

ONR Technical Inspection Guide (TIG)

The lonising Radiations Regulations 2017

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8	Updated to the latest template. Incorporated additional information on the application of IRR17 to transport dutyholders. Updated information in appendices.
9	Paragraph 10 added to provide inspectors with guideline inspection frequencies for IRR17 practices that are notified, registered or issued with a consent from ONR.

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1. Introduction

- 1. ONR inspects compliance with The Ionising Radiations Regulations 2017 (IRR17) (ref. [1]) at GB nuclear sites, authorised defence sites, nuclear warship sites and new nuclear build sites. ONR is also the enforcing authority for IRR17 in relation to transport by road, railway and inland waterway, except where transport is undertaken for defence purposes where the Health and Safety Executive (HSE) remains the enforcing authority.
- 2. To support inspectors undertaking compliance inspection, ONR produces a suite of guides to assist inspectors to make regulatory judgements and decisions in relation to the adequacy of compliance, and the safety of activities undertaken. This technical inspection guide (TIG) is one of the suite of documents provided by ONR for this purpose.

1.1. Purpose and Scope

- 3. This guide has been prepared as an aid to inspection activities carried out by ONR nuclear safety site inspectors and Radiological Protection (RP) specialist inspectors in judging the compliance with the requirements of IRR17. This guidance provides a framework for these inspection activities, within which inspectors are expected to exercise their discretion. This framework is provided to facilitate a consistent approach to compliance inspection of IRR17.
- 4. IRR17 apply to a wide range of practices and work with ionising radiation. ONR has regulatory responsibility for IRR17 at GB nuclear sites, authorised defence sites, nuclear warship sites and new nuclear build sites.
- 5. Except where transport is undertaken for defence purposes, ONR is the enforcing authority for IRR17 in relation to transport of radioactive material by road, railway and inland waterway. Transport for defence purposes remains with HSE as the enforcing authority.
- 6. To enable ONR to demonstrate that inspections against IRR17 meet relevant international standards, this guidance provides a matrix (Appendix 1) which relates individual regulations to topics identified in Requirement 29 (para., 4.53) of the International Atomic Energy Agency (IAEA) General Safety Requirements Part 1 (ref. [2]).
- 7. For liaison and joint inspections with relevant organisations, ONR has individual agreements with other regulators including HSE, Defence Nuclear Safety Regulator (DNSR), transport safety and security regulators and environmental regulators (including Environment Agency (EA), Scottish Environmental Protection Agency (SEPA) and Natural Resources Wales (NRW)).

- 8. Each ONR operational division has regulatory strategies for the inspection of licensees/dutyholders which may also be complemented by unplanned 'reactive' interventions. The frequency of IRR17 inspections and the areas and programmes to be inspected are set in accordance with a graded approach, reflecting the level of hazard and risk posed by the facility or activity and also the dutyholder's known safety performance. ONR's judgement is underpinned by intelligence informed qualitative and quantitative measures gathered through its routine regulatory activities with the dutyholders. For example, for licensees, ONR operational divisions stipulate the frequencies in which the standard 36 license conditions are inspected against and many of these contain generic requirements that mirror IRR17 specific requirements. Inspection plans should be consistent with the principles of enforcement described within ONRs Enforcement Policy Statement (ref. [3]) and, where practicable, integrated across all ONR purposes in a co-ordinated, proportionate and targeted way. These principles and factors are detailed in ONRs 'Guidance for Inspection Strategy Planning and Recording' (ref. [4], paragraphs 5 and 10 in particular). Additionally, Regulation 7 of IRR17 requires dutyholders undertaking higher risk activities to have received Consent by ONR and these Consents are reviewed and renewed at set frequencies.
- 9. As per the majority of ONR inspections, the content of inspection of all relevant safety aspects associated with IRR17 is undertaken using a risk informed and intelligence led sampling approach, to seek assurance that dutyholders' activities are undertaken in compliance with IRR17. The preparation and delivery of IRR17 inspections should follow the general approach outlined in ONRs 'General Inspection Guide' (ref. [5]) and the IRR17 specific requirements in this TIG. ONR Academy training course 'N8 ONR Inspection for Compliance against the Ionising Radiations Regulations 2017' complements this guidance for consistency in addressing the relevant safety aspects to be included in the scope of inspections.
- 10. For practices that are notified, registered or issued with a consent from ONR under Regulations 5, 6 and 7 of IRR17, if no inspections are instigated as a result of following the risk informed guidelines in paragraphs 8 and 9, then the appropriate degree of regulatory oversight in the graded approach should be considered. It is anticipated that guideline inspection frequencies should be:
 - Notified practices (Regulation 5) take place only where intelligence indicates it is necessary.
 - Notified radon levels (Regulation 5) should be followed up on upon receipt of notification and inspection undertaken where required;
 - Registered practices (Regulation 6) take place approximately every 6-8 years; and

- Consented practices (Regulation 7), unless inspectors become aware
 of a 'material change' to the practice being undertaken, are reviewed
 every 5 years in accordance with ONR guidance on issuing IRR17
 Regulation 7 consents (ref. [6]). Inspections of these higher risk
 activities are likely to be required as part of this review unless
 regulatory intelligence arising from ONR's regular interactions with the
 dutyholder during the intervening 5 year period deem inspection
 unnecessary.
- 11. In Section 5, a distinction is made between those topics which are likely to be suitable for planned compliance inspection by a non-specialist RP inspector, and those which may be suitable for referral to a specialist RP inspector. However, any topic may be referred to a specialist RP inspector at the discretion of the inspector.
- 12. It is not anticipated that all the recommended topics will be covered in a single inspection. A sampling approach, informed by risk, should be adopted to seek assurance that dutyholders' day-to-day activities are undertaken in compliance with IRR17. The preparation and delivery of IRR17 inspections should follow the approach outlined in ONRs 'General Inspection Guide' (ref. [5]).
- 13. Nuclear safety site inspectors should note that aspects of IRR17 compliance can also be included in planned compliance inspection against licence conditions (for example, LC 8 Warning Notices, LC 10 Training; LC 11 Emergency Arrangements, LC 12 DAPs and SQEPs, LC 18 Radiological Protection, LC 25 Operational Records, LC 26 Control and Supervision of Operations and LC 28 Examination, Inspection, Maintenance and Testing).

