Radiation Safety Audit
Guidance Notes on Completion

Radiation Protection Service
Department of Medical Physics and Engineering

September 2014
## Contents

- **Introduction** 2
- **Cover Sheet** 3
- **1 Risk Assessments** 6
- **2 Management of Radiation Protection** 10
- **3 Equipment Inventory** 14
- **4 Equipment Maintenance** 15
- **5 Management of Radioactive Materials** 18
- **6 Management of Designated Areas** 23
- **7 Local Rules** 27
- **8 Authorisation and Permitting** 31
- **9 Contingencies and Incidents** 32
- **10 Staff Training** 34
- **11 Personal Protective Equipment** 37
- **12 Quality/Safety Assurance** 39
- **13 IR(ME)R Procedures** 40
- **14 Previous Audits** 43
Introduction

These guidance notes are written to accompany version 2.0 of the radiation safety audit form. This form only need be completed if ionising radiation is used within the department.

The cover sheet should be completed prior to starting the main body of the audit form. Depending on the answers given to the questions on the cover sheet, some of the questions in the main body of the form may appear in a pale grey colour. This indicates that these questions are not relevant and should not be completed. All questions in black must be completed.

If you are unsure about the appropriate response to an audit point, mark it with a question mark. When the audit is completed request clarification on the point from the radiation protection service. All audit points should be marked as ‘Pass’ or ‘Fail’ prior to the audit being submitted, with appropriate evidence and, where relevant, comments, in the right hand column.

A blue box indicates one which requires input, a green box indicates one which has received input but can be altered and a yellow box indicates one which will complete automatically. For clarity, the responses to the audit points are indicated using a traffic-light system.

Any problems with audit completion or queries regarding questions and audit points should be directed to the radiation protection service.
Cover Sheet

What modality does this audit cover?

Selecting one of the options from the drop-down list will fill expected answers to the other questions on the cover sheet. It is important to check these answers and change any which require it. If the modality covered by your department is not listed, select the closest from the list and inform the radiation protection service. If you are unsure of the correct answer to one of the questions on the cover sheet, continue with the default answer but consult with the radiation protection service prior to submitting the completed audit form.

Does your department expose human patients to ionising radiation?

This includes any exposure of patients to ionising radiation for the purposes of medical diagnosis or treatment, either from radiation-producing equipment (such as x-ray sets and linear accelerators) or radioactive substances. This does not include veterinary radiography.

Does your department administer radioactive substances to human patients?

This includes all diagnostic and therapeutic administrations of radioactive substances to human patients, such as nuclear medicine or brachytherapy, but includes neither external irradiation, such as stereotactic radiosurgery or x-ray imaging, nor administration of radioactive substances to animals.

Does your department use radiation-producing equipment?

Radiation-producing equipment includes any equipment which delivers ionising radiation (such as an x-ray set or linear accelerator), as well as any equipment which directly controls or influences the extent of exposure (such as an automatic exposure control system or radiotherapy control system).

Does your department use mobile radiation-producing equipment?

Mobile equipment is any radiation-producing equipment which is not permanently installed in a single room.
Does your department use sealed radioactive sources?

Sealed sources are those which are permanently encased such that radioactive material cannot leak and contamination cannot be spread merely through contact. These include sources such as iodine seeds for brachytherapy or cobalt-60 sources for stereotactic radiosurgery.

Does your department use unsealed radioactive sources?

Any radioactive source which is not a sealed source will count as an unsealed source. This category includes, amongst others, all radiopharmaceuticals or radiolabelled samples.

Does your department have any areas controlled due to risk of contamination?

The majority of controlled areas are likely to be so designated due to instantaneous or time-averaged dose rate. Answer ‘yes’ to this question only if the department contains areas which are controlled in order to prevent the spread of radioactive contamination.

Does your department have any illuminated warning signs?

These signs will usually be fixed to the entrance of a controlled area.

Does your department use personal protective equipment?

This question refers only to personal protective equipment designed to reduce radiation dose, such as lead aprons, thyroid collars, leaded glasses or syringe shields.

Does your department have any staff classified under IRR99?

This refers to persons classified under regulation 20 of the Ionising Radiations regulations 1999 (those who are likely to receive an effective dose in excess of 6 mSv per year or an equivalent dose which exceeds three-tenths of any relevant dose limit).
Do staff regularly support patients during exposures in your department?

For this question ‘regularly’ means an average of more than four times per year.

Does your department have any lead-glass shields?

This includes windows, operators’ screens, portable shields and isolation cabinets which incorporate lead glass.

Does your department have any shielded doors?

This includes any doors which incorporate radiation shielding of any type.
1 Risk Assessments

1.a Have adequate radiation risk assessments been documented?

The Management of Health and Safety at Work Regulations 1999 require that the risk assessment is written down. If a risk assessment has been undertaken in principle, but not written down, this point must be marked as a ‘fail’.

1.b Have the risk assessments been reviewed recently/to an approved schedule?

It is usual to review risk assessments once every two years. Each risk assessment should include a review date when it is issued. If the date for the first review of the risk assessments has not yet been met, this point may be marked as a ‘pass’. It is not possible to pass this point if point 1.a has been failed.

1.c Are the risk assessments available for inspection?

Risk assessments must be accessible such that an inspector from a regulatory authority could view them as part of an unannounced inspection. It is not possible to pass this point if point 1.a has been failed.

1.d Have all staff who work with ionising radiation been identified?

This identification must be in a written format either separate to or, more likely, as an integral part of the risk assessment. It is acceptable for staff to be identified by role, rather than name (e.g. “all radiographers”). Regular checks should be undertaken to ensure that no person has been missed off of the list.

All staff, if any, who work with sealed and unsealed radioactive sources must also appear on this list. If sealed and unsealed radioactive sources are the only sources of ionising radiation in the department, or if the two lists in 1.d and 1.e are identical, it is not necessary to maintain two separate lists.

1.e Have all staff who work with sealed and unsealed radioactive sources been identified?

