Risk Assessment Health
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Ionising Radiation

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Working Safely with Unsealed Radioactive Sources

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LUNIVERSITY OF ASSESSMENT

CAMBRIDGE

WORKING SAFELY WITH UNSEALED RADIOACTIVE SOURCES

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APPENDICES – please refer to the <u>Safety Office website</u> to select individual appendices

1. INTRODUCTION

This document has been prepared by the University Safety Office (SO), and is designed to provide practical guidance to those working with unsealed radioactive sources, in order to promote safe working and good control and to support the production of 'Local Rules' within departments of the University. It is aimed primarily at individual research workers and their supervisors. The more general arrangements for managing work with ionising radiations, including the detailed roles of Heads of Departments and the nominated Radiation Protection Supervisors (RPS), are described in the separate document 'Management of Work with Ionising Radiation'. Any person requiring advice further to that provided in these books, in terms of work with unsealed radioactive sources, should consult their Research Supervisor and Radiation Protection Supervisor in the first instance, who may contact the University Radiation Protection Officer/Radiation Protection Adviser (RPA) in the Safety Office. Guidance on work with sealed sources and x-ray and other ionising radiation generating equipment is given in the two documents 'Working Safely with Sealed Radioactive Sources', and, 'Work with Radiation Generators'. All work with unsealed radioactive sources must comply with the requirements of the Ionising Radiations Regulations 2017 (IRR17) as enforced by the Health and Safety Executive and the Environmental Permitting Regulations 2016 (EPR16) as enforced by the Environment Agency. Other regulations apply in certain circumstances including transport of radioactive sources, and medical applications of ionising radiations. Further advice in respect of these issues can be obtained from the Safety Office.

2 ROLES AND RESPONSIBILITIES

2.1 The Radiation Protection Supervisor

The Radiation Protection Supervisor is a statutory appointee, carrying out tasks on behalf of, and reporting to the Head of Department on ionising radiations safety issues. The role of a University RPS is described in more detail in *Management of Work with Ionising Radiation* and includes the following tasks, which are much broader than the strict definition under the terms of the IRR17:

- 1. Ensuring that all departmental 'Local Rules' and other departmental written procedures are complied with.
- 2. Keeping in good contact with research groups within the department, so as to ensure that the Local Rules are complied with, and other radioactive substance control requirements are met.
- 3. Assisting with preparation of, and assisting with review of, risk assessments for work involving ionising radiations.
- 4. Offering practical advice and assistance to users of ionising radiations, where necessary in consultation with the RPA.
- 5. Authorising the acquisition of radioactive substances, subject to departmental limits as

- agreed with the Safety Office.
- 6. Supervising the department's system for accounting for radioactive sources and wastes.
- 7. Supervising, in consultation with the Safety Office, the department's system for the annual examination and testing of radiation monitoring instruments.
- 8. Carrying out formal annual audits of holdings of unsealed radioactive sources in the department.
- 9. Assisting with the preparation, maintenance and issue of departmental Local Rules and written procedures.
- 10. Provide assistance in dealing with emergencies within the department involving ionising radiation.
- 11. Responding with advice and help when notified of other incidents involving ionising radiations in the department.

2.2 The Research Supervisor

The research supervisor, principle investigator or 'line manager' will, in consultation with the Head of Department and the RPS:

- Generally, ensure that the written requirements set out in the Department's ionising radiations safety procedures (Local Rules) are complied with by those under their supervision.
- 2. Cooperate with others in the Department, to ensure that the Department's radiation safety requirements can be met.
- 3. Where appropriate, ensure that new work has been subject to a written risk assessment that has been agreed by themselves and the Radiation Protection Supervisor.
- 4. Ensure that the agreed practical precautions are followed by those workers that they are responsible for, and that they have received and records have been made of appropriate practical and theoretical instruction and training.
- 5. Ensure that appropriate personal protective clothing and other equipment is actually being worn and is properly maintained.
- 6. Ensure that the agreed programme of monitoring, safety checks and record-keeping is undertaken within their area of responsibility.

2.3 The user of ionising radiations

The individual research worker (the user) will:

- 1. Ensure that they have registered their work with their Department.
- 2. Ensure they are registered to attend the University (SO) and Departmental training courses relating to their uses of ionising radiations, even if they have attended training

courses elsewhere and/or have previously used ionising radiations in the course of their research.

- 3. Take all reasonable steps to protect themselves and others from any exposures to ionising radiations that that could result from their work.
- 4. Never misuse sources of ionising radiations or equipment provided to restrict exposure.
- 5. Cooperate with others involved in safety including their research supervisor and the RPSs.
- 6. BEFORE commencing any new work involving radioactive substances inform their research supervisor (where appropriate) and always inform the RPS.
- 7. If required by the department, prepare a written risk assessment prior to the work commencing, which should, where appropriate, be approved by their Research Supervisor and always seen by the RPS. Otherwise they must familiarise themselves with existing risk assessments prepared for very similar work in the department.
- 8. Ensure that they are aware of the underlying hazards associated with their work, as described in this document, the Local Rules, risk assessments and in their theoretical and practical instruction and training.
- 9. Observe the safety precautions identified in this document and in the department's Local Rules, and any special precautions identified in the risk assessment, experimental protocol or warning signs.
- 10. Ensure that they wear the appropriate protective clothing and other equipment including personal radiation dosimetry, as specified in the Department's Local Rules and relevant risk assessments.
- 11. Notify their research supervisor and the RPS in the event of losses, spills, or contaminations or other specified incidents (refer to departmental Local Rules for further information and for contingency plans).

