Guidance on the Completion of a Consent for Administration to Persons/Animals

Introduction

This guidance has been developed to augment that provided by HSE on the RADAN Safety Assessment Template. It is intended to define a level of response which should be sufficient to provide the HSE with the information they require – namely to understand the level of radiation hazard associated with the practice and the extent to which the employer manages the consequent risks to staff and others. By avoiding the gathering and submission of unnecessary information, we hope this will assist both healthcare providers and HSE in using their resources efficiently.

HSE input

The HSE have provided comments and additional information to the guidance provided in this document. However, this is not HSE approved guidance. Users should be aware that following the guidance should help to produce an acceptable Safety Assessment, but is not a guarantee of acceptance, or gaining consent from the HSE.

Scope

This guidance was created in the context of a Nuclear Medicine Department carrying out diagnostic and therapeutic procedures with unsealed radioactive material. It should be equally applicable to administrations using sealed sources in brachytherapy and, to a certain degree, to administrations to animals. It will also be applicable, to a considerable degree, to radiopharmacies seeking consent for the addition of radioactive materials to products. The principles applied in this document may also be of interest to those seeking consent for the use of accelerators in Radiotherapy.

General Guidance

For each section of the Safety Assessment Template, treat the text on the template as a series of questions to be answered.

Do not refer out to further documents. Your Safety Assessment, Local Rules and Contingency Plans, as submitted, form the suite of documents on which your consent is based and so cannot be reliant on information kept elsewhere. For example, you cannot respond to SA Section 2 by saying “details of our management structure can be found in the Radiation Safety Policy”. You need to describe the structure in your response, though you can add “This information is provided to all staff through the Radiation Safety Policy”.

Bear in mind that HSE are trying to gauge the level of hazard and the degree to which your employer is in control of the risks. This can be achieved without going into too much detail. If your responses are getting lengthy, ask yourself if there are parts which don’t

contribute to HSE's objective – eg they need to know how much ^{99m}Tc you have but not what is bound to, or what percentage of your EPR permit limit you use, or what ARSAC reference levels are.

The current RADAN template will probably be updated soon and may include aspects of this guidance, which will then be reviewed.

In the near future, transport is likely to have a section of its own in Addition consents, asking for a summary of IRR compliance.

Administration and Addition consents are likely to have a new section on radioactive material management, requiring a paragraph each on leak testing of sealed sources, accounting for radioactive material, and details of storage facilities.

The following guidance deals with each Safety Assessment section sequentially, starting with the existing text on the RADAN template, followed by our additional guidance.

We hope you find this guidance useful and wish you luck with your consent applications, but we can't accept any responsibility for the outcome.

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Section 1

RADAN Guidance

Give a general summary of the type of administration and the premises it is being performed at. This includes:

- type of administration (eg to people or animals)
- radioactive sources being used, the radionuclides and their maximum activities
- relevant work sector (eg healthcare, research, veterinary)
- intended purpose (eg diagnostic, therapeutic, research)
- locations where administration is being carried out

Additional Guidance

This section applies to radionuclides being administered. Any other radioactive materials you have/use which are not administered should go in Section 3, not this section.

1st, 3rd and 4th bullets are self-explanatory. For example:

“Radionuclide administrations are to people. They take place in a healthcare setting and are mostly for the purposes of diagnosis and therapy. However, some administrations are carried out on patients for research purposes as part of approved clinical trials”.

For the 2nd and 5th bullets, list, by site, the radionuclides, not radiopharmaceuticals, and the maximum activity for each radionuclide likely to be on each site at any one time and the maximum administered. List diagnostic and therapeutic separately. Give typical activities, or a range if there is significant variation. Interpret “maximum” as “top end of normal”, but if you occasionally do much higher activities, say so (eg 131I therapies are mostly up to 7.5GBq but on rare occasions we have administered 25GBq).

Specify whether the activity administered is via a sealed or unsealed source.