This identification must be in a written format either separate to or, more likely, as an integral part of the risk assessment. It is acceptable for staff to be identified
by role, rather than name (e.g. “all radiographers”). Regular checks should be undertaken to ensure that no person has been missed off of the list.

All staff on this list must also appear on the list required for point 1.d. If sealed and unsealed radioactive sources are the only sources of ionising radiation in the department, or if the two lists in 1.d and 1.e are identical, it is not necessary to maintain two separate lists.

1.f Where the risk assessment in a. demonstrates a need, are all appropriate staff issued with suitable dosimeters?

If the risk assessment has demonstrated no need for dosimetry, this point may be marked as a ‘pass’. If the matter of dosimetry has not been considered in the risk assessment, this point must be marked as a ‘fail’, unless all the staff listed in d. are routinely issued with dosimeters, regardless of the risk assessment. In either case, an explanatory note must be made in the comments box.

1.g Where dosimeters are issued, is there a record of personal dose monitoring covering the last 2 years?

If no dosimeters are issued because the risk assessment has demonstrated no need for dosimetry, this point may be marked as a ‘pass’, but this must be noted in the comments box.

It is not possible to pass this point if point 1.f has been failed.

1.h Do all staff issued with dosimeters record doses below relevant dose thresholds, as expected?

For staff who are not classified under regulation 20 of the Ionising Radiations Regulations 1999 (which will be most staff), the relevant dose thresholds are an annual whole-body exposure of 6 mSv, an annual exposure to the lens of the eye of 45 mSv and an annual exposure to the hands, forearms, feet, ankles or any 1 cm$^2$ of skin of 150 mSv.

For staff who are classified under regulation 20, the thresholds to which this question refers will be the annual dose limits (20 mSv, 150 mSv and 500 mSv to the whole body, lens of the eye and hands/forearms/feet/ankles/skin respectively).

If no dosimeters are issued because the risk assessment has demonstrated no need for dosimetry, this point may be marked as a ‘pass’, but this must be noted in the comments box. If no dose reports have yet been received because the
service is less than three months old, this point may be marked as a ‘pass’, but this must be noted in the comments box.

1.i Are dosimetry records available for staff to see or notified if non-zero?

It is not necessary for dosimetry records to be displayed in a communal area, but staff should be able to see their own dosimetry records upon request. If no dosimeters are issued because the risk assessment has demonstrated no need for dosimetry, this point may be marked as a ‘pass’, but this must be noted in the comments box.

It is not possible to pass this point if point 1.g has been failed. If no dose reports have yet been received because the service is less than three months old, this point may be marked as a ‘pass’, but this must be noted in the comments box.

1.j Is there a written procedure for continued dosimetry following an unexpected exposure?

Following a radiation incident, it may be necessary for staff to submit their dosimeters for reading partway through a wear period. If this is the case, a procedure should be in place to ensure that their dose for the remainder of the wear period is recorded.

If no dosimeters are issued because the risk assessment has demonstrated no need for dosimetry, this point may be marked as a ‘pass’, but this must be noted in the comments box.

1.k Has an appropriate dose investigation level been set?

The dose investigation level must be listed in the local rules and should be known by those responsible for staff dosimetry. An investigation level of $\frac{2}{10}$ of any dose limit (pro rata for any wear period) is common and a level above $\frac{3}{10}$ of any dose limit is not likely to be appropriate. It is inappropriate to set a dose investigation level for a site (e.g. finger or eyes) which is not monitored.

1.l Is there an appropriate dosimetry procedure for staff who also work for other employers?

An ‘appropriate’ dosimetry procedure is one which has been agreed with the radiation protection adviser. Even if no staff work for other employers, or their work for other employers does not involve ionising radiation, it is good practice
to have a written procedure for the eventuality of changes in staff or in the activities of current staff.

1.m When staff support patients/animals during exposures, do you have procedures to ensure that it is not always the same member of staff?

These procedures should be written and known by all staff involved with these exposures.
2 Management of Radiation Protection

2.a Has a suitable, certified Radiation Protection Adviser been appointed in writing?

It is necessary for a radiation protection adviser to be appointed in writing; a verbal agreement to provide advice is not sufficient. The appointment letter will need to be kept to provide evidence, in the event of an inspection by a regulatory body, that a radiation protection adviser has been consulted.

2.b Does the RPA’s written appointment include the scope of advice required?

The scope of advice must include all four points contained within Schedule 5 of the Ionising Radiations Regulations 1999, along with any other advice you may require the RPA to provide. Your RPA should be able to advise you on the scope of his appointment.

It is not possible to pass this point if point 2.a has been failed.

2.c Do you have current contact details for your RPA?

It is not possible to consult with an RPA if the contact details held for him are out of date. These details should be checked annually and updated if incorrect or whenever the RPA informs you of a change of details.

It is not possible to pass this point if point 2.a has been failed.

2.d Is a copy of the RPA’s certificate of competence available for inspection?

Regulation 2 of the Ionising Radiations Regulations 1999 requires that a Radiation Protection Adviser holds a certificate of competence from a body approved by the Health and Safety Executive for that purpose. It is evidence that the RPA consulted is appropriately qualified and inspectors from a regulatory body are entitled to see it during an unannounced inspection.

It is not possible to pass this point if point 2.a has been failed.

2.e Is the RPA’s certificate valid?

A radiation protection adviser’s certificate of competence is valid for a period of five years from its issue date.
It is not possible to pass this point if point 2.d has been failed.

2.f Has a lead manager been nominated?

For a lead manager to be suitably nominated, it is necessary for them to be aware of their position and the responsibilities which it entails.

2.g Have suitable Radiation Protection Supervisors been formally appointed in writing by the trust lead for radiation protection?

If the department/organisation is not a part of Leeds Teaching Hospitals NHS Trust, suitable Radiation Protection Supervisors should be appointed according to local procedures.

To be considered suitable, a Radiation Protection Supervisor should:

- know and understand the requirements of the Regulations and local rules relevant to the work with ionising radiation,
- command sufficient authority from the people doing the work to allow them to supervise the radiation protection aspects of that work,
- understand the necessary precautions to be taken and the extent to which these precautions will restrict exposures,
- know what to do in an emergency, and
- have received appropriate training for the role.