2.4 Other identified persons

In larger Departments it will normally be appropriate to nominate an individual, other than the RPS, within each research group to carry out regular tasks such as periodic monitoring in laboratories, maintaining local records, etc. These are not statutory appointments, unlike that of the RPS, but names and duties of these individuals will be specified in the Local Rules. Alternatively, it is acceptable to rotate these duties around members of the research group and this can have some advantages in giving all members of the group experience of radiation protection tasks.

3 CONTROL OF WORK WITH RADIOACTIVE SUBSTANCES

3.1 Registration of users

Before working with radioactive sources in the University for the first time, all users must have permission to do so from their department. This will be done by means of a system of *Registration of Users* that is administered by the Radiation Protection Supervisor. The user will be required to complete a form which is then countersigned by their research supervisor and the RPS (an example form is shown in Appendix 13). This form identifies the work AND the training requirements. All persons who have not previously used radioactive substances and users of radioactive substances from other institutions or countries will, in addition to attending departmental induction and training at the earliest opportunity, attend the standard induction training course for work with ionising radiations within the University (organised by the Safety Office).

3.2 Acquisition of radioactive sources

Strict controls on the acquisition of radioactive sources are required for several reasons.

- 1. To ensure that the Department can legally hold the radioactive sources under the terms of the Environmental Permitting Regulations 2016.
- 2. To assist in ensuring that the risks associated with each piece of work have been adequately assessed, with specification of the appropriate control measures in order to reduce exposure to ionising radiations to that which is as low as reasonably practicable (ALARP).
- 3. To ensure that there is a legal and workable means for disposal of any radioactive wastes resulting from the work, and that the production of such wastes is minimised in accordance with the statutory requirement in EPR 16 to use Best Available Techniques (BAT) for this purpose.

All purchases of radioactive sources must be done through the procedures set out in Departmental Local Rules. These will require a request form to be completed and signed by the user, and approved by the RPS. (Electronic request systems are used in some departments – these are only satisfactory if a robust demonstrable authorisation process for each requisition can be subsequently identified). Users should only purchase sufficient activity to complete the intended programme of work and should consider the availability of existing sources in the Department. Where radioactive sources are imported rather than purchased (e.g. brought in from another Department) the approval of the RPS is still required. Users must not start work with new radioisotope stocks until these have been entered into the Department's central record of receipt of radionuclides, a unique identifier number has been issued, and a local "usage and disposal" record card or electronic sheet has been started for the individual stock item (refer to the examples shown in Appendix 10).

At the same time the outer pot containing the radioactive stock item (in an inner vial or similar – often called the 'stock pot') must be marked with the unique identification number. Sub-

aliquotted stocks wherever practicable should be similarly identified. An RPS will normally organise these matters, but users must ensure that these steps have been carried out.

3.3 Risk assessment and Local Rules

Before any new work with unsealed radioactive sources is undertaken the user will usually be required to prepare a written prior risk assessment as described in detail in Section 5 of this manual. If an existing risk assessment is in place in the department relating to very similar work, it may be possible for this assessment to be cross referenced to the new work, but in any case users should familiarise themselves with the appropriate risk assessment and ensure that it is relevant to **them** and to **their** work. General precautions for work with unsealed radioactive sources appear in the risk assessment document, and in the relevant set of Local Rules prepared with RPS involvement within Departments. All users must have access to copies of both documents. In addition, any specific practical working procedures relevant to an individual piece of work must be recorded clearly and concisely in laboratory notebooks or similar, and referenced, if relevant, in the risk assessment. It is not necessary to repeat in such documents standard precautions that are already described in the Department's Local Rules, unless it is considered that there is a particular need to reinforce these precautions. Any directions required by radiation warning notices displayed in the working area should always be followed; these notices are part of Local Rules.

3.4 Notification of work

The RPO at the Safety Office must be notified of any significant_new work as early as possible in the planning stages. This is to ensure that appropriate arrangements, environmental Permits under EPR16 and notification, registration and consent under IRR17 are all in place before work starts.

4 HAZARDS AND RISKS ASSOCIATED WITH UNSEALED RADIOACTIVE SOURCES

This section provides a general assessment of the risks associated with this type of work as currently undertaken across the University. It supports, but does not replace, the specific risk assessments that must be carried out as described in Section 5 of this book. Some information regarding commonly used radionuclides is included in Appendices 1 – 3 of this manual, but further specific details relating to any radionuclide that is proposed for work can be obtained from the Safety Office.

The nature of the hazard

Work with unsealed radioactive sources can, depending on the radionuclide involved, lead to both *external* and *internal* exposure of persons to ionising radiations. The harm caused by exposure to ionising radiations may be manifest as early effects such as skin burns and, it is assumed, as late effects such as cancer. Early effects are associated with very high local

doses and dose rates, above biological thresholds, and it is not really conceivable that they could arise as a result of the work with unsealed radioactive sources normally undertaken at the University. The risk of late effects is assumed to be proportional to the dose received. It is assumed that there is no dose threshold and so the emphasis is on avoiding unnecessary exposure in the first place and keeping any unavoidable exposure as low as reasonably practicable. Statutory dose limits (IRR17) are in place in the United Kingdom, but it would never be acceptable with the type of work undertaken at the University for any person to approach these limits during normal work, although such a situation could occur in the event of an accident.

