the material to enter the body. A brush should never be used as this will damage the skin, however a soft cloth may be used if employed gently.
    d. Take special care with facial contamination to avoid the material entering the eyes, ears, nose, mouth or any wounds.
    e. Rinse the area, dry with a gentle patting motion and then re-monitor. Double bag all solid waste and place into a radioactive waste bin.
    f. Repeat the cleaning and monitoring stages until all residual contamination has been removed.
    g. If contamination remains, further abrasive actions may be taken, but only after discussion with the University RPA.
3. Any contaminated wound, however trivial, should be irrigated with plenty of water or saline solution, with care being taken to limit any spread of contamination to or from other parts of the skin.
4. If there is contamination suspected in the eye, use a saline eye wash bottle, and irrigate the eye fully, making sure that water runs from the inside edge of the eye outwards, to prevent any cross contamination of the face and the other eye. Use a sink or plastic bowl to collect the water and prevent the spread of contamination if possible.
5. The spread of contamination, particularly on shoes or items of clothing of persons leaving the affected area, should be prevented. Persons who may be contaminated must be monitored immediately before leaving the area and appropriate arrangements made for their decontamination.
6. An assessment of any potential dose through an open wound may be required. This will be carried out by the University RPA.
7. If considered necessary, any dosimetry normally worn by involved personnel should be sent off to the Approved Dosimetry Service for measurement immediately.

9.4 Loss or theft of radioactive material/waste

It is difficult to provide detailed information in a contingency plan for a lost source as generally the situation may be quite reactive. Below is a rough guide to the process to follow for a suspected loss/theft of a source.

1. If you believe that a source has been lost or stolen, immediately inform the RPS and also the Security Dept.
2. Try to determine when and where the loss/theft occurred. Who usually uses the source? Who last logged the source out? Are security aware of any breaches to the building? Who was the last person on the laboratory log to be in the room?
3. Have a good look around the immediate area, has the source been left out? Put back in the wrong storage place?
4. If it is still not located, a full search of the immediate area/building must be instigated and led by the RPS.
5. The RPS will lead on the investigation and inform the University RPA.
6. The University RPA will inform the relevant authorities, including the Police.
7. If the source is found, the RPS must carry a short dose estimate to any person that may have come into contact with the source.

9.5 Fire in the vicinity of the Controlled Area

In general, persons following contingency plans in the event of a fire would follow the normal fire evacuation procedures for the building/area.

1. If you are able to do so safely, make safe the working area by returning any sources being used to their source store.
2. If you are in the Controlled or Supervised Area when the fire alarm goes off, and you can do so safely, monitor yourself for contamination prior to leaving the Controlled or Supervised Area. If this is not possible, or you do not wish to delay your exit, take a contamination monitor with you and check yourself for contamination when safely away from the building.
3. If a fire is confirmed in the vicinity of the Controlled or Supervised Area, inform the fire coordinator of the potential activities and radionuclides in storage/use to allow them to inform the fire-fighting team. You should inform the RPS and the University RPA know at this point.
4. The University RPA would take the lead on informing the fire-fighting team about any potential dose implications or dose-rate cordons required.