Don’t forget Krypton generators

Note that the sites relate to where the administration takes place. A premises with a different postcode should be regarded as a different site. Give site names or postcodes. HSE will have access to the full address elsewhere in the application.

Don’t give EPR permit limits or start quoting EPR or ARSAC.

If you have a radiopharmacy on site, it would be helpful to mention this in this section.

Section 2

RADAN Guidance

Give a summary of the arrangements for managing ionising radiation protection.

Specify the radiation protection responsibilities and duties of management with clear lines of reporting established.

It is not sufficient to rely on the Radiation Protection Supervisor (RPS) and Radiation Protection Adviser (RPA) for the management of radiation protection. You should provide evidence to show that you manage radiation protection at a senior level.

You should also give details of how RPSs will be given sufficient time and resources to supervise the work so that it is done in accordance with local rules.

Additional Guidance

This section is where you describe the radiation protection management structure within your organisation. This could be captured in an organogram showing lines of communication from users, through local radiation user forums to a radiation protection committee, upwards to an identified role (eg Chief Medical Officer) with overall responsibility for radiation safety at the executive board level. It isn't necessary to list duties and responsibilities of everyone in this chain. This section is not asking for you to describe what documents (Local Rules, Radiation Risk Assessments etc) you have in place.

Add information about how local audits/monitoring/review of radiation safety are fed into this structure, who checks and monitors audits and how it responds to action plans. Mention specifically how the organisation responds to formal advice from the RPA.

Emphasis is required on the role of the RPS and how they are given enough time and resource to carry out their RPS duties. Include an estimate of the amount of time an RPS spends directly supervising work with radiation, eg a day a fortnight. If the RPS role is specifically covered by the line manager appraisals and related 1:1 meetings, include this as a means of ensuring the role is being carried out satisfactorily.

Include here also how reports following up on the enaction of a contingency plan are managed – who receives them, makes recommendations and implements recommendations.

Section 3

RADAN Guidance

A. Give details of the projected maximum number of occasions the administrations are carried out per year at each location.

B. Give information on other sources of radiation those engaged in the practice may be exposed to including:

- the results of the risk assessment for radon
- details of other sources of radiation those engaged in work with the administration are likely to be exposed to

Additional Guidance

A There is no need to repeat Section 1 here. Give an indication of the approximate total numbers of administrations carried out at each location for diagnostic/therapeutic/research purposes per year and say how you arrived at this (eg based on last year's data and unikely to change significantly). Indicate any dominant procedures (eg ^{99m}Tc and PET accounting for xx%) and any rare procedures. If research administrations are unpredictable, say so.

B **Radon**: If your premises are in a <1% risk area and work isn't carried out in the basement, that is a good enough risk assessment, but say you accessed the radon map and that you don't work in the basement or there isn't one. Don't just say it doesn't apply. If >1% HSE are looking for confirmation that a Rn risk assessment has been carried out, monitoring has taken place and that remediation is in hand where needed. If there happens to be a radon issue at one of the premises, it will be dealt with separately and won't delay the consent process.

Other Sources: Identify any other work with radiation (use of sealed sources for calibration – state radionuclides and max activity, DEXA, CT etc). If any staff involved in administrations to patients also work for other employers, state that here and refer to co-operation mechanisms you have in place. There is no need to give details of their work for other employers.

Section 4

RADAN Guidance

Give measurements/estimates of the radiation dose rates, activity concentrations in air, and contamination levels of each radionuclide to which anyone other than the patient /animal are exposed.

You must provide measurements and estimates of the dose rates that employees and others (not including patients/animals undergoing administration) could be exposed to during both routine operations and in the event of any reasonably foreseeable radiation accident. This will include the maximum dose rates and contamination levels to which employees and members of the public are and could be exposed to at each location.

These estimates must show that dose rates do not exceed $7.5\mu Svh^{-1}$ outside the controlled/immediate area. They must also detail the dose rates resulting from patients who leave the area.