External exposure arises from radioactive sources outside or in contact with the body, and involves the radiations emitted by gamma or beta emitting radionuclides. The radiation dose rate in proximity to the radioactive substance depends on the radionuclide, its activity and physical form, the distance from the source to the body and the nature and thickness of any intervening shielding. The data presented in Appendix 3 gives an indication of the magnitude of the radiation dose rates that are possible. It is, in principle, possible to predict doses from external radiation if the dose rate and time of exposure is estimated. Precise quantification of the dose and the risk is not always simple given that dose rates are typically highly localised and the exposure of the body is non-uniform. With the types of work undertaken at the University, significant extremity doses are very unlikely, except perhaps in a few situations:

- 1. Doses to the fingers and hands from poor technique with phosphorus-32 or other high energy Beta emitters.
- 2. Lengthy periods of work with high activities of gamma emitters, and during radiopharmaceutical preparation and use of substances produced in cyclotrons.

Internal exposure arises from radionuclide intake, which may occur via a number of pathways:

- 1. Inhalation of radionuclides in the form of gases, vapours, mists, sprays and dusts.
- 2. Ingestion of radioactive materials.
- 3. Direct incorporation of radionuclides into the body via contaminated cuts or by injection from contact with contaminated sharps.
- 4. Transfer of radionuclides through unbroken skin (known to occur with tritium and iodine compounds).

An estimate of the internal radiation hazard for a particular radionuclide can be gained by comparing the activity potentially ingested with the published Annual Limit on Intake (ALI) which corresponds to an annual effective dose of 20 mSv (the statutory dose limit for any worker). The risk assessment process currently in use within the University actually compares risk against a lower annual dose of 6 mSv (which includes any contribution to the effective dose from external radiation). Typical ALIs appear in Appendix 2. It should be noted that the ALI depends on the actual route of intake. Those in Appendix 2 correspond to the ingestion route, but some committed effective doses (CED) for inhalation, where these are significantly different from the ingestion figures are also given, and the ALIs can be calculated from that data. Given that the typical uses of radionuclides in the University are

generally modest, the committed effective dose is actually used in the risk assessment process. The committed effective dose is the lifetime exposure resulting from intake of the radionuclide. In general, estimating intakes of radionuclides and internal exposure is difficult, although there are some radionuclides that can be relatively easily measured in the body, e.g. tritium (measured in urine) and some types of radio-iodine (by thyroid monitoring). These assessments, if needed (as advised by the RPA) should always be carried out by an appropriate internal dose assessment laboratory. Nevertheless, with the types of work undertaken at the University significant intakes are generally unlikely provided that appropriate precautions are taken. The risk of routine as well as accidental intakes is highest where large amounts of activity are used in synthesis of labelled compounds, and is increased where radionuclides can be released in volatile forms, for example during iodination of proteins, or, handling of high activities of some Sulphur-35 labelled materials, particularly at elevated temperatures. In addition, the activity concentration of the radioactive material is also an important factor. Both the internal and external risks are higher when the radionuclide is in a concentrated form (e.g. in the supplier's stock solution). The risks usually reduce as the radionuclide becomes diluted and dispersed in experimental materials.

Finally, another very important hazard with unsealed radioactive substances is that of contamination of the workplace and work equipment. This may give rise to exposure of those not connected with the work as well as cross contamination and spoiling of experimental work. Regular and effective contamination monitoring is essential.

Who is at risk?

This will include the users and any co-workers, and those involved in disposal of radioactive waste, but may also include others such as laboratory cleaners, maintenance contractors, visitors etc, who may inadvertently come into contact with radioactive work materials or contaminated surfaces. Others are at risk if radioactive sources are lost or stolen and they come into contact with them.

Female employees are reminded that any work with ionising radiations presents a possible risk to the foetus (to which the public dose limit applies) and that work with unsealed radioactive sources presents a possible risk to the nursing infant. The University must inform female employers that this is the case, and that it is important that individuals notify the 'employer' (preferably the Department - the supervisor or line manager) in these situations. This is to enable the risk assessment to be reviewed, even though it should already have taken account of the situation of a pregnancy being declared. Ultimately, even if the results of risk assessments are favourable in allowing the worker continuing to carry out the procedure involving radioactive substances, a decision whether to continue or not, should be supported by the department, even if this means making alternative arrangements for another individual to carry out some or all of the procedure. These situations, and review of specific risk assessments in the event of declared pregnancy, must be discussed with Safety Office and the University Radiation Protection Adviser. Notification can also be given, in confidence, via the University's Occupational Health Service, who also will seek advice from the Safety Office and Radiation Protection Adviser. Any recommendations on changes to work patterns are likely to be determined by the need

to consider the risk of accidents, since with normal procedures routine exposures should be negligible. Given the risk of intakes it is likely to be appropriate that the individual avoids undertaking higher risk work such as synthesis of radio-labelled compounds, dispensing of aliquots from higher activity stock solutions, and dealing with significant spills of radioactive substances. Further guidance on this and other general safety issues also appears in the University's Maternity Policy. A Guidance leaflet from the Health and Safety Executive on working with radioactivity when pregnant or breast feeding is reprinted as Appendix 12.

Evaluation of precautions and risks

Typical precautions expected and applied in the University's work are described in Section 6. The risk of health effects associated with work with unsealed radioactive sources at the University is, in general, low. This type of work has been carried out for many years at the University and elsewhere and experience shows that significant exposure is normally only associated with serious accidents or demonstrable bad practice and even then the probability of the statutory dose limit being exceeded is low. However, notwithstanding this conclusion, it is necessary and required by the Regulations that the risks of individual pieces of work are adequately assessed and that the appropriate precautions are followed. The following section sets out the requirements for, and practical methods for carrying out prior risk assessments.