2.h Are all staff aware of the requirements of the radiation safety policy?

It is not necessary for all staff to know every part of the radiation safety policy, but they should all be familiar with the sections which refer to them or which impact on their role.

2.i Are staff aware of the requirement to notify the trust in writing as soon as possible if they are pregnant or breastfeeding?

It is necessary for the employer to complete a risk assessment to limit exposure to the foetus of a pregnant worker or the baby of one who is breastfeeding. The
dose limit of 1 mSv to a foetus only applies once the employer has been notified in writing.

2.j Is there an up-to-date record of Authorised Referrers?

Whilst the ideal is for authorised referrers to be listed by name, this is not always practical and, as such, they may be listed by role.

2.k Is there an up-to-date record of Authorised Practitioners?

Whilst the ideal is for authorised practitioners to be listed by name, this is not always practical and, as such, they may be listed by role.

2.l Is there an up-to-date record of Authorised Operators?

Whilst the ideal is for authorised operators to be listed by name, this is not always practical and, as such, they may be listed by role.

2.m Is there an up-to-date record of those authorising under Practitioner’s guidelines?

Whilst the ideal is for those authorising under practitioners guidelines to be listed by name, this is not always practical and, as such, they may be listed by role.

2.n Has a Medical Physics Expert been appointed in writing?

It is important to know who the medical physics expert is for every medical exposure. If you are unsure who your medical physics expert is, contact the Department of Medical Physics and Engineering.

2.o IR(ME)R requires audits to establish whether the employer’s written procedures are being complied with. Are records of these audits available for inspection?

This includes audits investigating issues such as compliance with patient identification procedure or the giving of information to patients to whom radionuclides
are administered. The radiation safety audit is not sufficient to fulfil the requirement of this point.
3 Equipment Inventory

3.a Is an inventory of equipment available for inspection?

This inventory is often in the form of an asset register.

3.b Is the inventory of equipment complete and correct?

To be considered complete, the inventory must include, for every item:

- the name of the manufacturer,
- a model number,
- a serial number or other unique identifier,
- the year of manufacture, and
- the year of installation.

It is not possible to pass this point if point 3.a has been failed.

3.c Is there a written policy for planned replacement, with a written schedule of replacement, for all equipment on the inventory?

For this point to be considered a ‘pass’, it is necessary for a suitable replacement schedule to be written. It is not necessary for the finance arrangements to have been agreed, although they should have been considered in the drafting of the schedule.

3.d Is the planned replacement programme available for inspection?

This programme must be accessible such that an inspector from a regulatory authority could view them as part of an unannounced inspection.

It is not possible to pass this point if point 3.c has been failed.
4 Equipment Maintenance

4.a Has each item of equipment had a critical examination?

Each item of radiation-producing equipment must have a critical examination whenever it is installed. This will often be combined with the acceptance tests performed by medical physics, but it is necessary for evidence of a critical examination to be available.

For mobile radiation-producing equipment, this examination will have been performed by the manufacturer when it was installed in its outer casing.

4.b Is there a procedure for formal handover of equipment to the service agent for maintenance?

For this point to be marked as a ‘pass’, it is not sufficient that a handover form exists. There must also exist a written procedure describing the process of equipment handover.

4.c Has all the equipment been maintained according to the manufacturer’s recommended schedule (or as identified in the risk assessment)?

If the manufacturer has not recommended a maintenance schedule, and no risk assessment states otherwise, equipment should be assumed to require maintenance annually. If the equipment is less than one year old, a successful acceptance check will allow for a ‘pass’ on this point.

4.d Is there a record of the formal handover of each item of equipment at each service visit?

There will often be a form covering both this requirement and the handover of a controlled area (point 6.j).

It is not possible to pass this point if point 4.b has been failed.

4.e Has all the work asked of, or recommended by, the Service Agent/Manufacturer been carried out?

If no work has been asked of, or recommended by, the Service Agent/Manufacturer, then this point may be marked as a ‘pass’, provided that this can be evidenced.
4.f Is there a procedure for formal handback of equipment from the service agent after maintenance?

As with point 4.b, for this point to be marked as a ‘pass’, it is not sufficient that a handback form exists. There must also exist a written procedure describing the process of handback.

It is not possible to pass this point if point 4.b has been failed.

4.g Does the handback process include a statement from the service agent about whether anything has been done that might affect patient/client dose or image quality?

This will often be on the same form as used in point 4.b.

It is not possible to pass this point if point 4.f has been failed.

4.h Has each radioisotope assay calibrator been calibrated to traceable Primary Standards to an appropriate schedule?

It is necessary for the calibration of each radioisotope assay calibrator to be traceable to an appropriate primary standard (often the national standard at the National Physical Laboratory). This is usually done using a secondary standard, but there must always be a paper trail showing the calibration process.

4.i Is the certificate of calibration for the equipment available for inspection?

This certificate will have been issued by the laboratory conducting the calibration and should show the traceability to the national standard.

It is not possible to pass this point if point 4.h has been failed.

4.j Are equipment maintenance records for all serviceable equipment available for inspection?

Maintenance records must be complete and correct and must be available such that an inspector from a regulatory authority could view them as part of an unannounced inspection.
4.k Is there a maintenance/fault log which demonstrates that faults and maintenance tasks are adequately tracked/reconciled?

If a maintenance/fault log exists, but is not used

4.1 Has the output of each item of equipment been assessed by the Medical Physics service to a schedule indicated in an appropriate standard?

The appropriate standards are shown in table 1. If no standard is shown for the modality being audited, contact the Medical Physics service to establish what standards are being used.