In all cases, all the relevant exposure categories (effective dose, equivalent dose [extremities, skin, eyes], committed effective dose) must be given as well as measurements or estimates of annual exposures in all relevant categories to employees, other persons and members of the public. Consent will not be granted if HSE do not consider these as low as reasonably practicable (ALARP).

You must also:

- give the number of times the investigation level has been exceeded in the last 2 years
- make monitoring records for the last 2 years available during the inspection

You can find out more in publication L121, which you can download at www.hse.gov.uk/pubns/books/l121.htm.

Additional Guidance

Consider this in stages for the maximum activity for each radionuclide. Consider dose rates to staff at unpacking/receiving, at drawing up and at administration. Consider dose rate from patient at administration, and when leaving the department. Actual measurements are fine, but calculated doses can be used (eg from RadPro) if needed. Draw on any relevant data in your radiation risks assessments, including where dose rates have been used to estimate annual doses. If you have estimated annual doses, quote them. If more convenient, calculation of doses in accident situations can be included in Section 13 and just referred to here.

eg for ^{99m}Tc:

- Use maximum vial activity and take account of the thickness of pot shielding for doserate when unpacking.
- Use maximum administered activity, syringe shield thickness and bench

shield thickness for doserate when drawing up.

- Use maximum administered activity, syringe shield thickness for doserate when injecting.
- Use maximum administered activity, and measured or published dose rates from patient directly post injection (consider if patient may leave the department at this point – see below).
- Use maximum administered activity, and measured, calculated or published dose rates from patient at time of leaving the department after scan.
- Say what activity concentration in air expected in routine operation – if none, say so – don't just not mention it.
- Say what activity concentration in air expected if the maximum vial activity spilled – may be none.
- Say what contamination levels expected in routine operation– may be none.
- Say what contamination levels expected if the maximum vial activity spilled.
- Say what dose rate would be from maximum vial activity spill, incorporating effects of shielding if appropriate.

It may not be necessary to state all these dose rates. One could possibly summarise as 'For ^{99m}Tc all dose rates to staff will be below XµSv/hr in routine operation with dispensing giving the highest doses. In the incident circumstance of a full vial spill dose rates to staff would be YµSv/hr and public would be ZµSv/hr as they would be at a greater distance/protected by shielding. There would be no airborne contamination.'

Don't repeat for each radiopharmaceutical, just worst case for each radionuclide.

With regards patients leaving the department, indicate that instruction is given to patients, if needed, to keep their distance in order to restrict exposure to others. For patients who leave before their scan and then return for the scan, also indicate any instructions given, including returning to the department to use the toilet.

For effective and equivalent doses, refer to summary of staff dose results for previous year and results of environmental monitoring for public doses (can refer to Section 8). For eye doses, refer to measurements taken or published studies if no recent measurements are available. Some publications address why eye dosimetry is not required for nuclear medicine. Make reference to estimated doses to carers or comforters if relevant.

State how many times a formal/local dose investigation level has been exceeded in the last 2 years. If none have been exceeded, state this.

Section 5

RADAN Guidance

Give a summary of the engineering control measures and design features already in place or planned.

Engineering control measures and design features include but are not limited to:

- mechanical and electrical interlocks
- barriers
- control panels
- emergency stop arrangements
- access restriction or prevention measures
- contamination control measures
- washing and changing facilities
- monitoring stations
- video equipment

In all cases, their type and numbers and mode of operation should be given and their location marked on a sketch plan of the facility (or facilities).

The plan(s) must also show the type, nature and thickness of any radiation shielding and the location of where the administration(s) and associated work will take place. This will include:

- source preparation and storage areas
- patient injections room(s)
- gamma-camera room(s)
- patient toilets
- other ‘active’ areas

Designated controlled and supervised areas should be described/indicated on the sketch plan.

This is to comply with the requirements of the IRR17, regulation 9 (Restriction of Exposure), associated with the work practice. You can find guidance on this regulation in publication L121, which you can download at www.hse.gov.uk/pubns/books/l121.htm.