5 RISK ASSESSMENTS

Adequate PRIOR assessment of the risks of work with unsealed radioactive material is fundamental to safe working and is a requirement of both the Ionising Radiations Regulations 2017 and the Management of Health and Safety at Work Regulations 2017. Risk assessments must be recorded, and for all new work this is done using a standard proforma developed by the Safety Office and available from departmental RPSs or the Safety Office website. The advised risk assessment format and supporting guidance is reprinted in Appendix 11 of this document. Completed risk assessments may be passed to the Safety Office for comment by University's Radiation Protection Officer/Adviser - this must be done for new procedures that have not previously been assessed within the particular department (unless the RPO/RPA advises the RPS that this is not necessary).

Responsibility for preparing risk assessments rests with the University. To enable this to occur on an efficient and practical basis, the University requires users to be closely involved with the preparation of their own assessments, with assistance from and approval by their research supervisor where appropriate, and always by the lead or Senior RPS of the department. Users should not begin new work until a risk assessment has been agreed by the Research Supervisor/RPS and if appropriate, has been reviewed by the RPA. This does not mean that a separate risk assessment will be prepared for every single piece of experimental work. For example a series of experiments perhaps with some minor variations could be undertaken under the same risk assessment. Departments must use their own judgement in this matter, although the University RPO/RPA is available to provide advice and

assistance on preparing risk assessments for work with unsealed radioactive sources.

Once the risk assessment is complete a copy should be held by the user in the same file as the experimental protocol or other Local Rules documents. Anyone directly or indirectly involved with the work covered by the assessment must be familiar with its findings. Risk assessments must be regularly reviewed as set out in the guidance in Appendix 11.

6 PRACTICAL PROTECTION MEASURES

A summary of the essential practical precautions for work with unsealed radioactive sources can be found in Appendix 4 of this document. This must be read in conjunction with the additional guidance provided here and in the Department's Local Rules, and in any written procedures specific to the area or the particular piece of work.

6.1 Facilities and designation of areas

The RPA must be consulted when a Department is planning new facilities for work with unsealed radioactive sources, or if considering doing such work for the first time in any existing facility. Most 'low level' work with unsealed radioactive sources can, however, be undertaken in modern, general-purpose laboratories with standard finishes and fittings, with minimal upgrading. A fume cupboard must be available for work if there is risk of significant exposure to airborne radionuclides. The Environment Agency has published guidance in respect of the construction of new and refurbished laboratories for the use of unsealed radioactive substances. This primarily relates to ensuring that surfaces do not become readily contaminated, and that any resultant contamination is readily removable. Additionally, design aspects of laboratories and similar facilities that may impact on the *safety* of those working there, are provided for by compliance with the requirements written into the lonising Radiations Regulations.

Laboratories, or areas of laboratories in which lower risk work (as determined by prior risk assessment) is undertaken in the University, will normally be designated as 'Supervised Areas' and will be demarcated with the trefoil sign with the legend "Supervised Area – Risk of Contamination". It is advised that work involving unsealed radioactivity, and especially those stages such as dispensing from stock solutions, are segregated from other activities within the laboratory. In many cases it may be appropriate to establish a more localised supervised area within the laboratory, for instance a 'bay' or one side of a 'bay' and to demarcate this in a suitable manner, rather than the whole laboratory. The significance of the extent of the supervised area is that it defines the area that is subject to formally recorded contamination monitoring, and hence conditions are kept under review and spread of contamination prevented. Local rules and supervision by an RPS are also usually required in these areas. Secure storage for radioactive substances in these areas must be provided as set out in Section 6.4 below.

Higher risk work (risk of significant exposure or spread of contamination) will be undertaken

in dedicated laboratory facilities designated as 'Controlled Areas'. The need for, and the precautions associated with such areas must have been agreed in advance with the RPA. Access to controlled areas must be restricted by locked doors, key-code access systems, or similar, and work in these areas will be carried out in accordance with clearly defined special procedures. It must not be possible for unauthorised persons to enter the area. Exceptions to locking or other access systems might be made where there is continuous close supervision of the area by the user but this situation is by no means ideal and such cases must be agreed with the RPA. In each controlled area there must be a record containing brief details of work in the area including the names of persons involved and dates the room is used. This is necessary since, when combined with monitoring results, it provides the means of demonstrating that exposure of persons is being suitable restricted. Monitoring and supervision arrangements will be required as for supervised areas.

Some types of very low risk work (e.g. scintillation counting of samples and loading of autoradiography cassettes) are undertaken in non-designated areas subject to local agreement with the RPS. The risk of generation of contamination in these areas must be very low and this should be confirmed by monitoring.

Radioactive waste stores will generally be designated supervised areas, and thus require supervision and monitoring. However, they must be kept locked when access is not required, in order to ensure security of materials stored within. In this case the requirement to restrict access derives *mainly* from the need to provide adequate security for the radioactive wastes in the store as opposed to the need to control occupational exposures. However, if materials that could produce volatile radioactive products are stored in these facilities, arrangements must be made, subject to RPA advice, to provide natural or possibly mechanical ventilation for the area.

6.2 Personal protective equipment (PPE)

The following are mandatory for all work with unsealed radioactive substances where there is any risk of personal contamination, for example during dispensing from vials, or for work with dispersible substances:

- 1. A laboratory coat (or equivalent) properly fastened at the neck.
- 2. Disposable gloves of an appropriate type refer to University published guidance (Website) in terms of glove selection (HSD059C).
- 3. Protective eye-wear.