<table>
<thead>
<tr>
<th>Modality</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brachytherapy</td>
<td>IPEM Report 91</td>
</tr>
<tr>
<td>Dental Radiography</td>
<td>IPEM Report 91</td>
</tr>
<tr>
<td>Diagnostic Radiography</td>
<td>IPEM Report 91</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>IPEM Report 81</td>
</tr>
<tr>
<td>Gamma Knife</td>
<td></td>
</tr>
<tr>
<td>Nuclear Medicine</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Appropriate standards for point 4.1
5 Management of Radioactive Materials

5.a Is there a clear, day by day record of the arrival, storage, use and disposal of all radioactive materials?

This record needs to be accurate, clearly legible and easily accessible. Each entry in this record needs to include:

- the date of the entry,
- the batch number of the radionuclide to which the entry refers,
- the radionuclide to which the entry refers,
- the activity of the radionuclide to which the entry refers,
- the reference time/date of the activity, and
- the usage or disposal route of the radionuclide to which the entry refers.

5.b Does this record demonstrate that the accumulation and disposal of radioactive waste is always within the permitted monthly limits for each nuclide?

This record is the primary evidence for demonstrating compliance with the environmental permit. The record should demonstrate that the limits applied by the permit are being met and it must match the reality of accumulation and disposal of radioactive waste.

It is not possible to pass this point if point 5.a has been failed.

5.c Does this record demonstrate that stocks of radioactive materials for use are always within the permitted limits for the premises?

This record is the primary evidence for demonstrating compliance with the environmental permit. The record should demonstrate that the limits applied by the permit are being met and it must match the reality of the radioactive material stocks held.

It is not possible to pass this point if point 5.a has been failed.
5.d  Is there a system to notify hospitals and nursing homes, to which nuclear medicine patients are returned, of the disposal amount and type of radioactive material for which they will become responsible?

It is likely that the records will be held by the nuclear medicine department, rather than the receiving hospital or nursing home. It is still necessary, however, to inform the receiving hospital or nursing home that they are responsible for radioactive material and the actions which they will need to take in order to comply with legislation.

5.e  Are the sealed sources owned or stored by the department listed in and tracked by a register?

This may be the same record as point 5.a.

5.f  Is this register up to date?

It is necessary for this to be verified by an audit of sources which, for this point to be marked as a ‘pass’, must have been completed within the previous 12–18 months.

It is not possible to pass this point if point 5.e has been failed.

5.g  Is each of the sources listed on the register appropriately labelled?

Labels should include:

- the radionuclide,
- the chemical form,
- the reference activity,
- the reference date and time, and
- where applicable, the batch number and expiry date and time.

The label should be sufficiently clear and legible that an inspector from one of the regulatory bodies could easily identify the information on it.

It is not possible to pass this point if point 5.e has been failed.
5.h Has the output of each radiation source been assessed by the medical physics service to a suitable national/international standard?

If you are unsure of the relevant standard, contact the medical physics service. For clarification, the gamma knife unit as a whole may be considered a single source for the purposes of this point.

5.i Have appropriate HASS records been submitted to the Environment Agency?

It will be stated on your permit if it is necessary for HASS (high activity sealed sources) records to be submitted to the Environment Agency. If it is not necessary, this point may be marked as a ‘pass’, but this should be noted as a comment on the audit form.

5.j Are working practices such that doors are kept locked as appropriate, to prevent inadvertent entry to controlled areas, and theft of radioactive sources?

If doors are not kept locked, this point may only be marked as a ‘pass’ if another appropriate working practice is in place and followed.

5.k Are radioactive sources kept in a suitable store?

Stores for radioactive sources must comply with the requirements of the Ionising Radiations Regulations 1999 and with the security requirements issued by the National Counter Terrorism Security Office. Advice on these requirements can be obtained by contacting the radiation protection service.

5.l Are sources transported according to appropriate regulations?

The regulations governing the transport of radioactive sources are the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009. All departments which use radionuclides will be involved in the transport of radioactive sources, even if it is only during their initial acquisition and final disposal.
5.m  Is there a written procedure for the disposal of radioactive waste or sources at the end of their useful life?

This procedure must allow for waste to be disposed of in accordance with the Environmental Permitting Regulations 2010, the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 and the permits issued to by the Environment Agency.

5.n  Is there a written contamination monitoring/decontamination procedure?

This procedure should cover the monitoring and decontamination of areas, equipment and personnel, both routinely and in the event of an incident.

5.o  Is a suitably equipped emergency decontamination/spill kit available for immediate use?

The contents of the kit should be informed by, amongst others, the risk assessment, the contingency plans and the written decontamination procedure. It should be in a location known to those members of staff who may have a need to use it and its location should be accurately listed in the local rules. If the contingency plans make reference to medical treatment, this audit point will refer to both the decontamination kit and the first aid kit.

If a kit is provided but inappropriately stocked, this point may be marked as a ‘pass’, but point 5.p must be marked as a ‘fail’. If no kit is provided because the risk assessment deems one unnecessary, this point may be marked as a ‘pass’, but an explanatory note must be included in the comments box. If the need for a kit has not been considered (in writing) in the risk assessment, this point must be marked as a ‘fail’.

5.p  Is this kit appropriately stocked?

The kit should be stocked according to the list drawn up as part of the development of contingency plans. All equipment included must be in good repair as well as, where relevant, in date and with intact packaging. Any electronic equipment such as radiation monitors and electronic personal dosimeters must have been calibrated within the past year. If the contingency plans make reference to medical treatment, this audit point will refer to both the decontamination kit and the first aid kit.
If no kit is provided because the risk assessment deems one unnecessary, this point may be marked as a ‘pass’, but an explanatory note must be included in the comments box. It is not possible to pass this point if point 5.o has been failed.

5.q **Have staff been trained to use this kit?**

This training will include the location and contents of the kit, when it is appropriate to use it, how to use it, when additional help will need to be sourced and how to do so. If points 5.o and 5.p also refer to a first aid kit, this point may only be marked as a ‘pass’ provided sufficient appointed persons are available and appropriately trained.

If no kit is provided because the risk assessment deems one unnecessary, this point may be marked as a ‘pass’, but an explanatory note must be included in the comments box. It is not possible to pass this point if point 5.o has been failed.

