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| ONR Guidance Document  Applying for IRR17 Consent - Guidance for applicants |

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ONR Guidance Document

Applying for IRR17 Consent - Guidance for applicants

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# Introduction

1. This guidance advises employers on how to apply to the Office for Nuclear Regulation (ONR) for an Ionising Radiations Regulations 2017 (IRR17) regulation 7 consent to carry out specified practices.
2. IRR17 provides a framework for ensuring that exposures to workers and other persons to ionising radiation arising from work activities in Great Britain are restricted so far as is reasonably practicable and do not exceed specified dose limits.
3. The Health and Safety Executive (HSE) and Office for Nuclear Regulation (ONR) regulate compliance with IRR17 in Great Britain. ONR does this for all nuclear premises (GB nuclear sites, authorised defence sites, nuclear warship sites and new nuclear build sites) as well as the transport of radioactive materials by road, railway and inland waterway (except where transport is undertaken for defence purposes where HSE is the enforcing authority/regulator). HSE is the enforcing authority/regulator for all other premises.
4. Included within this legal framework is a ‘graded approach’ – this is where the degree of regulatory control over practices is proportionate to the size and likelihood of radiation risks resulting from the work.
5. 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. Other guidance is available on the ONR website that advises on how to comply with regulations 5 and 6 of the IRR17 graded approach.
2. 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.
3. Employers requiring consent from ONR now apply using the online ONR application system.
4. This guidance explains:

* Which practices require employers to gain consent from HSE or ONR.
* Who is the appropriate regulator that employers gain consent from.
* What information is required from employers who apply for consent.
* How to apply for consent.
* Material changes to an existing consent.
* Certificates of consent.
* Procedures for revocations and appeals.

1. This guidance will help employers understand the process of gaining consent and ONR strongly advise that employers consult with their Radiation Protection Adviser (RPA) before applying.

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# Which practices require consent?

1. Consents are not site-specific – they apply to the practice carried out by the employer at all premises specified in their application. As part of an application, employers will provide details of all premises where the practice will be carried out.
2. In IRR17, there are nine specific work practices involving ionising radiation that require consent from the appropriate regulator before the work can be carried out. If an employer is carrying out more than one work practice that requires consent, that employer will need to apply for a separate consent for each relevant work practice.
3. Under the graded approach, consents are required for higher-risk practices and ONR will only grant consent if it is satisfied that suitable and sufficient arrangements are in place by the employer that ensure compliance with IRR17 and that radiation exposures from the practice are/will be properly restricted.
4. The nine specific work practices listed in regulation 7(1) of IRR17 are:

(a) the deliberate administration of radioactive substances to persons and, in so far as the radiation protection of persons is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;

(b) the exploitation and closure of uranium mines;

(c) the deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products;

(d) the operation of an accelerator (except when operated as part of a practice within sub-paragraph (e) or (f) below and except an electron microscope);

(e) industrial radiography;

(g) any practice involving a high-activity sealed source (other than one within sub‑paragraph (e) or (f) above);

(h) the operation, decommissioning or closure of any facility for the long-term storage or disposal of radioactive waste (including facilities managing radioactive waste for this purpose) but not any such facility situated on a site licensed under section 1 of the Nuclear Installations Act 1965;

(i) practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment.

## The deliberate administration of radioactive substances to persons or animals

1. If radioactive substances are administered to persons for medical purposes, or to animals for veterinary purposes, the employer will need consent for this practice. This consent will apply to all fixed sites operated by the employer where this practice is carried out.
2. Administration includes inhalation, injection, ingestion and by topical or internal techniques (brachytherapy).

## The exploitation and closure of uranium mines

1. There are currently no active uranium mines in Great Britain.

## The deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products

1. If the employer is manufacturing or producing products that have radioactive substances deliberately added to them, they will need consent for this practice.   
   This includes the addition of radioactive substances to medicinal products by radiopharmacies. This consent only applies to the addition of radioactive substances in the production and manufacture of these products. Any other practice associated with these products, including the sale of such products, is not covered by this consent. This consent will apply to all fixed sites operated by the employer where this practice is carried out.
2. The deliberate addition of radioactive substances in the production or manufacture of any consumer product will also require justification under the Justification of Practices Involving Ionising Radiation 2004. <http://www.legislation.gov.uk/uksi/2004/1769/contents/made>

## Operation of an accelerator

1. Accelerator is defined in regulation 2 of IRR17 as: "accelerator means an apparatus or installation in which particles are accelerated and which emits ionising radiation with energy higher than 1 MeV”.
2. If the employer is working with an apparatus or installation that meets this definition, they will need consent from the appropriate regulator for this practice unless they are working with an electron microscope. (Use of an accelerator in industrial radiography and/or industrial irradiation will require a consent under the specific categories below). This consent will apply to all premises operated by the employer where this practice is carried out.