Additional PPE – protective clothing and equipment – may be required in some situations. In controlled areas the user should change from their normal laboratory coat to a dedicated coat which is reserved for use in the facility and stored within a 'clean' area outside the entrance barrier to the controlled area, where hand-wash facilities will also be available. These coats should be labelled as to their purpose and monitored carefully before laundering. If the Local Rules for the controlled area require it, the user must also use disposable overshoes or any separate footwear reserved for use in the controlled area.

Other types of protective clothing may be specified, in the Local Rules, subject to RPA advice, such as face visors and eye protection, lead shielded gloves, aprons and eye-protection for some types of work with certain gamma emitters.

6.3 Personal dosimetry

Whole body dosimetry must be worn when working with gamma emitters including iodine-125 and chromium-51, and when working with high-energy beta emitters including phosphorus-32. Normally this should be worn on the front of the body near the lapel area, as this is the area of the body likely to be most exposed when a worker sits at a bench. Note that dosimetry will not work for 'soft' (low energy) beta emitters including carbon-14, phosphorus-33, sulphur-35 and Tritium.

Users of Phosphorus-32, Sodium 22, and PET radionuclides may be required to wear extremity (finger) TLD dosimetry, changed at monthly intervals, if they manipulate more than 5 MBq in a single aliquot. The need for this type of additional monitoring must be discussed between the user, RPS and RPA and should be identified in the risk assessment. This type of monitoring must be for a minimum of three months from starting the work, the RPS can then review the necessity for continuing this monitoring with further advice as necessary from the RPA.

In addition, RPSs should consider providing extremity dosimetry for those dispensing from any stock solutions (other than low energy Betas) and the RPA may recommend this in some cases. Experience has shown that poor technique can give rise to significant doses, and that wearing extremity dosimetry at least for a trial period is useful while a new worker is developing his/her technique.

Extremity dosimetry should also be worn by those working with significant amounts of gamma emitting radionuclides, i.e. manipulation of more than 10 MBq in a single aliquot, unless the RPA has agreed that this is not necessary. They may be provided for work involving lower activity levels if the RPS considers this appropriate (this should be discussed with the RPA and included in the risk assessment).

Individuals undertaking iodinations must monitor their thyroid for uptake of iodine before starting work and then once between 6 and 24 hours after the work using a sodium iodide scintillation detector instrument (for example a 'Mini' monitor with a 42A or 44A probe). The RPS should demonstrate this technique (monitoring must be done well away from any sources). The results of this monitoring must be recorded in the log-book for the room. Any reading in excess of twice the normal background for the monitor must be reported to the departmental RPS who must then contact RPA for advice. (The University has an arrangement that would allow the individual to visit the nuclear medicine department at Addenbrooke's Hospital where a more systematic assessment of uptake and dose is possible.)

Individuals working with greater than 1 GBq of Tritium in a single piece of work should be subject to bioassay (assessment of intakes by analysis of urine samples). The University RPA should be contacted for details of this, and, in case, this should be identified as part of

the prior risk assessment process.

6.4 Keeping and storage of radioactive sources

Each and every radioactive source, where "source" typically means the container housing a vial containing a radioactive stock solution or solid, will be assigned to a named person in a Department who is made responsible for its safe keeping (the source owner/holder). When not actually in use (under direct surveillance), the source must be kept in a suitable locked store approved by the RPS. Keys to these stores should be removed when the laboratory is unoccupied by the source users. Sources must not be left out in the open on benches, etc. where they can be readily removed or mislaid. The overall philosophy is that radioactive sources must not be accessible to 'unauthorised' persons – this applies not just to visitors to the department, contractors and so on, it also includes members of the department who do not need (or are not authorised) to access these materials in the course of their work.

Each source will have a "usage and disposal sheet" used both to record dispensing from the stock solution and also the fate of the radioactivity (disposals). Only those standard records designed by the Safety Office should be used unless the RPS and the Safety Office agree that an alternative format is acceptable in a particular situation. Detailed information in respect of the required record keeping systems, including a 'model' record sheet can be found in Appendix 10. Since the user(s) of the source within a research group, may not necessarily be the nominated holder, the user(s) must also accept that they too are responsible for the safe keeping of the source and for proper completion of the record. Each incoming stock container must be 'wipe tested' to demonstrate that there is no removable contamination present on the outside of the container. This test can be carried out by the RPS or the source owner/holder.

Other radioactive materials such as sub-stocks, gels, samples for counting, etc, also need to be kept safely and securely. Again, as far as practicable, they should be kept in locked stores when not in use and under direct surveillance, although it is accepted that this is not always possible. However, attention should still be paid to security, shielding and additional containment if necessary, and minimising the risk that they may be accidentally disturbed by others. Liquid radioactive solutions should always be stored over drip trays or inside unbreakable outer containers so as to ensure that any failure of the immediate containment will not lead to contamination of the store or the floor underneath. Always consider the risk to other persons who might encounter the radioactive materials, e.g. laboratory cleaning staff, maintenance personnel, and visitors.

6.5 Labelling of sources

Correct labelling and identification of sources is an essential statutory requirement. For stock solutions this labelling must include:

- 1. The radiation trefoil sign and the legend "RADIOACTIVE"
- 2. The unique identification number issued by the department that enables sources to be

speedily related to the local usage and disposal record and the department's central record.

- 3. Details of the radionuclide and name of the chemical compound.
- 4. A nominal activity (in MBq) and a reference date.