5.r **Are the security requirements relating to high activity sealed sources being met?**

High activity sealed sources must be secured in accordance with the recommendations of the National Counter Terrorism Security Office. Advice on these requirements can be obtained by contacting the radiation protection service.

5.s **Is there a record that both environmental and personal contamination monitoring is being carried out?**

This should be carried out in accordance with the procedure referred to in point 5.n, with results appropriately recorded and acted upon, if necessary.
6 Management of Designated Areas

6.a Do you know why each controlled or supervised area is designated as such?

Each controlled area is likely to be designated as a controlled area for one of several reasons, including

- the average dose rate over a working day,
- the risk of spreading radioactive contamination,
- the need to prevent, or closely supervise, access to the area whilst work is on-going, or
- the likelihood of employees exceeding 6 mSv in a calendar year.

It is important to know why each area is (or does not need to be) designated as controlled or supervised.

6.b Are all Supervised and Controlled Areas demarcated appropriately with approved radiation warning signs clearly visible at each entrance?

It is extremely unusual that the controlled area surrounding permanently installed equipment (except dental equipment) does not extend to the walls of the room. If this is not the case, there must be appropriate demarcation of the controlled area (e.g. a line drawn on the floor). Signs need to be located at every entrance to the controlled area. If all signs are present, but are incorrect or incorrectly displayed, point 6.c must be marked as a ‘fail’, even if this point is marked as a ‘pass’. If some signs are missing, but those present are adequate and correct, this point must be marked as a ‘fail’, but point 6.c may be marked as a ‘pass’.

6.c Are approved radiation warning signs adequate and correct?

This point may only be marked as a ‘pass’ if the signs displayed at the entrances to the controlled areas are all the correct signs displayed in the correct positions as advised by the radiation protection adviser. If some signs are missing, but those present are adequate and correct, this point may be marked as a ‘pass’, but point 6.b must be marked as a ‘fail’. If all signs are present, but are incorrect or incorrectly displayed, this point must be marked as a ‘fail’, even if point 6.b is marked as a ‘pass’.
6.d Are doors at the entrances to controlled areas lockable or controlled in some other way?

In order for an area to be controlled, it must be possible to control access to it. This is usually done using locks on the doors, but can be done in any other way which allows for adequate control of access.

6.e Do illuminated warning signs operate correctly?

Illuminated signs should illuminate such that their writing and pictograms are clearly visible. Split signs such as are common with x-ray sets (e.g. yellow ‘controlled area’ portion on permanently, red ‘do not enter’ portion on when radiation is being emitted) must operate in the way they are intended to and checks, such as observing the signs during an exposure, should be made to ensure that this is the case. This is often done during quality assurance checks of the equipment.

6.f Are door locks/other controls in good operating condition?

It is necessary to annually check the operating condition of door locks (both electronic and manual), and any other controls which are in place. If there are no controls in place, this point may be marked as a ‘pass’, but a comment to this effect must be made on the audit form.

6.g Are lead glass shields marked with their lead equivalence?

All protective glass screens must be marked showing both the protection in terms of a lead sheet thickness equivalent and the radiation energy at which this equivalence is measured (e.g. 1.32 mm Pb at 80 kV).

6.h Are shielded doors intact, and do they close correctly?

Shielded doors should show no evidence of significant wear and tear to the door panel, the lock and handle, any portion of the door frame or the wall surrounding the door. The doors should close easily and firmly and no light should be visible around the perimeter of the door. Motorised doors should close effectively without additional human intervention. Shielded doors should have been tested for continuity of shielding on installation. Further advice on inspection of doors, or action to be taken if you suspect damage or excessive wear to a shielded door, can be obtained from the radiation protection service.
6.i  Is any other shielding/engineering control intact/functioning correctly?

‘Engineering controls’ includes, but is not limited to, devices such as door interlocks, covers for fluoroscopy foot pedals, last man out buttons and emergency stops. Other shielding includes, but is not limited to operator screens, syringe shields and shielded walls, ceilings and floors.

6.j  Is there a written procedure for the handover of controlled or supervised areas?

As with points 4.b and 4.f, for this point to be marked as a ‘pass’, it is not sufficient that a handover form exists. There must also exist a written procedure describing the process of handover.

6.k  Is there a written procedure for the handback of controlled or supervised areas?

As with points 4.b, 4.f and 6.j, for this point to be marked as a ‘pass’, it is not sufficient that a handback form exists. There must also exist a written procedure describing the process of handback.

6.l  Are suitable hand washing facilities provided, preferably at the exit from radioactive substances controlled areas (defined because of the potential for contamination)?

If an area is defined as a controlled area to prevent the spread of radioactive contamination, it is essential that there are controls which enable any contamination on the skin or clothing of members of staff to be identified and removed.

6.m  Are suitable contamination monitoring facilities available, preferably at the exit from radioactive substances controlled areas (defined because of the potential for contamination)?

If an area is defined as a controlled area to prevent the spread of radioactive contamination, it is essential that there are controls which enable any contamination on the skin or clothing of members of staff to be identified and removed.
6.n Have these contamination monitoring facilities been suitably calibrated in the last 12 months?

This point refers to the contamination monitoring facilities located at the exit from radioactive substances controlled areas. It is not necessary that the calibration of these facilities to be traceable to a national standard, but the calibration must be sufficient to allow a reasonable estimation of the extent of radioactive contamination.

It is not possible to pass this point if point 6.m has been failed.
7 Local Rules

7.a Do local rules exist:

i for each controlled or supervised area?

Local rules must exist for every controlled area and for the majority of supervised areas. If local rules do not exist, this point must be marked as a ‘fail’. If local rules exist but have not been read, overdue for review or are insufficient in any other way, this point may be marked as a ‘pass’, but the other relevant points must be marked as a ‘fail’.

ii for each item of mobile radiation-producing equipment?

It is necessary to define local rules for mobile equipment, including the definition of the controlled area. If local rules do not exist, this point must be marked as a ‘fail’. If local rules exist but have not been read, overdue for review or are insufficient in any other way, this point may be marked as a ‘pass’, but the other relevant points must be marked as a ‘fail’.