## Industrial radiography

1. Industrial radiography is defined in regulation 2 of IRR17 as: “industrial radiography means the use of ionising radiation for non-destructive testing purposes where an image of the item under test is formed (but excluding any such testing that is carried out in a cabinet which a person cannot enter)”.
2. If the employer is performing work defined as industrial radiography using either radioactive sources (e.g. high-activity sealed sources (HASS)), accelerators or radiation generators, they will need consent from the appropriate regulator for this practice. This consent will apply to industrial site and enclosure radiography on all premises where this practice is carried out and, where relevant, consent will include the transport of the HASS sources used for the purposes of industrial site radiography between premises.
3. HSE and ONR do not consider the use of X-rays for the inspection of mail, packages or baggage, or for security purposes as ‘industrial radiography’.

## Working with a high-activity sealed source (HASS)

1. A high-activity sealed source is defined in regulation 2 of IRR17 as: “high-activity sealed source means a sealed source for which the activity of the radionuclide is equal to or exceeds the relevant activity value set out in Part 4 of Schedule 7”.
2. If the employer is performing work with sealed sources that are defined as HASS, including the transportation of HASS, they will need specific consent from the appropriate regulator for this practice, unless they are performing the specified practices of industrial radiography and/or industrial irradiation and already have consent for these. This consent will apply to all premises, or relevant transport routes, where this practice is carried out.

**Example:** A transport company is employed to transport a HASS source to/from a nuclear licensed site to another employer’s site (not a nuclear premises). In this instance, the transport company would require consent to transport the source and should apply to HSE. The nuclear premises would require consent to work with the source and should apply to ONR.

## Working on any facility for the long-term storage of radioactive waste or disposal of radioactive waste

1. HSE and ONR consider the long-term storage or disposal of radioactive waste to be a very specific practice and, therefore, only applicable to a small number of sites in Great Britain.
2. This practice applies to you if the following applies to your work:

* You work in a recognised installation for the long-term storage of radioactive waste.
* You work on a site that disposes of (non-exempt) radioactive waste to land, such as a landfill.

## Discharging significant amounts of radioactive material with airborne or liquid effluent into the environment

1. If the employer discharging radioactive material with airborne or liquid effluent into the environment expects the quantities of radioactive material, in one or more single discharges, to exceed the quantities specified in IRR17 column 5 of part 1 of Schedule 7, the employer will need consent from the appropriate regulator. (Contact the appropriate regulator regarding radionuclides not specified in Schedule 7.)
2. This consent will apply to all premises operated by the employer where this practice is carried out.

## Consents over multiple sites

1. For each consent that ONR issues for a practice, the employer only needs to apply for the consent once for all premises where they carry out that work with ionising radiation.

## Consents issued by another enforcing authority

1. ONR grants consent to an employer for practices carried out exclusively or primarily on nuclear premises and in all other cases HSE will grant consent.
2. Consents granted by HSE are valid for work on nuclear premises.

**Example:** A radiography contractor carrying out occasional industrial radiography on a nuclear premises only needs consent from HSE.

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# Who is the appropriate regulator that employers gain consent from?

1. ONR and HSE both grant consents under regulation 7(2) of IRR17 and who the appropriate regulator is depends on the type of premises upon which the work is carried out.
2. Employees wishing to carry out a practice exclusively or primarily on a nuclear premises should apply to ONR for a consent. Those employees who work on other (non-nuclear) premises and those who only occasionally work on nuclear premises should apply to HSE for consent.

**Example 1:** A hospital administering radioactive substances to persons or working with HASS should apply to HSE.

**Example 2:** A nuclear site operator working with HASS on a nuclear licensed site should apply to ONR.

**Example 3:** A transport company transporting HASS for their clients should apply to HSE.

**Example:** A nuclear site operator transporting HASS to/from their premises should apply to ONR.

**Example 4:** An industrial radiography company who does most of their work on non‑nuclear premises should apply to HSE.

**Example 5:** An industrial radiography company who is contracted to carry out site radiography work on a nuclear premises where this work is a large part of their business, although they also have other contracts off nuclear premises, should apply to HSE.

**Example 6:** A nuclear site operator employing their own staff as radiographers to carry out industrial radiography within (‘primarily’) the nuclear site boundary should apply to ONR.