Stock solution vials should normally be kept within the manufacturer's purpose made container. This can generally be expected to offer sufficient (if not complete) shielding for gamma and high-energy beta emitters as well as providing suitable labelling once the departmental identifier is added. Other containers of radioactive materials should also be suitably labelled. The minimum requirement is the use of trefoil stickers or trefoil tape <u>and</u> identification markings sufficient to enable them to be traced to their owner and to his/her experimental notes so that the radioactivity content can be established. Other details (see above) should be included where practicable. Very small volume aliquots may need to be kept securely within a labelled box or rack, which is clearly marked with the above information relating to the aliquots rather than the very small aliquot tubes themselves.

6.6 Source checks and records

All sources are subject to at least formal monthly checks organised by the RPS, but more frequent checks by the source holder/users are required. The objective here is to confirm that all sources can be accounted for. In addition, details of use and disposal of unsealed sources are collated into totals for the Department. These are then passed monthly to the University Radiation Protection Officer who produces annual reports to the Environment Agency that enable the University to show that it is complying with its Permits issued under EPR16. All users must cooperate with these disciplines, and a nominated member of each research group or section is expected to carry out these record keeping tasks on behalf of their respective group.

6.7 Monitoring of ionising radiations (contamination monitoring, etc.)

Whilst the University retains responsibility for ensuring a safe place of work, the day to day responsibility for monitoring ionising radiations rests with each individual worker, and each RPS, who must ensure that any contamination is suitably controlled so that they and their coworkers are not put at risk. The monthly (or more frequent), formally recorded monitoring undertaken by the research group or by the RPS is NOT a substitute for diligent day-to-day monitoring by each user. Users must ensure that they know which type of contamination monitor to use for the radionuclide they are working with and its proper use (if in doubt consult the RPS). Guidance on different types of monitor appears in Appendix 5. Guidance on how to use the monitor, when to use, and what to record appears in Appendix 6. An example of a monitoring form appears in Appendix 7. Safety Office training courses are available.

6.8 Transport and movement of radioactive substances

When moving radioactive substances within and between laboratories, and on non-public areas of sites, users must use common sense and take all reasonable precautions to avoid the risk of accidents including spills leading to contamination and to limit the consequences of any spill should it arise. All materials must be contained, and all containers labelled, so that in the event of a foreseeable accident, no radioactive substance will be released from the container, and that ownership of the material is clear. Work should be planned so that, for example, it is not necessary to carry around open containers holding significant amounts of activity. Stock solutions in vials should be carried in the supplier's purpose made containers (pots) with the lids secured. With other materials, where significant activity is present, suitable containment should be provided for liquids, e.g. placing the immediate container in a water-tight plastic or metal outer container, lined with absorbent material to soak up any leakage of liquids. It is also important to ensure that sources are not mislaid during movements.

When radioactive sources must be transported to other parts of the University or elsewhere by vehicle or otherwise on public roads or through public places, this must be discussed with the RPS beforehand, who can obtain advice on the current statutory requirements for the transport of radioactive materials. The RPS must contact the RPA for the current information and advice in respect of transport issues. The University has published an *outline* of the requirements for transport of radioactive substances on the Safety Office website.

7 DISPOSAL OF RADIOACTIVE WASTES

Safe disposal of radioactive wastes in accordance with statutory provisions is an essential part of work with unsealed radioactive sources. Each piece of work is not complete unless the radioactive wastes have been dealt with. Before beginning any work, users should be familiar with the permitted disposal routes for their waste and the limits and conditions that apply in their department. Before starting a particular piece of work they must know how to correctly dispose of the radioactive wastes it will generate. The risk assessment documentation for the work will identify how Best Available Techniques (BAT) will be used to ensure that the activity of disposed waste is minimised, and that the volume of waste transferred to other locations is also minimised. BAT is now a specific compliance issue required by the Permits issued under the terms of the Environmental Permitting Regulations 2016. The RPS must be consulted in respect of waste disposal issues before new work commences.

The University's general policy is that radioactive wastes should be disposed of promptly either in the laboratory, in the case of aqueous wastes, or transferred to the department's radioactive waste store from where they will be regularly collected by the Safety Office for disposal via the University's facility at the High Cross Site. The Safety Office operates this service in accordance with a plan designed to meet the relevant Transport Regulations. Radioactive waste should not be allowed to accumulate on laboratory benches, in fume

cupboards, or elsewhere in laboratories, although accumulation for short periods, e.g. in beta-boxes at the back of a work-bench in a secure laboratory, is acceptable provided it is under control and the wastes are regularly cleared (within a week). Very short lived radionuclides, in solid waste, with half lives of a few hours or so may be decayed in the laboratory. Any other deliberate storage for decay requires the approval of the RPS and the RPA. Aqueous radioactive waste *must not* be accumulated, except in situations with explicit prior agreement of the RPA.

When placing wastes in their Departmental radioactive waste stores, users must observe any notices and follow the Local Rules or SoPs for the store. They must complete the necessary records when placing waste in one of the designated containers. Waste must be contained (bagged, taped up, and clearly labelled regarding contents and origin). The correct bag should be used, that is, clear, heavy duty plastic bearing the radiation symbol. The types of bags used for general, non-hazardous waste, should not be used for radioactive waste. (Yellow or Clinical Waste bags MUST ONLY be used for clinical waste, including radioactive clinical waste destined for an incinerator). Any special instructions must be followed (e.g. special containers for the disposal of contaminated sharps). To assist tracking of wastes and their possible retrieval if a problem is identified later each bag or other package of waste should be labelled by the user in the laboratory before placing it into the waste store. Details recorded must include the user's name (or at least initials), department, the date, the radionuclides present and the estimated activity.