Additional Guidance

Many of the engineering controls listed aren’t necessarily relevant in a nuclear medicine context. That’s fine but state the ones that are and any others that are relevant. Although not listed on the SA template, it is recommended that you use this section to summarise

what protection equipment is used a) when drawing up and b) when administering. Eg, vial pig, leaded glass screen, syringe shields, shielded waste and sharps bins, use of cannulas.

Include access control points (swipe access etc) any monitoring stations for staff to check themselves before they leave controlled areas, emergency stops on CT. You could also include warning signs at entrances to designated areas.

Note that only a sketch map is required. It doesn't need to be an as-built architectural plan.

For shielding it will be sufficient to detail the shielding material and thickness.

In terms of location, HSE are interested in the areas surrounding the controlled areas to which there may be unrestricted public access, including adjacent floors. If shielding has been designed such that surrounding areas are assumed to be 100% occupied by public (or non-radiation workers) and a 0.3mSv per annum constraint has been used, it is useful to state that here.

Section 6

RADAN Guidance

Give a summary of the maintenance and tests schedules for all safety critical controls such as interlocks, warning devices and other safety features.

Include the maintenance schedules and testing regimes for all the items referenced in Section 5.

State the pass/fail criteria and specify the routine and failure replacement regimes.

Additional Guidance

Some of this will be covered by manufacturers' PPM. Verify that emergency stops are checked by service engineers. It is OK to say that emergency stops are only tested by engineers because of the risk of critical equipment not recovering from an emergency stop operation. Pass/fail criteria should be fairly obvious.

Illuminated warning signs linked to the CT aspect of scanners are OK not failing to safe (ie cutting off power to the CT if the lights fail). That warning signs are still in place and illuminated ones correctly operate can be stated as part of daily start-up procedures. If warning lights do fail, indicate what your action is likely to be (temporary fixed sign, cessation of use etc).

It should be acknowledged that shielding is tested periodically, and refer to Section 7 (for initial acceptance) and section 8 (for routine ongoing tests).

Section 7

RADAN Guidance

Give a summary of:

- the results for the critical examinations
- any planned critical examinations and their pass/fail criteria

These are the requirements of IRR17, regulation 32(2). You can find out more about this regulation in publication L121, which you can download at www.hse.gov.uk/pubns/books/l121.htm.

Additional Guidance

This requires reviewing all critical exam records. The answer might be as simple as listing the equipment, relevant to the administration consent, that required a critical exam, what the pass/fail criteria were, and saying that it all passed. Or highlighting any issues that were identified at critical exam and how they were rectified.

If critical examinations for some older equipment cannot be found, it is sufficient to report on tests/checks you have done to ensure the installation is restricting exposure as far as reasonably practicable.

If some items of equipment are not subject to a critical examinations (as might apply to gamma cameras), but that equipment is nevertheless subject to detailed acceptance or commissioning testing, that could be mentioned in this section, along with any testing of shielding at installation.

Section 8

RADAN Guidance

Specify the radiation dose rate monitoring regimes, particularly the monitoring, which will confirm if the shielding and control methods are adequate and maintained.

During the inspection, make records available of the radiation dose rate and contamination monitoring regime for the facility(s) and its surroundings, including any areas which the public may have access to.

Provide information on how:

- monitoring results are reviewed and by whom
- records are kept and for how long.

Additional Guidance

This section requires a description of how environmental monitoring is performed (and by whom) to ensure shielding is sufficient to keep dose rates within the facility and in adjacent areas at or below planned levels. Make sure that this includes adjacent areas with public access and any areas occupied by staff not involved in the radiation work. This can be by taking instantaneous dose rate measurements inside the department and around the outside of controlled areas (whilst radiation is present in the controlled area), and/or through use of passive dosemeters kept in situ for a period of time to give time averaged dose rates and extrapolated annual doses. Note that actual results of monitoring should NOT be included and details of the instruments used are not required.

If spaces beyond the controlled area boundary are not readily accessible, it is sufficient to measure dose rates inside the boundary and estimate transmission with knowledge of the boundary properties.