1.2. Definitions

Table 1 – Table of Definitions

Term/Acronym	Description
ACoP	Approved Code of Practice
ADS	Approved Dosimetry Service
ALARP	As Low As Reasonably Practicable
CEFAS	Centre for Environment, Fisheries and Aquaculture Science
CNS	Civil Nuclear Security (Office for Nuclear Regulation)
DAP	Duly Authorised Person
DNSR	Defence Nuclear Safety Regulator
HASS	High Activity Sealed Source
HSE	Health and Safety Executive
IAEA	International Atomic Energy Agency
IRR17	Ionising Radiations Regulations 2017
LC	Nuclear Site Licence Condition
MoD	Ministry of Defence
NRW	Natural Resources Wales
NVQ	National Vocational Qualification
PPE	Personal Protective Equipment
RIFE	Radioactivity in Food and the Environment
RP	Radiological Protection
RPA	Radiation Protection Adviser
RPE	Respiratory Protective Equipment
RPS	Radiation Protection Supervisor
SFAIRP	So Far As Is Reasonably Practicable
SEPA	Scottish Environment Protection Agency
SQEP	Suitably Qualified and Experience Person

2. The Ionising Radiations Regulations 2017

14. IRR17 are set out together with the guidance in HSEs Approved Code of Practice (ACoP) "Work with Ionising Radiation, Ionising Radiations Regulations 2017 (ref. [1]). Inspectors should consult this document in preparing for, and carrying out, their compliance inspection.

3. Purpose of the Ionising Radiations Regulations 2017

15. IRR17 require that radiation exposures to workers and members of the public are restricted so far as is reasonably practicable. This is achieved by placing duties on employers to protect employees and other persons against ionising radiation, arising from work with radioactive substances and other sources of ionising radiation, and by placing certain duties on employees.

4. Guidance on Arrangements for the Ionising Radiations Regulations 2017

- 16. The dutyholder should have arrangements in place to demonstrate compliance with IRR17. The following list considers aspects of the requirements. The list is neither exclusive, nor exhaustive, and will be subject to review and revision in the light of operational experience. If dutyholders have generic models for arrangements, then it is for the dutyholder to justify any deviation from the models.
- 17. Procedures shall address the requirements of IRR17. The role responsible for compliance should be identified. Procedures should be readily available and should be up to date, signed by an appropriate person and be controlled in-line with the dutyholders document management arrangements. Brief guidance is given below for each of the seven parts of IRR17.

4.1. Part 1 (Preliminary – Regulations 1 – 4)

18. This defines the terms used in and the scope of the Regulations. The term 'Radiation employer' is no longer used in IRR17 and instead the term 'an employer who carries out a practice that involves ionising radiation' is used.

4.2. Part 2 (General principles and procedures - Regulations 5 -13)

19. The Regulations:

- Require certain work with ionising radiation to be notified to the appropriate authority (ONR or HSE).
- Prohibit the carrying out of registrable practices without a registration from the appropriate authority (ONR or HSE).
- Prohibit the carrying out of specified practices without the consent of the appropriate authority (ONR or HSE).
- Require employers to make a suitable and sufficient assessment of the risks arising from their work with ionising radiation, to assess the hazards likely to arise from that work and to prevent and limit the consequences of identifiable radiation accidents.
- Require employers to take all necessary steps to restrict, so far as is reasonably practicable, the extent to which employees and other persons are exposed to ionising radiation.

- Require respiratory protective equipment used in work with ionising radiation to conform with agreed standards and require all personal protective equipment and other controls to be regularly examined and properly maintained.
- Impose limits (specified in Schedule 3) on the doses of ionising radiation which employees and other persons may receive.
- Require employers to estimate doses to members of the public from their practice(s) and that these doses are ALARP.
 Authorised discharges and disposal of radioactive material are enforced by the relevant environment agencies (Environment Agency, NRW or SEPA).
- Require in certain circumstances the preparation of contingency plans for radiation accidents which are reasonably foreseeable. If all or part of the plan is carried out, the circumstances leading to the event to be analysed, so far as is reasonably practicable, to prevent a reoccurrence.

4.3. Part 3 (Arrangements for the Management of Radiation Protection - Regulations 14-16)

20. The Regulations require that employers consult suitable Radiation Protection Advisers (RPAs) for the purpose of advising the Employer as to the observance of the Regulations and must consult the RPA in respect of matters specified in Schedule 4. Employers must ensure that adequate information, instruction and training are given to employees and other persons. Employers are required to co-operate by exchanging information, to enable compliance by others with requirements to limit the exposure of employees to ionising radiation.

4.4. Part 4 (Designated areas - Regulations 17-20)

21. The Regulations require that areas in which persons need to follow special procedures to restrict exposure, or in which persons are likely to receive more than specified doses of ionising radiation, be designated as controlled or supervised areas, and that suitable arrangements are in place.

4.5. Part 5 (Classification and monitoring of persons - Regulations 21-27)

22. The Regulations require that:

 Employees who are likely to receive an effective dose greater than specified levels must be designated as classified persons.

- Doses received by classified persons are assessed by one or more
 Dosimetry Services formally approved by HSE, i.e. an Approved
 Dosimetry Service (ADS). (Sometimes licensees/dutyholders use
 different ADS services for different aspects of dosimetry, such as for
 external whole-body radiation and for the separate assessment of
 internal radiation dosimetry. Similarly, a record keeping ADS must be
 appointed, recognising that the dose assessing ADS is not necessarily
 the same as the record keeping ADS).
- Records of such doses are made and kept for a specified period for each such person. The Regulations also include requirements for medical surveillance and investigation, notification and dose limitation in the event of overexposures.

4.6. Part 6 (Arrangements for the Control of Radioactive Substances, Articles and Equipment - Regulations 28-32 and 34)

23. The Regulations:

- Require that where a radioactive substance is to be used as a source
 of ionising radiation, it must, whenever reasonably practicable, be in the
 form of a sealed source.
- Require any articles embodying or containing radioactive substances to be suitably designed, constructed, maintained and tested.
- Cover the accounting for, keeping and moving of radioactive substances and require that incidents in which more than specified quantities of radioactive substances are spilt, released lost or stolen be notified to the appropriate authority, which for activities carried out on any nuclear premises is ONR.
- Require that radioactive substances are kept in a suitable receptacle within a suitable store and are kept in a suitable receptacle, suitably labelled, while it is being moved).
- Impose duties on manufacturers, etc. and installers of articles for use in work with ionising radiation to ensure that such articles are designed, constructed and installed to restrict, so far as is reasonably practicable, exposure to ionising radiation.
- Prohibit interference with sources of ionising radiation.