7.b Have the local rules been read in the last 3 years, and signed for by all staff participating in any procedures involving ionising radiation?

It is not necessary to maintain a traditional ‘signature list’-style record if an alternative means of recording is maintained. It is important, however, that it can be actively demonstrated that all staff have read, and are familiar with the contents of, the most up-to-date version of local rules for the areas in which they are entitled to work.

It is not possible to pass this point if point 7.a has been failed.

7.c Is the RPA named in the local rules?

The radiation protection adviser should be named in the local rules. Reference by role is not sufficient.

It is not possible to pass this point if either point 2.a or point 7.a has been failed.
7.d Is the procedure for contacting the RPA detailed in the local rules?

If this procedure exists, is up to date and contains accurate, up-to-date contact details, but is not listed in the local rules, this point must be marked as a ‘fail’, but point 9.h may be marked as a ‘pass’. If this procedure is not sufficient, but is contained within the local rules, this point may be marked as a ‘pass’, but point 9.h must be marked as a ‘fail’.

It is not possible to pass this point if either point 2.a or point 7.a has been failed.

7.e Is the RPS named in the local rules?

The radiation protection supervisor must be named in the local rules. Reference by role is not sufficient.

It is not possible to pass this point if either point 2.g or point 7.a has been failed.

7.f Is the nominated manager named in the local rules?

The nominated manager may be referred to in the local rules either by name or by role. If reference is made to the lead manager by name, this name must be correct and the local rules will need to be updated if the person holding this position changes.

It is not possible to pass this point if either point 2.f or point 7.a has been failed.

7.g Is the employer named in the local rules?

The employer is the corporate entity responsible for the safety of members of staff, rather than the head of this organisation (e.g. Leeds Teaching Hospitals NHS Trust, not the chief executive).

It is not possible to pass this point if point 7.a has been failed.

7.h Are contingency/emergency plans documented in the local rules?

Contingency plans must cover all reasonably foreseeable accidents and incidents. They are covered in more detail in section 9 of the audit. All relevant contingency plans, including plans for loss, theft or breakage of sealed sources, must be contained within the local rules, even if they are also documented elsewhere.
It is not possible to pass this point if either point 7.a or point 9.a has been failed. If current contingency plans are included in the local rules, this point may be marked as a ‘pass’, even if the plans themselves are outdated or inadequate.

7.i Are the local rules appropriate?

The local rules must refer to the area in which they apply and to the work practices within this area. It is not acceptable to simply implement a generic set of local rules.

It is not possible to pass this point if point 7.a has been failed. It is also not possible to pass this point if the local rules have not been reviewed within the past 3 years.

7.j Are the local rules marked as being due for review no more than 3 years from their issue date?

Local rules should be treated as a version-controlled document which are published with a review date. This should never be more than three years from the issue date.

It is not possible to pass this point if point 7.a has been failed.

7.k Is the extent of controlled or supervised areas described in the local rules?

The controlled or supervised areas to which the local rules relate must be accurately described within the body of the document (likely to be a room or within a certain distance of a piece of mobile equipment). If the area is only controlled for some of the time, the circumstances in which it is or is not controlled must be detailed.

It is not possible to pass this point if point 7.a has been failed.

7.l Is control of access to controlled or supervised areas described in the local rules?

Point 6.d requires the access to controlled areas to be appropriately controlled. The system of work accompanying this should be described in the local rules and should include a list of those persons permitted access to the controlled area and under what circumstances.

It is not possible to pass this point if point 7.a has been failed.
7.m  Are the arrangements for personal dosimetry detailed in the local rules?

This should include the requirement (or lack thereof) for staff classified under regulation 20 of the Ionising Radiations Regulations 1999, details of which staff are issued dosimeters and which sorts (e.g. whole body, extremity, eye etc.) of dosimeter they are issued.

It is not possible to pass this point if point 7.a has been failed.

7.n  Is the dose investigation level detailed in the local rules?

The dose investigation level is described in point 1.k. The level shown in the local rules should match the current investigation level set by the employer.

It is not possible to pass this point if either point 1.k or point 7.a has been failed.

7.o  Are the local rules displayed and available for staff to read?

In addition to the routine reading of the rules when members of staff commence their employment and each time a new set of local rules is issued, the local rules should be displayed in the controlled area to which they refer, so that staff are able to make reference to them at any time.

It is not possible to pass this point if point 7.a has been failed.
8 Authorisation and Permitting

8.a Does the department have a current, valid permit?

This refers to a permit issued by the Environment Agency under the Environmental Permitting Regulations 2010 enabling the department to keep radioactive substances on the premises, as well as accumulate and dispose of radioactive waste.

8.b Are the current permits displayed in a suitable location within the department?

It is not possible to pass this point if point 8.a has been failed.

8.c Are relevant annual summaries, as required by the department’s permits, sent to the Environment Agency, by the specified deadline?

Permits require notification to the Environment Agency of the quantity of radioactive waste disposed by each permitted route on an annual basis, usually by the end of February for the previous calendar year. Additionally, Category 5 permits (low activity sealed sources) require annual notification that the conditions of the permit continue to be met. If no notifications are required by the department’s permit, this point may be marked as a pass, but an explanatory note must be made in the comments box.

8.d If necessary, has a radioactive waste adviser been appointed in writing?

If this is necessary, it is likely to be specified as a condition of the permit.

8.e Do all Practitioners hold up-to-date ARSAC certificates appropriate to the work of the department?

ARSAC certificates are valid for a specified period of time (usually two or five years) and are site- and investigation-specific. Different ARSAC certificates cover ‘normal care’ exposures and exposures in the course of research.
9 Contingencies and Incidents

9.a Are there up-to-date contingency plans?

Contingency plans must cover all reasonably foreseeable accidents and incidents. They should have been reviewed within the past three years, in line with the risk assessments, and be documented in the local rules.

9.b Do you know what constitutes an incident and what to do?