Refer to the records made of the results in your description, how they are kept and for how long (at least 2 years). Also include who reviews them (role/job title), where they are reported and how any results exceeding action levels are dealt with.

Although the current template does not require a similar description of the regime for contamination monitoring, this should be included in the response to this section. The aim is to demonstrate that contamination control measures are in place and effective. Include a broad description of where monitoring is carried out, the frequency of monitoring and as above for records of results.

Section 9

RADAN Guidance

Summarise the personal dosimetry provided to employees and others, including the:

- type of dosemeter(s)
- details of the employee groups and others to whom they will be issued
- issue periods – such as monthly or quarterly
- name(s) of the approved dosimetry services to be used for assessment and record keeping
- dosimetry management processes – including the issue, return, supervision, results review and by whom

Make dose records available during the inspection.

Additional Guidance

This section is mostly self-explanatory.

Type of dosimetry should cover TLD, OSL as well as whole body, extremity etc.

If bioassays are carried out, include details of it. If you monitor outside workers, include that too.

Section 10

RADAN Guidance

Give the rationale for designating employees as classified persons.

Describe the classification rationale which is dependent on routine exposures and/or the likely exposures as a result of an accident or incident. In most circumstances HSE expects those employees directly involved in the administration to be classified. If this is not the case you must provide an adequate justification.

This is to ensure compliance with Regulation 21 of IRR17. You can find out more about this regulation in publication L121, which you can download at www.hse.gov.uk/pubns/books/l121.htm.

Additional Guidance

Straightforward – answer with brief policy outline, indicating which groups of staff are classified. Specify whether classification is on basis of body and/or extremity doses as well as whether for routine or accident scenarios. If staff directly involved with administration of radioactive materials are not classified, include your justification for that here.

Section 11

RADAN Guidance

Give a summary of the radiological protection training that will be or has been provided to employees and other persons, including planned frequency and refresher training.

This must be sufficient to ensure that all those carrying out the administration or likely to be affected by it have received the appropriate information, instruction and training to enable them to restrict their exposures to levels which are as low as reasonably practicable (ALARP).

Provide a summary of how local rules, contingency plans and other relevant procedures are brought to the attention of employees. How the effectiveness of training is evaluated will be relevant, as are plans for refresher training.

This is to meet the requirements of Regulation 15 of IRR17. You can find out more about this regulation and ALARP in publication L121, which you can download at www.hse.gov.uk/pubns/books/l121.htm.

Additional Guidance

State the headline topics covered by various types of training that different staff groups may have, considering frequency and whether there's an assessment or a pass mark. Don't go into detail of the training syllabus. Include general awareness training for staff affected by this work. The intention is to demonstrate that all staff, whatever their level of involvement (including management, porters, security etc) have received enough information, instruction and training to enable them to restrict their exposure to ALARP.

Indicate that you have means to demonstrate that all staff receive the appropriate level of training – for example by attendance records.

A table could be used to present this information, indicating a training level for each staff group. Don't forget to include RPS training.

Include details of your arrangements for refresher training at each level, again indicating frequency.

Is there an induction pack or induction training that bring LRs, RRAs and contingency plans to attention of new staff? State how you know that all staff have read and accept Local Rules and Radiation Risk Assessments and Contingency Plans – eg by gathering signatures or logs in quality management system software.

Describe what provision is there for contingency plan training – how to decide which things are rehearsed with which staff groups, and in what depth.

You could also include here how any training needs identified by a review following contingency plan enactment is managed.

Post-training assessment will help demonstrate effectiveness of training in the short term, but in the longer term you could cite routine (6 monthly) proactive observation of practice by RPSs, including RPSs observing each other. Or other such means.

Section 12

RADAN Guidance

Give a summary of the information supplied to employees concerning their work with ionising radiations in connection with pregnancy and breast feeding.

Explain how you communicate this requirement to your employees.

In most cases HSE expects that special adjustment will be necessary for those involved in the practice who are pregnant or breastfeeding.