4.7. Part 7 (Duties of employees and miscellaneous - Regulations 35-43)

- 24. The Regulations impose duties upon employees engaged in carrying out work with ionising radiation and:
 - Provide for the approval of dosimetry services by HSE.
 - Provide for a defence on contravention of certain regulations.
 - Provide for exemptions to be granted by HSE/ONR.
 - Extend the provision of the regulations outside Great Britain.
 - Contain transitional provisions.
 - Introduce modifications relating to the Ministry of Defence (MoD); and
 - Require the Secretary of State to carry out and publish a review of the regulatory provision provided by the IRR17.

Guidance on Inspection of Arrangements and their Implementation

- This section assists inspectors in judging the adequacy of the dutyholder's arrangements. The following list is neither exclusive, nor exhaustive, and will be subject to review and revision in the light of operational experience. It does, however, provide a list of aspects of IRR17 that can be examined during routine inspections.
- 26. Check that adequate arrangements are in place and procedures have been made to demonstrate compliance with IRR17. Check that these arrangements are implemented by the dutyholder.
- 27. Examine the procedures documentation layout and check that it is consistent. Review the procedures to establish validity, whether any changes have been made since the last review and whether the identified responsible persons are correct. Note whether instructions, methods and quality assurance requirements claimed in procedures have been followed and whether any changes that have been made have been correctly incorporated and validated.
- 28. Employers, should be able to refer to documentation showing how they discharge their duties under IRR17 including:
 - Radiation Risk Assessments (Regulation 8)
 - Restriction of Exposure SFAIRP (Regulation 9)
 - Provision of PPE (Regulation 10)
 - Contingency Plans (Regulation 13)
 - Appointment of a Radiation Protection Adviser (Regulation 14)
 - Local Rules and Appointment of Radiation Protection Supervisors (Regulation 18)
 - Arrangements with one or more Approved Dosimetry Service (ADS) for Dose Assessment and Recording (Regulation 22)
 - Arrangements for Medical Surveillance of Classified Persons (Regulation 25)
 - Control of Radioactive Substances (Regulations 28 30)
 - Investigations and Notifications (Regulations 26 and 31)

- 29. Dutyholders often refer to a compliance matrix, which sets out the procedures and documents that secure compliance with each regulation, together with the person responsible. For a nuclear licensed site, such a matrix is likely to be similar to that for compliance with nuclear site licence conditions.
- 30. Dutyholder's arrangements are often set out in generic rules (for example, "Radiological Safety Rules") that are intended to deliver compliance with IRR17. These are sometimes produced by the dutyholder centrally and implemented at each site via lower tier procedures/instructions. Inspectors should seek to ensure that such documents are included in arrangements for document control and are regularly reviewed to reflect the requirements of IRR17.
- 31. It is for inspectors to apply their experience and discretion to determine the extent and depth of a particular inspection, taking due account of several factors such as safety significance, complexity and technical specialism.
- 32. Guidance is given here on some of the key requirements. In deciding which relevant arrangements to sample, inspectors should consider reported information, events or previous enforcement action taken on the dutyholder, and, where appropriate, the findings of related licence compliance inspections (for example, LC 8 Warning Notices; LC 11 Emergency Arrangements; LC 12 DAPs and SQEPs; LC 28 Examination, Inspection, Maintenance and Testing).
- 33. A range of HSE guidance on specific aspects of IRR17 is available (for example, via the HSE website). ONR inspectors should be aware of and follow this guidance.
- 34. Where inspection indicates that a dutyholder's arrangements fall significantly short of IRR17 requirements, and especially where enforcement action appears to be warranted under the Enforcement Management Model (EMM), the inspector should seek advice from a specialist RP inspector. Examples of relevant formal enforcement action taken by ONR are provided in Appendix 2.

5.1. Topics likely to be suitable for planned compliance inspection

5.1.1. Regulatory Duties

- There are additional duties on those employers who carry out work with ionising radiation. For example, on a nuclear site there could be employers who are not undertaking practices with ionising radiation for example, cleaning contractors.
- 36. The IRR17 duties on the employer are also imposed on the holder of a nuclear site licence, as far as the work relates to the licensed site

(Regulation 4 (3)). ONR have taken the view that the employers under consideration here include contractors and visiting employers to a licensee's site, thereby placing a duty on the licensee to ensure that the work undertaken by these employers is compliant with any relevant duty under the IRR17. However, it is recommended that legal advice is taken on this interpretation, prior to taking any enforcement action under Regulation 4(3) for an alleged breach by a Licensee of an IRR17 duty that, in the first instance, is a duty on a contractor or a visiting employer to its site.

- 37. The Licensee (a corporate body) normally appoints individuals to specific posts, defined in their corporate arrangements or in regulations, with specific responsibilities for carrying out the regulatory duties on behalf of the corporate body. At nuclear licensed sites, the duties of the Employer are normally discharged by the most senior person on the site (Site Director, Station Manager, etc.) delegated as appropriate through the management organisation structure.
- 38. Inspectors should consider holding discussions with dutyholders notably, Nuclear Site Licensees, site operators, employers (for example, contractors), transport dutyholders and employees, as well as RPAs and RPSs, to ensure that they understand their duties under the regulations.
- Inspectors should discuss the dutyholder's own arrangements for regularly auditing (monitoring and reviewing) (as per Management of Health and Safety at Work Regulations 1999, Regulation 5) to ensure effective compliance with the duties imposed by IRR17.

5.1.2. The Employer

- 40. It is suggested that inspections include an interview with the appropriate person(s) identified in the corporate arrangements to confirm that they accept and understand their regulatory duties and responsibilities under the Regulations.
- 41. Copies of appointment letters for Radiation Protection Advisers and Radiation Protection Supervisors should be available and should include the scope of their appointment.
- The appropriate person(s) should be able to demonstrate that they have sought advice from a number of sources including their appointed RPA(s), and where appropriate, their professional health physicists and the nuclear safety committee.
- 43. All employers have responsibilities under IRR17 for dose investigation (Regulation 9 (8)), dose limitation (Regulation 12), training, etc. (Regulation 15), co-operation between employers (Regulation 16) and classification/monitoring (Regulations 21 25).
- 44. Additional duties are placed on those in control of, or who designate, radiological areas (Regulations 17 and 19).