Users are required to make realistic estimates of the activity in their wastes and can be called upon to justify these. Great precision is not normally required and estimation of activities should not involve significant effort in most cases. Information that can be used when estimating activity includes the following.

- Known partitioning between e.g. solid and liquid waste for common techniques, which
 may be available in literature or known to other users (the RPS may be able to assist in
 this).
- 2. Direct experimental measurements, e.g. results of counting of samples.
- 3. For gamma emitters including chromium-51 and iodine-125 simple measurements at a set distance from a waste bag or package using a scintillation detector instrument (e.g. Mini Instruments 5.44 probe) are fairly robust the manual for the monitor usually includes a rough calibration.
- 4. For surface contamination (beta emitters) an estimate of the contamination level multiplied by the area in question provides an estimate of total activity.

The method used to assess activity in waste can usefully be recorded in the experimental protocol or similar documents. Except for very short half-life radionuclides (half-lives of a few hours), users are not expected or required to make corrections for radioactive decay when assessing activity in wastes. Any variation to this policy must be agreed with HSO. The required record keeping systems are detailed in Appendix 10.

Aqueous radioactive wastes

Disposal to drain provides a safe route for disposal of these wastes, subject to any other (e.g. chemical) restrictions applying. Disposal may only be done where the department has an appropriate sub-permit of authorisation issued by the Safety Office. Only the designated and labelled sinks or other disposal points may be used. Wastes should be washed down with plenty of running water and the sink should be monitored both before and after the disposal. Dilutions down to at least 100 Bq/ml should be achieved at the sink where practical (otherwise consult the RPA/RWA). Radio-iodine solutions should be stabilised with alkaline thiosulphate solution (for iodinations this should be already be prepared for use in case of accidents during the procedure). Drain disposals must be recorded both on the usage and disposal sheet for the stock solution, AND on a local record kept close to the sink. The purpose of this second record is to enable RPSs to investigate the cause of any unexpected contamination found in the area, and is an instantly accessible record if maintenance work needs to be carried out on part of the drainage system. Daily limits will be set by departmental management (including the RPS) for each laboratory and must be adhered to. This is designed to avoid the risk of separate disposers inadvertently combining to breach the department's disposal limit.

Solid radioactive wastes

Subject to Departmental arrangements and Local Rules, uncontaminated waste should not be put unnecessarily into the solid radioactive waste stream. Wastes including disposable gloves should be properly monitored at the laboratory bench. Any wastes showing no readings above the typical monitor background, using the monitor of choice for the radionuclide, should be put into the general waste bins that are used for non-radioactive waste. For Tritium or other radionuclides which are difficult to monitor by direct means, this waste stream must only be used when there is absolute certainty that the items are uncontaminated. (This is subject to any other constraints applying to the non-radioactive properties of the wastes). It is most important that uncontaminated waste put in these bins is not labelled as radioactive. Any such labelling must be carefully removed or completely obliterated otherwise there could be unnecessary concern if the item is discovered during disposal.

Radioactive waste (but NOT waste contaminated with clinical materials, GM materials or non-modified pathogens except by prior agreement with the external contractor) should be bagged and taped up in clear plastic bags, labelled with brief contents information: departmental name, radionuclide and a *visible radiation trefoil sign*. The waste must be transferred regularly to the containers located in the Department's radioactive waste store. Certain Departments on the Addenbrookes site are permitted to dispose of some radioactive waste to the Addenbrookes incinerator under certain conditions and limits. However, most of the waste from University Departments will eventually be consigned by the Safety Office to an external contractor (normally for incineration). The quantity (in total) of all radioactive substances within a waste container must not exceed 200 MegaBecquerels.

Appropriate transfer boxes (Perspex for Phosphorus-32 and metal for Gamma emitters),

must be used to move waste to the store. Note that the waste containers (red burn bins) provided by the external waste contractor do not provide significant shielding and these containers should be kept in waste stores, not in laboratories (unless permitted by the RPA). Significant quantities of lodine-125 (e.g. separation columns containing above about 10 MBq) should be enclosed in additional shielding, e.g. a disposable metal can, and small volumes of higher activity Phosphorus-32 waste can be enclosed in a disposable glass jar before placing in the waste container. Care is also required with other gamma emitters (e.g. Chromium-51 and Selenium-75), in ensuring that surface dose rates of containers and doses to staff handling the waste are minimised although these will be more difficult to shield (steel black drums are available as additional shielding for the plastic waste container). However, lead metal shielding and lead pots must NOT be placed in this waste stream – they should be monitored and the RPS contacted regarding disposal. Details (radionuclide/activity etc) of the waste taken to the departmental waste store must immediately be recorded in the book or other system provided in the store.

The waste containers are designed to meet excepted package conditions under the relevant transport regulations, but in some cases the surface dose rate may exceed 5 microSieverts per hour on the surface of the container. In these cases, the Safety Office will place the container into a larger steel container for transport.

Important note: The University's authorisations under the Environmental Permitting Regulations 2016 actually do permit small amounts of radioactivity in wastes that are put into normal refuse collected from Department, if the route for this waste is to landfill. This is referred to in authorisations as "very low level waste" and is subject to limits on activity per unit volume and on any single item. This route is <u>not</u> currently used by the University to a significant degree and should <u>not</u> be used unless approved by the RPA and the RPS. In these cases the precise conditions for the use of this waste route will appear in the Local Rules.