Additional Guidance

State how you ensure that all relevant employees receive information about what to do if pregnant or breastfeeding. This should be received before staff start work, so indicate how this is achieved for new staff. Refer to any ongoing reminders in, for example, Local Rules.

State what the procedure is when staff inform their manager that they are pregnant/breastfeeding. How are special adjustments decided upon and by whom? Indicate what the likely arrangements would be (eg no drawing up, no responding to spills) – draw on where the potential doses are highest.

Demonstrate that you have considered who does/doesn't need a pregnancy risk assessment.

Section 13

RADAN Guidance

Give a summary of all possible radiation accident situations as identified in the radiation risk assessment.

Include information on the consequences of possible failures of control measures – such as electrical interlocks, ventilation systems and warning devices – or systems of work.

List all the possible accidents identified as part of the radiation risk assessment. State their likelihood and give estimates of their potential severity. The latter will include:

- reasonable estimates of exposures to employees and members of the public in the event of the accident
- the likely exposures to those engaged in accident mitigation

Additional Guidance

The RADAN template asks for a summary of ALL possible radiation accident situations, but you can exclude those not reasonably foreseeable and those that don't warrant a contingency plan. Say you have done this. Otherwise make sure that what is included here is consistent with the accident scenarios identified in the Radiation Risk Assessments. Don't give a lot of detail and don't repeat the contingency plans – these are being submitted along with this Safety Assessment anyway.

List potential incidents identified by RRAs. Note that not all these will be 'accidents' eg a radionuclide therapy patient who becomes unwell after discharge and returns to A&E - control measures need to be followed to limit dose to staff but this is not an accident.

Likelihood may be based on the number of times these have occurred in the last x years. Could state as 'once in last 5 years' or could set a high/medium/low/very low scale where 'very low = has never happened' 'low=may occur every x years' etc. Your hospital may have a system which you can say you align with in these definitions.

Some of these incidents may not result in a dose to the public or someone engaged in accident mitigation, eg a radioactive needlestick injury. It's fine to say the dose to others would be negligible.

For some incidents it might be hard to quantify the dose to someone – it may depend on the magnitude of the incident. Potentially pick a reasonable worst case, eg spill involving breakage of a full vial. Again, dose to someone engaged in accident mitigation may be negligible if the action they take when following the contingency plan is to close the area and wait for it to decay without attempting cleanup. Estimating the potential dose with and without control measures (where control measures follow contingency plan) may be

useful. Ultimately, if there are too many potential variables to make a reasonable assessment of dose, indicate that this is the case and state what you do know (activity, dose rate etc). HSE will check if this seems reasonable.

Indicate that, if any accident does occur, your review of the contingency plan enactment will include a review of dose estimates, either to verify they remain reasonable, or to lead to a change.

For a RNT patient leaving before discharge the dose to the public would be difficult to quantify and entirely dependent on contact patterns. Could either assume a standard contact pattern (from literature or from discharge risk assessment) or just state dose rate.

For fire, it is sufficient to consider the maximum activity likely to be out on a work surface (bench, fume cupboard or isolator) at any one time and leave your answer as Bq rather than attempting to model any release of that activity to air. If you have a grab-pack of radionuclide information to give to emergency responders, mention this, but say what it contains (eg location of radioactive materials and indicative amounts) rather than “refer to emergency grab-pack for more details”.

It is not necessary to include flood as an accident scenario.

Section 14

RADAN Guidance

Provide evidence that you have considered the applicability of the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR) and taken any action required by those regulations.

Where you have found that REPPIR does not apply you must provide a justification for this decision. If REPPIR does apply, you should attach the hazard evaluation report to the safety assessment.

Additional Guidance

Just do an initial REPPIR assessment for each site using maximum quantities specified in Schedule 1 of REPPIR19 (not EPR permit limits) and state the results and any actions required. Include the actual fraction obtained, rather than indicating it was <1. If the initial assessment shows no dose >1mSv a detailed REPPIR assessment isn't necessary.

Don't just say REPPIR does not apply.