45. Inspectors may consider interviewing contractor's staff, to ensure that adequate arrangements are in place for co-operation with the licensee and for discharge of these responsibilities.

5.1.3. The Nuclear Site Licensee

46. Nuclear site safety inspectors may choose to confirm that the licensee has adequate arrangements in place to ensure that all duties under IRR17 are discharged in relation to contractors working on the site. For example, the licensee should have arrangements in place to ensure that contractors working on the site are given adequate instruction, information and training (for example, via induction training) and for ensuring that contractors are classified, as appropriate, for the purposes of dose assessment and recording.

5.1.4. The Employee

- 47. Inspectors should be aware that employees themselves have the following duties under IRR17 (Regulation 35):
 - Avoid unnecessary exposure to themselves and other persons.
 - Make proper use and look after PPE.
 - Take care of radiation passbook where issued.
 - Comply with contingency plans and dose assessment arrangements.
 - Comply with medical surveillance arrangements.
 - Notify the employer of incidents.

5.1.5. The Radiation Protection Adviser

48. On most nuclear sites, the RPA function is provided in-house, typically by one or more members of the radiological protection function on the site. Individuals may be appointed to fulfil only a limited number of RPA responsibilities, with other functions being fulfilled by other appointed individuals (who may or may not be based on the site). All individuals appointed in this way should, between them, cover all the RPA regulatory duties and are sometimes referred to as an "RPA Body". Most contractors working on nuclear sites use the site's RPA services whilst others, and most transport operators, employ external RPA consultancy services.

- 49. Suitable and sufficient RPAs must be appointed in writing by the employer and they must be aware of any limitations on the scope of their written appointment. They should hold a valid certificate from an assessing body (for example, RPA 2000) or a relevant NVQ.
- 50. Frequently an individual appointed as an in-house RPA may have a senior line management role in the organisation and may also have separate regulatory duties (for example, as Head of the Approved Dosimetry Service). Inspectors should seek to ensure that such individuals are clear about the scope and delineation of their duties, and that adequate procedures are in place to ensure that an RPA is consulted on those matters set out in Schedule 4 of IRR17:
 - Implementation of requirements for controlled and supervised areas.
 - Installation of new or modified sources of ionising radiation.
 - Regular calibration/checking of radiation monitoring equipment.
 - Periodic examination of systems to restrict radiation exposure.
- 51. In addition, ONR would expect the employer to consult the RPA on the observance of the regulations in all areas.
- 5.1.6. The Radiation Protection Supervisor
- The RPS must be appointed by the employer for the purpose of securing compliance with IRR17 with respect to work carried out in an area subject to Local Rules. Contractors may appoint one of their own employees or other suitable person (for example, an employee of the licensee or of the site operator) as an RPS.
- 53. Some dutyholders appoint staff at team leader level as an RPS, even though they may be based in an area some distance from the area subject to Local Rules. This may be acceptable, so long as adequate control is exercised. If RPSs are appointed at a higher level than the team leader, they still need to be able to personally ensure that personnel comply with the Local Rules.
- Inspectors should consider interviewing one or more RPSs. An RPS should be clear about their appointment, have received adequate training, know and understand the requirements of IRR17 and the relevant Local Rules, and understand the precautions to be taken in an emergency. RPSs should command sufficient authority from people working under their supervision.
- 55. In addition to the advice in the ACoP and Guidance, information on good practice is available in HSE Information Sheet Ionising Radiation Protection Series No. 6, which is available on the <u>HSE website</u>.

- 5.1.7. Radiation Risk Assessments (Regulation 8) and Contingency Plans (Regulation 13)
- The employer must carry out a risk assessment, sufficient to show that all hazards with the potential to cause a reasonably foreseeable radiation accident have been identified and the nature and magnitude of the associated risks have been evaluated.
- 57. At nuclear licensed sites, reasonably foreseeable radiation accidents are likely to include, not only the major hazards for which emergency arrangements are in place under Licence Condition 11, but also other hazards (for example, those arising from radiography and the use of radioactive solids or solutions that may be spilt in an active laboratory) or chemo toxic hazards, (such as with uranium hexafluoride, where the chemo toxic hazard predominates over the radiological hazard, but both hazards need to be addressed). The employer must take steps to prevent such accidents, and following consultation with the RPA, have prepared a Contingency Plan that seeks to limit the consequences of any such accident.
- 58. For transport dutyholders, assessed accident doses for reasonably foreseeable radiation accidents greater than 1 mSv indicate that a radiation emergency is possible, and a prescriptive CDG09 emergency plan is required to be produced. This plan must also meet the requirements of IRR17 Regulation 13 Contingency Plans. ONR have published additional guidance on producing Radiation Risk Assessments (RRAs) in relation to the transport of radioactive material (ref. [7]).
- 59. Contingency Plans must be rehearsed at suitable intervals. People affected by the Contingency Plan must be provided with suitable training, instructions and dosimetry. Some Contingency Plans may be generic (for example, where operations such as radiography are carried out at different locations at various times). Inspectors should ensure that such plans identify those responsible for taking action, immediate actions for assessing and mitigating the effects of any accident, the location of any PPE that might be needed, personal dosimetry requirements, sources of advice, the circumstances under which the on or off site emergency services should be called, the need to establish the building and/or site emergency control centre, together with provisions for dose assessment, both in immediate response to and following the accident. Arrangements for the provision of dosimetry to emergency services personnel need to be addressed. The provision of adequate prior information to both the 'on' and 'off' site emergency services should be evident. Emergency arrangements developed to comply with the provisions of REPPIR should also be considered.