Generally, this would be any occurrence where someone receives a radiation dose significantly different from that expected. This can be a lower or a higher dose than expected. You should have one or more written procedures to manage these situations (and may need to rehearse these contingencies).

9.c Does contingency plan training/rehearsal occur to an approved schedule?

Contingency plan rehearsal needs to occur regularly, most likely on an annual basis. Although it may be considered beneficial occasionally, it is not necessary to have a full emergency exercise for each rehearsal; a table-top exercise or ‘what if’ questions posed to members of staff will often suffice.

It is not possible to pass this point if point 9.a has been failed.

9.d Do records of contingency plan rehearsals exist?

It is necessary to make records of contingency plan rehearsals in order to evidence to an inspector from a regulatory body that these rehearsals are carried out.

It is not possible to pass this point if point 9.c has been failed.

9.e Are there records of any investigations of incidents, or reports of incidents to enforcing bodies, in the last 2 years?

It is acceptable to mark this point as a ‘pass’ if there are no incidents to record, provided that this can be evidenced. If there are no records, this point must be marked as a ‘fail’, regardless of whether or not any incidents have occurred.
9.f Is there a procedure for reporting untoward incidents?

This may be a paper system, such as an IR1 form, or an online system, such as Datix-web. If there is a procedure in place, but it requires revision due to it being ineffective, this point may be marked as a ‘pass’, but point 9.g must be marked as a ‘fail’.

9.g Is this procedure satisfactory?

If the procedure in point 9.f is in place, but is not used by staff, this point may be marked as a ‘pass’ only following an investigation to demonstrate that the problem does not lie with the procedure itself. This should be detailed in a comment on the audit form.

It is not possible to pass this point if point 9.f has been failed.

9.h Is there a procedure for contacting the RPA?

If this procedure exists, is up to date and contains accurate, up-to-date contact details, but is not listed in the local rules, this point may be marked as a ‘pass’, but point 7.d must be marked as a ‘fail’. If this procedure is not sufficient, this point must be marked as a ‘fail’, regardless of its presence in the local rules.

It is not possible to pass this point if point 2.c has been failed.
10 Staff Training

10.a Are all staff using only equipment which they are trained to use?

Records should show that staff have been trained on all of the equipment which they use and the audits referred to in point 2.o should show that they do not use equipment which is outwith their proven competency.

10.b Does the departmental induction programme contain appropriate radiation safety training?

The exact content of this training will vary depending on the activities of the department, but its content should be informed by the radiation risk assessment, reviews of past incidents and the equivalent training provided by other similar departments. The radiation protection service may be able to give advice on the necessary content of radiation safety training.

10.c Are records of training for all Operators responsible for radiation exposures available for inspection?

Operators’ training records must be accurate, must demonstrate the competency of the individuals to act as operator and must be accessible such that an inspector from a regulatory authority could view them as part of an unannounced inspection.

It is not possible to pass this point if point 2.l has been failed.

10.d Have all operators received appropriate initial and update training involving the IR(ME)R “Core of Knowledge”?

This will usually to be renewed at least once every 5–7 years.

It is not possible to pass this point if point 10.c has been failed.

10.e Does each Operator’s training record show dates of training?

Operators’ training records must show the dates any training was undertaken so that it is obvious when the operator is due for re-training, renewal of qualifications or update training sessions.
It is not possible to pass this point if point 10.c has been failed.

10.f  Are records of training for all Practitioners available for inspection?

Practitioners’ training records must be accurate, must demonstrate the competency of the individuals to act as practitioner and must be accessible such that an inspector from a regulatory authority could view them as part of an unannounced inspection.

It is not possible to pass this point if point 2.k has been failed.

10.g  Have all Practitioners received appropriate initial and update training involving the IR(ME)R “Core of Knowledge”?

This will usually to be renewed at least once every 5–7 years.

It is not possible to pass this point if point 10.f has been failed.

10.h  Does each Practitioner’s training record show the dates of training?

Practitioners’ training records must show the dates any training was undertaken so that it is obvious when the practitioner is due for re-training, renewal of qualifications or update training sessions.

It is not possible to pass this point if point 10.f has been failed.

10.i  Are records of training of all Radiation Protection Supervisors available for inspection?

Radiation protection supervisors’ training records must be accurate, must demonstrate the competency of the individuals to act as RPS and must be accessible such that an inspector from a regulatory authority could view them as part of an unannounced inspection.

10.j  Have all RPSs received appropriate initial and update training?

This will usually to be renewed at least once every 3 years.
It is not possible to pass this point if point 10.i has been failed.
11 Personal Protective Equipment

11.a Is an inventory of personal protective equipment available for inspection?

The personal protective equipment inventory must be accurate and must be accessible such that an inspector from a regulatory authority could view it as part of an unannounced inspection. It is possible that this requirement may be incorporated into an asset register.

11.b Is sufficient personal protective equipment available?

The need for personal protective equipment should be informed by the radiation risk assessment, as well as by staff experience. If there is a shortage of personal protective equipment for a known reason, this point must be marked as a ‘fail’, but the reason documented in the ‘comments’ box.

11.c Are sufficient and suitable syringe and vial shields available?

The need for syringe and vial shields should be informed by the radiation risk assessment, as well as by staff experience. If there is a shortage of syringe or vial shields for a known reason, this point must be marked as a ‘fail’, but the reason documented in the ‘comments’ box. If syringe and vial shields are not considered necessary by the department’s risk assessment, this point may be marked as a ‘pass’, but this should be documented in the ‘comments’ box.

11.d Has the safety equipment been inspected within the last year?

This must be a formal inspection, more in-depth than the visual check performed each time the equipment is used. It may include, for example, taking radiographs of lead aprons to look for cracks. If the equipment is less than one year old, this point may be marked as a ‘pass’.

11.e Are records of the last 2 year’s inspections available for inspection?

This may include the archiving of, for example, radiographic images, or a simple statement of who performed the inspection, when and what their findings were. If no inspections have yet been performed, this point may be marked as a pass,
provided that the date of the first inspection has been set and that this can be evidenced.