Clinical and Biohazardous wastes

Non-clinical solid radioactive waste must not be put into any waste stream that is being routed to the incinerator unless this also has been agreed with the Safety Office and RPS. Radioactive clinical wastes, and waste containing genetically modified pathogens, other GM materials, or non-modified pathogens, will require separate disposal, (usually after pretreatment), normally via the Addenbrooke's Hospital incinerator or to an external contractor. Details of this will appear in the department's Local Rules. The definition of what constitutes such waste, and how it may be rendered safe, is not a straightforward matter, therefore any work which is likely to generate this type of waste and other bio-hazardous waste, MUST be discussed with the RPO/RPA *before* such work commences. The particular arrangements, including the required transport documentation, for transfer of waste to the Addenbrooke's Incinerator must have been discussed before any clinical waste is generated. Yellow bags/clinical waste bags must be used.

Organic liquids (mainly scintillation counting media)

Most of the scintillants in use at the University are of a type that allows them to be disposed of via the same initial route as solid wastes, i.e. via the Safety Office to an external contractor or directly to the Addenbrooke's hospital incinerator. Most scintillants and all other solvents require incineration. Details of disposal routes will be specified in the Department's Local Rules or safety manuals. Work that would require the disposal of any type of organic/inorganic liquid radioactive waste including contaminated oil, solvents, etc. must be referred, prior to generation of the waste, to the RPS and the RPA.

Discharging of radioactive substances to atmosphere

Any Department considering work that may give rise to discharges of radioactive gases, mists or vapours *must* consult the University Radiation Protection Adviser. Examples are the use of Sodium Boro [3H] Hydride, Tritiated water vapour, gaseous Carbon-14, gaseous Positron emitters such as Fluorine-18 or Carbon-11 or the use of any other radioactive gases. These types of work and the subsequent releases to atmosphere, require them to be specifically permitted under EPR16.

8 CONTINGENCY PLANS

The risk assessment carried out before work with unsealed radioactive sources commences should consider if there could be incidents or accidents that would require action to be taken to prevent or reduce subsequent exposure of persons or spread of contamination. In general, it is not expected that any accident within the University would give rise to significant exposure of staff, emergency service personnel, or others, but this does depend on the nature of the work being undertaken, and a correct response being made in the event of an emergency. Regulation 13 of the Ionising Radiations Regulations 2017 requires that where a radiation accident is reasonably foreseeable, a contingency plan must be prepared and, where appropriate, rehearsals of the arrangements in the plan are carried out. The contingency plan must be identified in Local Rules and any person who may be affected by, or involved with, the arrangements in the plan must be given suitable and sufficient instruction as necessary about their involvement in the plan. Radiation Protection Supervisors within the University have been advised of the requirements of contingency plans and of the need for them to understand their role in these plans. There are certain requirements for follow up of accidents under Regulation 13 where contingency plans are implemented, but the guidance states that this level of follow up is not needed for minor accidents, "for example, small contained spillages of radioactive material and other incidents that could not result in exposures of concern". Set out in Appendix 8 are some general accident scenarios and recommendations on how these should be dealt with.

9 REPORTING INCIDENTS

All significant accidents and incidents involving radioactive substances should be reported to the local RPS, Departmental Administrator and/or Head of Department. Departments must report these occurrences to the University Safety Office, since some of these will require reporting to the regulators. The RPA should be notified by phone or email as soon as possible to ensure that appropriate immediate action has been taken. It is important that the circumstances of incidents and accidents are investigated locally by the Safety Office, RPA and the RPS, in order that any lessons can be learned and other departments advised as necessary as to the recommendations to prevent re-occurrence.

Accidents that are significant include the following (these must be reported to the Safety Office in the first instance – contact the Safety Office directly and immediately regarding any significant spills, losses or significant exposures):

- 1. Loss or suspected loss of any radionuclide stock solution, including loss during transport.
- Release or spill of significant quantities of any other radioactive materials including all situations where the activity is in excess of the quantities given in Column 5 of Schedule 7 of the Ionising Radiations Regulations 2017 or loss/theft under Column 6 of Schedule 7.
- 3. Unauthorised entry to a department where there is likelihood that radioactive sources have been disturbed or removed from the premises, even if this is not yet confirmed.
- 4. Fires, floods or structural collapse that involve or might have involved radioactive sources or given rise to radioactive contamination.
- Any event where the accident, or actions such as clean-up, resulted or could result in a significant exposure, i.e. an exposure which significantly exceeds normal planned exposures.
- 6. Any contaminated injury (either suspected or identified by monitoring).
- 7. Any suspected intakes including positive detection of thyroid uptake of radioiodine.
- 8. Any bodily contamination of a person, e.g. skin, eyes.
- 9. Contamination of a persons clothing including laboratory coats (excluding surfaces of disposable gloves).
- Any spill requiring a laboratory, other area, or part of such to be closed pending decontamination.
- 11. Contamination, including minor contamination, found in unexpected areas, i.e. other than on benches and sinks or in work trays (for example contamination of walls and floors).
- 12. Any contamination detected outside of a designated controlled or supervised area.
- 13. Any unexpected delivery of radioactive sources to a department, or unexplained failure of

an expected item to arrive.

14. Any suspected loss or unauthorised interference with materials in a radioactive waste store.

In these situations the RPS will always discuss the situation with the University Radiation Officer and if necessary the RPA. Any notifications to the regulators will be done through the Safety Office.