5.1.8. Restriction of Exposure (Regulation 9)

- 60. The employer has overall responsibility to take all necessary steps to restrict, so far as is reasonably practicable, the extent to which their employees and other persons are exposed to ionising radiation. In other words, their exposure must be ALARP. Priority should be given to elimination or reduction of the radiological hazard, and then engineering controls, in preference to management controls. Undue weight should not be placed on "time at risk" arguments, dose sharing or PPE.
- 61. Enforcement action has been taken where employee exposures were well below the dose limits but were not ALARP and there was a clear potential for significantly greater dose uptake than was actually incurred. Inspectors should ensure that data is collected and reviewed for the maximum individual radiation doses, rather than just average radiation exposures. The exposures of contractors and others should also be assessed, not just employee doses. The exposure should also consider work undertaken in areas with elevated levels of radon.
- The application of relevant good practices and standards is part of the ALARP justification. Examples of good practice are given in Appendix 3.
- 63. Employers are required to utilise dose limits and dose constraints in restricting exposure at the planning stage of radiological protection (for example, in plant design) and to carry out investigations where an employee receives an effective dose of 15 mSv per year (or any lower effective dose specified by the employer). Inspectors should consider referring such aspects to a RP specialist inspector.
- 64. The requirement for restriction of exposure extends to all persons, including members of the public. As part of their arrangements to demonstrate that effective doses received by members of the public do not exceed dose constraints and dose limits are ALARP, licensees measure radiation dose rates at their site perimeter. ONR annually collects data from licensees on doses to members of the public from all potential exposure pathways. ONR makes licensees' dose estimates from direct radiation exposures available to Centre for Environment, Fisheries and Aquaculture Science (CEFAS) for publication in the annual UK Radioactivity in Food and the Environment (RIFE) reports. ONR radiation protection specialist inspectors also carry out interventions at sites to assess the adequacy of licensees' arrangements for assessing and controlling public dose from direct shine. Currently, and as part of a rolling programme, a technical support contractor is contracted by ONR to carry out an independent assessment of annual dose to members of the public and compares their findings to the data reported by the licensee.

- 5.1.9. Personal Protective Equipment (Regulations 10 and 11)
- 65. PPE must comply with the provision of the Personal Protective Equipment Regulations 2002 (as amended). Details are given in the guidance to the PPE at Work Regulations 1992 and in document HSG 53 for respiratory protective equipment. Nuclear safety site inspectors should ensure that PPE is readily available (in sufficient quantity), in good condition, is appropriately stored, is fit for purpose, and is subject to regular examination and maintenance. A Nuclear Industry Good Practice Guide to Respiratory Protective Equipment provides additional guidance on specific management arrangements required where assigned workplace protection factors higher than those typically used are claimed. (ref. [8])
- 5.1.10. Dose Limits (Regulation 12) and Overexposures (Regulations 26, 27)
- Ose Limits are set out in Schedule 3 Part 1 of the Regulations. Any known or suspected overexposure must be investigated as required by Regulation 26. The Employer must notify ONR as soon as any such overexposure is suspected, such as implementing the Licence Condition 7 arrangements/by a formal "INF 1" notification.
- Where an employee has been subjected to an overexposure, inspectors should check that the employer has introduced a reduced dose limit for the remainder of the calendar year and has implemented measures to restrict their doses accordingly.
- 5.1.11. Co-operation between employers (Regulation 16)
- Where work undertaken by one employer is likely to give rise to the exposure to ionising radiation of the employee of another employer, this regulation requires those employers to co-operate to ensure that both comply with the regulations. Examples would be where a contractor might carry out radiography on a nuclear site or a consignor of radioactive material using a third-party carrier to transport the material. In such a case, where the employees of either employer may be exposed to ionising radiation arising from work that is under the control of the other, the allocation of responsibility between the employers should be clear and documented.

5.1.12. Local Rules (Regulation 18)

- 69. The employer is required to set down in writing Local Rules for any controlled area or where appropriate, having regard to the nature of the work carried out there, any supervised area, as is appropriate to the radiation risk and nature of operations. Safety inspectors should check that these exist, are periodically reviewed and include key working instructions to restrict exposure during normal work and in the event of a radiation accident. The employer must ensure that any relevant Local Rules are brought to the attention of those employees and other persons who may be affected by them. These can take a variety of forms, including instructions, booklets and circulars. Visitors must be instructed in the requirements of the Local Rules. Information on contamination levels and/or local radiation levels, sometimes in the form of contour maps, may be appropriate. PPE requirements to enter the work area should be clear.
- 70. Essential content of the Local Rules is set out in HSEs ACoP (para., 336) (ref. [1]). They should include the name of the relevant RPS and refer to the relevant Contingency Plan, which should cover a range of incidents, including minor events (for example, spills of radioactive liquids or solids or gaseous releases).
- 71. The Employer must consult the RPA regarding implementation of requirements as to controlled and supervised areas within the Local Rules.

5.1.13. Control over Entry to Controlled Areas (Regulation 19)

- 72. Inspectors should check that controlled (and supervised) areas are suitably demarcated, such as by barriers, including signs indicating the risks arising from any sources or contamination in the area. Arrangements should be established for maintaining the means of demarcating the boundaries and for maintaining effective signage. Note that licensees and site operators often use a colour-coded system, set out in safety rules, for such signage.
- 73. Access to controlled areas must be limited to classified persons and others who are permitted entry only under the terms of written arrangements, (such as a written system of work). Such arrangements should be aimed at restricting exposure to ionising radiation by, for example, close supervision, restrictions on the type of work done, restriction on the time spent in the area and the use of PPE.

- 74. Provision must be made for estimating the dose likely to be received by non-classified workers, but this need not necessarily involve the issue of a personal dosimeter to them. For example, it may be acceptable for the host of a group of non-classified persons to wear a dosimeter, to give an indication of the dose received by group members. This practice can be applied to both external and neutron criticality dosimeters. Where classified persons are Outside Workers, then they must be subject to suitable training, instruction, dosimetry and PPE provided, following co-operation between their employer and the dutyholder.
- 75. The requirement for an area to be designated as 'supervised' is based on the need to keep the conditions of the area under review to determine whether the area should be designated as a controlled area, or on the likelihood of an employee receiving an effective dose more than 1 mSv per year or an equivalent dose of one tenth of any dose limit. Hence, those routinely working in supervised areas need not be designated as classified workers. Monitoring should normally involve individual dose estimation and recording and health surveillance. Where individual dose estimation and record keeping of non-classified persons is carried out by an ADS, the standard of service should be the same as that for classified persons.