It is not possible to pass this point if point 11.d has been failed.

11.f Are there sufficient and suitable protective screens for the protection of operators handling radioactive materials?

This includes permanently-installed protective screens, mobile protective screens and lead blocks for forming makeshift screens. Screens will considered suitable if they match the specifications provided by the radiation protection adviser (and usually also included in the risk assessment). If sources are only handled by staff from an external company operating under their own procedures, risk assessments and local rules, this point may be marked as a ‘pass’, but an explanatory note must be made in the comments box.

11.g Is the personal protective equipment suitably stored in sensible locations?

Personal protective equipment must be stored in a location where it is easily accessible for use. It must also be stored suitably (e.g. lead aprons should be stored on appropriate hangers, protective eyewear should be stored in appropriate places). Advice on PPE storage can be obtained from the radiation protection service.

11.h Is the PPE inspection schedule being followed?

If there is no equipment requiring inspection more often than once per year, then the response to this point will be the same as for 11.d.

It is not possible to pass this point if point 11.d has been failed.
12 Quality/Safety Assurance

12.a Are appropriate quality and safety assurance procedures documented for each item of equipment?

This requirement relates to measures taken to restrict radiation exposure. You should have written procedures that define a schedule of tests and/or checks carried out to confirm that engineering controls remain suited to their intended purpose.

12.b Are these procedures followed?

It is not possible to pass this point if point 12.a has been failed.

12.c Are records of QA testing available for each item of equipment?

Quality assurance testing records must be accessible such that an inspector from a regulatory authority could view them as part of an unannounced inspection.

12.d Is the QA schedule being followed?

The schedule should be informed by the manufacturer’s recommendations and by the risk assessment. If the schedule is not being followed, this point must be marked as a ‘fail’ and, where possible, the reason documented as a comment on the audit form.

It is not possible to pass this point if point 12.c has been failed.

12.e Have environmental dose rates been monitored in the last year?

Each area where ionising radiation is used will have been designed to constrain radiation dose to a level that is ALARP (As Low As Reasonably Practicable) outside of that area. Environmental monitoring should be carried out at suitable intervals (1 year is suggested by the question) to confirm that the design dose constraint is not being exceeded.

Please record the date that the last survey was completed as a comment on the audit form.
13 IR(ME)R Procedures

13.a Do you have written protocols for all standard procedures?

Written protocols may take the form of, for example, a standardised procedural document or a chart of exposure factors. For the majority of standard diagnostic radiology procedures, these protocols should be standardised across the organisation.

13.b Can you demonstrate that all exposures are justified?

The justification process must be completed by a practitioner and the records must show that this is the case.

13.c Can you demonstrate that all exposures are authorised?

The authorisation must be completed either by a practitioner or by an operator working to a practitioner’s guidelines and the records must show that this is the case.

13.d Does your department assess representative doses from medical exposures?

The dose may have been recorded in multiple ways, as covered in point 13.k, but it is necessary for the representative radiation dose to patients to be assessed.

13.e Can you demonstrate that an outcome is recorded for each medical exposure?

An ‘outcome’ is generally a report from a healthcare professional, such as a diagnostic report from a radiologist or a report on the effectiveness of radiotherapy treatment from an oncologist.

13.f Do written patient identification procedures exist?

If these procedures exist, but are inadequate, this point must be marked as a ‘fail’. If these procedures exist but are not followed, this point may be marked as
a ‘pass’, but a comment must be recorded on the audit form.

13.g Do written procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding exist?

If these procedures exist, but are inadequate, this point must be marked as a ‘fail’. If these procedures exist but are not followed, this point may be marked as a ‘pass’, but a comment must be recorded on the audit form.

13.h Are written instructions available, as appropriate, for radioactive patients who are to be discharged from hospital?

If no written instructions are given due to patients not being discharged until the activity has fallen to a safe level, this point may be marked as a ‘pass’, provided that a procedure is in place explicitly stating this.

13.i Do written procedures for medico-legal exposures exist?

If your department does not undertake medico-legal exposures, this may be noted, but there is still a legal requirement for a written procedure to be in place. It may be sufficient that the written procedure indicates a redirection of the referral to another department or organisation.

13.j Have appropriate reference levels been set for each standard procedure?

‘Reference levels’ apply to both DRLs (for radiodiagnostic procedures) and reference levels for x-ray verification imaging within radiotherapeutic procedures. These will usually be set by the medical physics service following a dose survey. If you are unsure whether reference levels have been set, contact the medical physics service.
13.k Is a record of dose kept for each standard procedure on each patient?

This may be through recording dose-related factors (such as DAP), recording exposure factors or, for therapeutic exposures, confirming that the dose delivered matched that prescribed by the patient’s clinician.

13.l Is there a recent assessment of whether reference levels are adhered to?

This assessment should have been made within the previous three years.

It is not possible to pass this point if either point 13.d or point 13.j has been failed.

13.m Have efforts been made to correct any deficiencies where reference levels are not adhered to?

Records should indicate the lack of adherence to reference levels, the action taken to rectify the situation and a follow-up dose survey. This applies whether patient doses are higher or lower than the reference levels. If there have been no instances of non-adherence, this point may be marked as a pass, but an explanatory note must be made in the comments box.

It is not possible to pass this point if point 13.l has been failed.
14 Previous Audits

14.a Do records of previous Ionising Radiation Safety audits exist?

If the department started using ionising radiation within the past two years, this point may be marked as a ‘pass’, since it is possible that no other radiation safety audits have been completed (although this must be documented in the ‘comments’ box on the audit form). Otherwise, this point may only be marked as a ‘pass’ if all of the audits for the previous five years (or since the department began using ionising radiation, if less than five years) have been retained.

14.b Have recommendations of previous Ionising Radiation Safety audits been implemented?

It is expected that a year-on-year improvement in compliance will be observed and that, where it is not possible for issues to be resolved locally, advice is sought from the radiation protection service.

It is not possible to pass this point if point 14.a has been failed.