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| ONR Guidance Document  Applying for IRR17 Consent - Information and guidance for safety assessments relating to practices involving the deliberate addition of radioactive substances to products |



ONR Guidance Document

Applying for IRR17 Consent - Information and guidance for safety assessments relating to practices involving the deliberate addition of radioactive substances to products

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Table 1 - Revision Commentary

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| 1 | New document. |

# Introduction

1. The Ionising Radiations Regulations 2017 (IRR17) provide a framework for ensuring that exposures to workers and other persons to ionising radiation arising from work activities are restricted so far as is as reasonably practicable and do not exceed specified dose limits.
2. Included within this legal framework is a ‘graded approach’. This is where the degree regulatory control over practices is proportionate to the size and likelihood of radiation risks resulting from the work.
3. The graded approach aspects of IRR17 refer to:

* Regulation 5 – Notification of certain work involving ionising radiation to HSE/ONR
* Regulation 6 – Registration of certain work practices involving ionising radiation to HSE/ONR
* Regulation 7 – Consent from HSE/ONR to perform specific work practices.

1. The introduction of the graded approach in IRR17 represented a change from the previous system of notifications and prior authorisations in the previous Ionising Radiations Regulations (IRR99) and included a requirement, with corresponding flat fee, for registrations and consents. In accordance with government policy changes to the process of applying for and gaining consents were made in order to better align with the International Atomic Energy Agency’s (IAEA) standards and guidance on application of the graded approach.
2. This document gives the content required for a Safety Assessment relating to any practice involving the deliberate addition of substances to products as stated in Regulation 7(1)(c) of IRR17 along with guidance on what information should be provided.

# Safety Assessment Content and Guidance

| Section | Content | Guidance |
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| 1 | A general summary of the type of addition of radioactive substances to be performed and the location(s) at which the practice is to be performed | Applicants should provide information on the addition to be performed and details of the types of radioactive sources to be used, the radionuclides, their maximum activities and the locations. |
| 2 | A summary of the arrangements for managing radiation\* protection  (\*radiation refers to ionising radiation throughout this document) | The radiation protection responsibilities and duties of management must be specified with clear lines of reporting established. Reliance on the RPS and RPA for the management of radiation protection is not sufficient. Evidence should be provided to show that the applicant manages radiation protection at a senior level. Details of how Radiation Protection Supervisors (RPS) will be given sufficient time and resources to supervise the work so that it done in accordance with local rules should be given. |
| 3 | A. Details of the frequency of additions, the radioactive substances to be used, or likely to be used.  B. Details of the nature of other sources of radiation in the working environment   * Information on the accumulation of radon in the working environment * Information on other sources of radiation exposure that industrial radiography employees may be exposed to | 1. The projected maximum number of occasions additions will be carried out per year at each location should be given 2. (i) The results of the risk assessment for rad 3. (ii) Details of other sources of radiation those engaged in work with the administration are likely to be exposed to. |
| 4 | Estimates of the radiation dose rates, activity concentrations in air, contamination levels of each radionuclide to which anyone can be exposed   * The maximum dose rates including those outside any shielding to which employees and members of the public can be exposed to at each location * The maximum activity concentration in air and contamination levels to which employees and members of the public can be exposed to at each location * The maximum dose rates, activity concentration in air and contamination levels which employees and members of the public can be exposed to at each location if an accident occurs * All of the above should include all relevant exposure categories – effective dose, committed effective dose equivalent and equivalent dose (extremities, skin, eyes) * Estimates of annual doses in all relevant categories for employees and other persons. | Applicants must provide reasoned estimates and/or measurements of the dose rates to which employees and others can be exposed 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 could be exposed to at each location. These estimates must show that dose rates will not exceed 7.5Svh-1 outside the immediate area. In all cases estimates of all the relevant exposure categories (effective dose, equivalent dose [extremities, skin, eyes]) must be given as well as 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 ALARP |
| 5 | A summary of the engineering control measures and design features already in place, or planned, to comply with the requirements of IRR17 Regulation 9 (Restriction of Exposure), associated with the work practice. | 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 and video equipment. In all cases their type, number, mode of operation etc. should be given and their location marked on a sketch plan of the facility(s) These sketch plans must also show the type and nature of any radiation shielding and the location of where the addition(s) and associated work will take place. Designated controlled and supervised areas should be described/indicated on the sketch plan. |
| 6 | Summary of the maintenance and tests schedules for all safety critical controls and other safety features | All the proposed maintenance schedules and testing regimes should be detailed for all the items referenced in Section 6. The pass/fail criteria should be stated, and the routine and failure replacement regimes specified |
| 7 | A summary of and results of Critical Examinations that will be or have been conducted in accordance with Reg 32(2) of the IRR17 | A summary of the results for the critical examinations must be supplied. A summary of any planned critical examinations and their pass/fail criteria must also be given. |
| 8 | A summary of the planned radiation dose rate and contamination monitoring regime for the facility and its surroundings including any areas to which the public may have access | The planned radiation dose rate and contamination monitoring regimes should be specified and details of the instruments to be used given. Of particular importance is the monitoring which confirms the shielding and contamination control methods are adequate and maintained. Information on how the monitoring results will be reviewed and by whom is required as well as how the records will be kept and for how long. |
| 9 | A summary of the personal dosimetry to be used including types, issue periods, approved dosimetry services. | A summary of the personal dosimetry provided to employees and others must be given. The type of dosemeter(s) must be given and details of the employee groups to whom they will be issued and the issue periods – monthly, quarterly etc. The name(s) of the Approved Dosimetry Services used for assessment and record keeping should be supplied. Any bioassay dosimetry must also be detailed. Dosimetry management processes – issue, return, supervision, results review and by whom should be stated. |
| 10 | The rationale for designating employees as Classified Persons | The classification rationale ensuring compliance with Regulation 21 of the IRR17 should be described. Classification is dependent upon routine likely 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 addition of radioactive substances to be classified. If this is not the case the applicant must provide an adequate justification. |
| 11 | A summary of the radiological protection training that will be or has been provided to employees and other persons, including planned frequency of refresher training. | A summary of how the requirements of Regulation 15 of the IRR17 for information, instruction and training are met must be provided. This must be sufficient to ensure that all those carrying out the addition, or are 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 ALARP. How the effectiveness of training is evaluated will be relevant, as are plans for refresher training. |
| 12 | Summary of the information supplied to employees concerning their work with ionising radiations in connection with pregnancy and breast feeding | Summary of how you communicate this requirement to your employees. |
| 13 | A summary of possible radiation accident situations as identified in the radiation risk assessment, their likelihood and potential severity. This will include   * Information on the consequences of possible failures of control measures or systems of work | All of the possible accidents identified as part of the Radiation Risk Assessment should be listed. Their likelihood should be stated and estimates of their potential severity given. The latter will include reasonable estimates of exposures to employees and members of the public in the event of the accident and the likely exposures to those engaged in accident mitigation. |
| 14 | Evidence that the applicability of the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR) has been considered and that the employer has taken any action required by those regulations | Evidence should be given that shows the applicability of REPPIR has been considered. Where it has be found that REPPIR does not apply a justification must be supplied. If REPPIR does apply the Hazard Evaluation report should be appended to the SA. |