5.1.14. Monitoring of Designated Areas (Regulation 20)

- 76. Inspectors should ensure that all employers (i.e. contractors as well as the dutyholders) have arrangements to ensure that levels of ionising radiation are adequately monitored and that working conditions are kept under review. Suitable monitoring equipment must be provided. This may include external dose rate monitors, airborne contamination monitors, dust samplers, beta/gamma contamination monitors and alpha contamination monitors. Such instruments must be regularly maintained and tested and records kept of maintenance, test and monitoring results.
- 77. Inspectors should check that available radiation and contamination data is regularly collected and reviewed, to confirm that an area designation remains appropriate and no inadvertent spread of contamination or increase in does rates has occurred. It is not sufficient to rely solely on dose uptake trends for this purpose.
- 78. Monitoring of supervised areas can provide information on which to base estimates of personal dose for occupationally exposed employees who are not subject to individual assessments by an ADS. Inspectors should confirm that employers have arrangements in place to ensure that doses to employees working in supervised areas are sufficiently well understood to enable compliance with Reg. 9 (Restriction of Exposure), Reg. 12 (Dose Limitation) and Reg. 21 (Designation of classified persons). Personal dosimetry for non-classified employees may be necessary, particularly where they are working in supervised areas where dose rates are known to be variable or where they are working in several different supervised areas.

- 5.1.15. Storage and Accountancy of Radioactive Substances (Regulation 29 and 30)
- 79. The environment agencies (Environment Agency, NRW and SEPA) also have regulatory powers relating to tenants who hold radioactive substances on a dutyholder's premises. They may specify conditions within environmental permits or authorisations granted under the Environmental Permitting (England and Wales) Regulations 2016 or the Environmental Authorisations (Scotland) Regulations 2018. On defence sites, MoD is the enforcing authority for the High Activity Sealed Sources (HASS) Regulations and security; however, those aspects relating to IRR17 are enforced by ONR. The MoD has agreed to comply with notifications issued by the environment agencies regarding HASS requirements.
- 80. Inspectors should consider inspecting the arrangements for storing and accounting for radioactive substances, calling in support from RP specialists as necessary. In addition to the advice in the ACoP and Guidance, information on good practice is available in HSE Information Sheet Ionising Radiation Protection Series No. 8, which is available on the HSE website.
- 81. The definition of 'sealed sources' specifically excludes any radioactive substance inside a nuclear reactor or any nuclear fuel element.
- 82. Inspectors, supported as appropriate by RP specialist inspectors, should check that adequate arrangements are in place for accounting for the location of all radioactive substances at any one time. The dutyholder should specify the precise type and nature of all sources held on their premises. Arrangements should be in place to account for these at suitable intervals. When in use, they should be logged in and out of storage facilities.
- 83. In view of security issues, the inspector should discuss arrangements for the accountancy and storage of radioactive substances with RP specialist inspectors, CNS and Safeguards site inspectors where appropriate, and should address any perceived weakness in the security arrangements as a matter of urgency. Enhanced focus should be given during inspections to HASS source accountancy, in consultation with CNS (Civil Nuclear Security) and Safeguards site inspectors where appropriate. Additional training is required for HASS due to specific requirements for the safe management and control of these sources, as outlined in the HSEs ACoP (para., 278, ref. [1]).

- 84. Sources should be clearly labelled with a unique identifier. They should be stored in secure receptacles, which prevent dispersal and provide appropriate shielding. The particular requirements of HASS sources should be recognised by the dutyholder and inspectors should confirm this during the inspection. Surface dose rates on the receptacle should always be less than 2 mSv per hour (and in most cases should be much less than this). As well as having sources uniquely identified, it is worth noting that photographs can be useful in case a source is lost. This is not a requirement, but it can help when a source becomes misplaced.
- 85. Radioactive substances should be held in secure, weatherproof stores, which provide a suitable level of fire resistance and shielding. Stores should provide physical security and should normally be kept locked. They should be used only for the storage of radioactive substances and ancillary containers, shielding and equipment. The store should be segregated from flammable or explosive materials. The store entrance should bear a suitable warning sign indicating that it contains radioactive substances. Inspectors should ensure that radiological surveys are routinely carried out within and surrounding the store to confirm the appropriate area designation. Ventilation should be available to prevent airborne accumulations (sometimes including radon arising from the ground or from the building materials) and may need to be operated for a period before entering the store.
- 86. Dutyholders should be actively encouraged to dispose of all unwanted sources, as these can present avoidable safety and security risks.
- 87. A register should be maintained, using appropriate media, including the identifier of each source, its date of receipt, activity at a specified date, current location and, where appropriate, the date and manner of disposal and to whom it was sent. The arrangements should be audited regularly (preferably at least annually). Records should be kept for at least two years from the date of the last record entry or disposal.
- 5.1.16. Dose Assessment (Regulation 22) and Approval of Dosimetry Services (ADS) (Regulation 36)
- 88. All employers must make arrangements for the assessment and recording of radiation doses incurred by classified persons in their employ, where such doses may be significant. Employers are required to co-operate in this respect and, in many cases, contractors or tenant organisations use the dosimetry services appointed by nuclear site licensees. Employers should be an "intelligent customer" of such services.

- 89. HSE approves dosimetry services under the arrangements set out in Regulation 36. Approved services are required to meet the published requirements. Such services are usually inspected by ONR specialist radiological protection inspectors and non-specialist RP inspectors would not normally be expected to address this topic.
- 90. Inspectors should raise any query concerning the services provided by ADS with the relevant ONR specialist radiological protection inspector.
- 91. HSE provides information on the requirements for the approval of dosimetry services on their website.

5.1.17. Transport

92. Depending upon the amount of radioactive material an employer is planning to transport, they will need to make a notification (Reg. 5), apply for registration (Reg. 6), or seek consent (Reg 7), as transport is specifically defined as a practice in IRR17. Dutyholders (including licensees) engaged in the practice of transport need to apply through the relevant competent authority's online system.

5.1.18. Notifications

- 93. Non-specialist RP inspectors should discuss the following IRR17 related notifications with the specialist RP:
 - A request has been made for ONR/HSE consent for a special entry to be made in an individual's dose record to remove a recorded dose in excess of a statutory dose limit [IRR17 Regulation 23 (8) and the associated ACoP (paras., 516-518, ref. [1])].
 - There has been, or there was potential for, a dose to an individual above a statutory dose limit [IRR17 Regulation 26 (1)].
 - There has been, or there is likely to have been, a release of radioactivity or spill of radioactive material that was above or approaching the statutory reporting limits [IRR17 Regulation 31 (1)]. Such events, which meet the Ministerial reporting criteria, are also recorded in the quarterly statement of events on nuclear sites reported formally to Ministers and recorded on the <u>ONR website</u>.
 - There is reasonable cause to believe that radioactive material above the statutory reporting limit has been lost or stolen [IRR17 Regulation 31 (3)]. The enhanced significance of HASS sources should be recognised by the dutyholder and by the inspector. When appropriate, the ONR-CNS inspector should also be promptly informed in such instances.

6. Further Reading

- 94. Further useful information can be found in:
 - HSE Guidance relevant to the Ionising Radiations Regulations can be found on the <u>HSE website</u>.
 - General HSE guidance on Controlling Airborne Contaminants in publication HSG 258, <u>Controlling airborne contaminants at work: A</u> guide to local exhaust ventilation (LEV) - HSG258 (hse.gov.uk).
 - Publications of the United Kingdom Health Security Agency provides an additional source of information on the hazards of ionising radiation.

References

- [1] Health and Safety Commission, "Work with Ionising Radiation: Ionising Radiations Regulations 2017: Approved Code of Practice and Guidance," 2018. [Online]. Available: www.hse.gov.uk/pubns/books/l121.htm.
- [2] IAEA, "Safety Standards Series No. GSR Part 1 General Safety Requirements -Governmental, Legal and Regulatory Framework for Safety," 2016. [Online]. Available: https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1713web-70795870.pdf.
- [3] ONR, Enforcement Policy Statement, 2021.
- [4] ONR, "ONR-INSP-GD-059 Guidance for Inspection Strategy Planning and Recording".
- [5] ONR, "ONR-INSP-GD-064 General Inspection Guide".
- [6] ONR, "ONR-RP-GD-012 Applying for IRR17 Consent Guidance for Inspectors".
- [7] ONR, Ionising Radiations Regulations 2017 (IRR17) Regulation 8 Radiation Risk Assessment Guidance in Relation to the Civil Transport of Radioactive Material by Road, Rail and INland Waterway, Office for Nuclear Regulation, 2022.
- [8] Industry Radiological Protection Coordination Group, The UK Nuclear Industry Good Practice Guide to: Respiratory Protective Equipment, Nuclear Industry Safety Directors' Forum, 2016.

Appendix 1 – Comparison to International Safety Standards

Table 2 - IRR17 Comparison to Relevant IAEA Safety Aspects for Inspections

IAEA GSG-1 Requirement 29: relevant safe	IAEA GSG-1 Requirement 29: relevant safety aspects for inspections ¹						
IRR17 Regulation	Structures, systems and components and materials important to safety	Management systems	Operational activities and procedures	Records of operational activities and results of monitoring	Liaison with contractors and other service providers	Competence of staff	Safety culture
Citation and commencement							
2. Interpretation							
3. Application							
4. Duties under the Regulations							
5. Notification of certain work		5*			5*		
6. Registration of certain practices		6			6		
7. Consent to carry out specified practices		7			7		
8. Radiation risk assessments	8	8	8	8	8		
9. Restriction of exposure	9	9	9	9	9	9	9
10. Personal protective equipment		10	10		10		
11. Maintenance and examination of engineering controls etc and personal protective equipment	11	11	11	11	11	11	
12. Dose limitation	12	12	12	12	12		
13. Contingency plans		13	13	13	13	13	13
14. Radiation protection adviser		14			14	14	14
15. Information, instruction and training		15	15		15	15	15
16. Co-operation between employers		16	16	16	16		16
17. Designation of controlled or supervised areas		17	17	17	17		
18. Local rules and radiation protection supervisors		18	18	18	18	18	18(3)

¹ Relevant safety aspects to be included in IRR17 inspections as recommended by IAEA IRRS 2019 Report Recommendation 14.

IAEA GSG-1 Requirement 29: relevant safety aspects for inspections ¹							
IRR17 Regulation	Structures, systems and components and materials important to safety	Management systems	Operational activities and procedures	Records of operational activities and results of monitoring	Liaison with contractors and other service providers	Competence of staff	Safety culture
19. Additional requirements for designated areas		19	19	19	19	19	
20. Monitoring of designated areas		20	20	20	20	20	
21. Designation of classified persons		21		21	21		
22. Dose assessment and recording		22	22	22	22	22	
23. Estimated and notional doses and special entries		23	23	23	23	23	
24. Dosimetry for accidents etc		24			24		
25. Medical surveillance		25		25	25	25	
26. Investigation and notification of overexposure		26		26	26		
27. Dose limitation for overexposed employees		27			27		
28. Sealed sources and articles containing or embodying radioactive substances	28	28	28	28	28		
29. Accounting for radioactive substances		29	29	29	29		
30. Keeping and moving of radioactive substances	30	30	30		30		
31. Notification of certain occurrences		31		31	31		
32. Duties of manufacturers etc of articles for use in work with ionising radiation		32	32	32	32		
33. Repealed							
34. Misuse of or interference with sources of ionising radiation						34	34
35. Duties of employees						35	35
36. Approval of dosimetry services							
37. Defence on contravention							
38. Exemption certificates							

IAEA GSG-1 Requirement 29: relevant safety aspects for inspections ¹							
IRR17 Regulation	Structures, systems and components and materials important to safety	Management systems	Operational activities and procedures	Records of operational activities and results of monitoring	Liaison with contractors and other service providers	Competence of staff	Safety culture
39. Extension outside Great Britain							
40. Modifications relating to the MoD etc.							
41. Transitional provisions and savings							
42. Modifications and revocation							
43. Review							

^{*}Does not apply to Nuclear Licensed Sites.

Appendix 2 – Examples of relevant formal enforcement action taken by ONR

Date	Enforcement Action Taken	Regulation Breach
October 2004	Improvement Notice issued. Nuclear matter stored in crates was not stored in accordance with adequate arrangements and was not, so far as was reasonably practicable, kept in suitable receptacles and in a suitable store. (Improvement sought by May 2005).	IRR99 Regulation 29 (1) – Every radiation employer shall ensure, so far as is reasonably practicable, that any radioactive substance under his control which is not for the time being in use or being moved, transported or disposed of – (a) is kept in a suitable receptacle; and (b) is kept in a suitable store.
October 2004	Improvement Notice issued. Nuclear matter was not stored in accordance with adequate arrangements and was not, so far as was reasonably practicable, kept in suitable receptacles and in a suitable store. (Improvement sought by May 2006).	IRR99 Regulation 29 (1) – Every radiation employer shall ensure, so far as is reasonably practicable, that any radioactive substance under his control which is not for the time being in use or being moved, transported or disposed of – (a) is kept in a suitable receptacle; and (b) is kept in a suitable store.
December 2006	Improvement Notice issued. Licensee's arrangements were unsuitable, such that significant radiation doses to workers on the licensed site could go unassessed and hence unrecorded. This related to a requirement to assess an internal radiation dose uptake and to revise the related compliance arrangements. Compliance sought by September 2007.	IRR99 Regulations 21 (1) and 21 (2)

Date	Enforcement Action Taken	Regulation Breach
July 2008	Improvement Notice issued. Within a decommissioning area, the employer did not make a suitable and sufficient assessment of the radiation hazards in the area, to adequately restrict exposure to ionising radiation. This related to a shortfall in the assessment of radiation hazards in a decommissioning area, to identify the measures required to restrict exposure, by using engineering controls and design features.	IRR99 Regulation 7 (1) and Regulation 7 (2)
August 2008.	Improvement Notice issued. Failure to make and implement adequate arrangements for the regular and systematic examination, inspection, maintenance and testing of glove box equipment.	IRR99 Regulation 10 (1)
July 2011	Improvement Notice issued. Repeated examples of employees failing to use monitoring equipment. Verbal and written advice provided by ONR to licensee but observed shortfalls repeated, hence an Improvement Notice was issued, due to repeated observed failures by licensee staff to monitor on exiting from areas designated under IRR 1999 (in contravention of Local Rules).	IRR99 Regulation 17 (2) - The radiation employer shall take all reasonable steps to ensure that any local rules made pursuant to paragraph (1), and which are relevant to the work being carried out are observed.
June 2013	Improvement Notice issued. Failure to take the steps necessary to ensure that plant equipment was designed and constructed that they are safe and without risks to health including risks from ionising radiation, when they are being set, used, cleaned, or maintained by a person at work.	IRR99 Regulation 31

Date	Enforcement Action Taken	Regulation Breach
June 2015	Improvement Notice issued. No plan in writing setting out emergency arrangements appropriate for the carriage of packages containing class 7 goods, no was there such a plan made in writing by you as the carrier ahead of road carriage of packages containing Class 7 goods on at least two occasions during 2014.	Regulation 24 (2) Schedule 2 Part 4 (1) and (2) of the Carriage of Dangerous Goods and the use of Transportable Pressure Equipment Regulations 2009
October 2015	Improvement Notice issued. ONR requires transport companies carrying radioactive material to have a written emergency plan in place, before carriage begins, that details their actions, should an emergency arise whilst transporting radioactive material (Class 7 goods) by road. In this case, the carrier had no such written plan, and transported packages containing radioactive material on at least six occasions between September 2014 to August 2015.	Regulation 24 of the Carriage of Dangerous Goods and the use of Transportable Pressure Equipment Regulations 2009
March 2018	Improvement Notice issued. On the 22 March 2018 ONR inspected the company and found that they had not carried out a suitable and sufficient radiation risk assessment under the requirements of Regulation 8 of the Ionising Radiations Regulations 2017 which are regulated by ONR in respect of the transport of radioactive substances.	IRR17 Regulation 8

Date	Enforcement Action Taken	Regulation Breach
January 2019	Improvement Notice issued. The dutyholder carried Class 7 dangerous goods, radioactive material, without making a suitable and sufficient assessment of the risk to any employee and other person. As such they have failed to identify the measures needed to restrict the exposure to your employees or other persons to ionising radiation.	IRR17 Regulation 8
April 2019	Prosecution Crown Court A worker received a puncture wound to one of his hands while working in a glovebox used to process radioactive materials. The incident resulted in the worker receiving an intake of plutonium equal to approximately eight times the maximum legal annual exposure limit for workers in the nuclear industry.	Section 2 (1) of the Health and Safety at Work etc. Act (1974)
October 2021	Improvement Notice issued. Transport dutyholder had an inadequate risk assessment as required by IRR17 Reg 8. Required to review and update risk assessment in line with regulatory requirements and ONR guidance.	IRR17 Regulation 8

Appendix 3 – IRR17 Regulation 9 – Restriction of Exposure – Good Practice

- 1. Dutyholders should be aware of and apply relevant good practice. Good practice is the generic term for those standards for controlling risk which have been judged and recognised by HSE/ONR as satisfying the law when applied to a particular relevant case in an appropriate manner. The main sources of written, recognised good practice include Approved Codes of Practice (ACoPs), in particular the combined ACoP and Guidance document for IRR17, ONR and HSE Guidance, ICRP recommendations and guidance, British Standards and guidance produced by a relevant recognised body such as the Society for Radiological Protection, as well as good practices used at other facilities and sites which can be promulgated by ONR. There may also be unwritten sources of well-defined and established standard practice adopted by the radiation protection community.
- 2. Work planning and scheduling programmes should be adopted which include the use of:
 - Decision aiding techniques.
 - ALARP checklists to identify those factors that need to be considered before work is carried out.
 - Checklists for pre-job and post-job briefings.
 - Task feedback.
- 3. Estimates should be made of the likely occupational exposures prior to the commencement of work and these estimates should be reviewed after the work, investigating the reasons for differences between estimated and actual accrued doses. Dose sharing as a primary means of managing exposures should be avoided.
- 4. Dose reduction working groups, set up to identify improvements in plant operations and work practices that would reduce occupational doses. Such groups often involve members from the plant operations and management; many examples of workforce engagement, often through safety representatives, continue to deliver reduced occupational doses.
- 5. The adoption of a hierarchy of controls. The restriction of doses should be preferably by means of engineering controls and design features, then supporting systems of work and lastly personal protective equipment.
- 6. Training of staff at all levels about radiation doses and the importance of reducing occupational doses.

- 7. Training on tasks to be carried out for example, the use of mock-ups, in order to familiarise workers with potential problems and to improve their skills in carrying out the tasks. In this way, tasks can be carried out more efficiently in a challenging radiation environment, thus reducing occupational doses.
- 8. The setting of realistic dose targets for specific tasks or for work carried out during a specific period for example, shift targets. Close attention to such dose assessments, for example, by closely monitoring predicted and then assessing actual radiation doses can identify measures to reduce occupational radiation exposure.
- 9. There should be reviews of the effectiveness of the ALARP measures (for example, expected doses and actual doses may be compared during major projects, whilst work is in progress, or detailed task doses).
- 10. There should be demonstrable management commitment to these radiation exposure control practices.