1. HSE and ONR require information from the employer in order to grant applications for consents. Third parties can advise on the application process, but the legal duty is on the employer to submit the application.
2. In accordance with regulation 4(3) of IRR17, where a nuclear operator employs another employer/contractor to carry out a consentable practice on the operator’s nuclear premises, that nuclear operator also requires a consent for this practice from ONR.

# What information is required from employers who apply for a consent – Safety Assessments?

1. In order for a consent to be granted ONR requires the submission of a suitable and sufficient Safety Assessment.
2. The primary purpose of the submission of a Safety Assessment (SA) is to enable the employer to determine if adequate safety arrangements are in place for the practice, as defined in IRR17, and give an assurance to the appropriate regulator that compliance with IRR17 is, or will, be achieved and maintained.
3. The SA should include an assessment of the provisions in place for radiation protection. It should show that radiation risks are being properly controlled and that all radiation exposures resulting from the practice are restricted so far as is reasonably practicable (SFAIRP). The radiation risk assessment required by the IRR17 may form the basis of the SA but other information, e.g., on the management of radiation protection, must be included in the SA. The SA will also address all radiation risks that arise from the practice during normal operations and from reasonably foreseeable radiation accidents.
4. Once consent for the practice has been granted, its continuation is dependent upon the employer maintaining the validity of the SA. ONR expects employers to review their SAs periodically so that they are confident that all safety measures in place remain adequate. (This is likely to be part of the employers’ overall routine reviews of their health and safety arrangements as required by regulation 5 of the Management of Health and Safety at Work Regulations 1999.) Any subsequent material change(s) (see section below) to the SA must be notified immediately to ONR.
5. The compilation of information for the SA will usually be a team effort involving senior representatives of the employer, local managers, appropriate employees and the Radiation Protection Adviser (RPA). However, only a properly authorised employee can submit SAs to ONR.
6. The content of Safety Assessments and the new Consent system was developed jointly with HSE to ensure consistency. HSE will be introducing a similar system later in 2023 using the same Safety Assessment templates

# How to apply for a consent from ONR

1. In the first instance an employer should decide which consents they require and which appropriate regulator to apply to, following the guidance given in this document.
2. Each employer will need to complete some generic details that are common to all consent types. A template for this is available on the ONR website.
3. Each consent requires completion of an additional practice specific template. These templates can be downloaded from the ONR website.
4. Please see the appropriate regulators’ website for details on the security classification of information that can be accepted.
5. If an employer currently holds one or more consent certificates but is asked to submit a Safety Assessment by ONR, as with new consents, each consent will require its own separate application.

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# Material changes to an existing consent

1. IRR17 requires that any material changes to the Safety Assessment related to a consent are notified to HSE or ONR.
2. Broadly speaking, material changes are significant changes to the information you have provided during the application process. For example, the following are considered as material changes, please note this list is not exhaustive:

* use of new or different technologies;
* use of different radioactive substances;
* use of significantly different quantities of the same radioactive substances;
* changes in the physical form of the radioactive substances in use;
* a change of premises;
* changes in the working practices that increase the exposures to individual employees or other persons or introduce additional exposure pathways;
* changes to the working practices that could expose additional employees or other persons;
* significant changes in the management arrangements associated with the consented practice.

1. You are expected to use your judgement as to what else amounts to a significant change to the information you have provided.
2. Any consent certificates will be issued on the basis of certain information provided as detailed in the certificate and associated schedule. If any of this information changes, you should notify ONR of this change.
3. A name change of the employer will require a notification of cessation of work for the old employer and a new consent application in the name of the new employer.
4. ONR will assess the material changes notified and may undertake an inspection of the facilities. Depending upon the extent and radiological significance of the changes, the outcome may be a variation in the certificate of consent or a requirement to apply for a new consent.

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# Certificates of consent

1. ONR will review consents every five years or, if required, any time within that period.
2. All material changes must be notified and will be reviewed by the appropriate regulator. Significant material changes may require re-application.
3. If an employer stops working with ionising radiation and therefore no longer needs the relevant consent, they are required to inform the appropriate regulator about this change.

# Procedures for revocations and appeals.

## Revocation process

1. HSE and ONR have the power under IRR17 to revoke consents at any time (regulation 7(4)) where it’s considered appropriate to do so. ONR will consider revocation if, for example:

* A pattern of poor performance has emerged, demonstrating evidence of poor radiological protection and/or poor compliance with IRR17.
* There has been an extremely serious incident where significant breach(es) of the Ionising Radiations Regulations 2017 have occurred. The failures that led to the breaches may be so significant that it is considered necessary to initiate revocation proceedings irrespective of whether or not enforcement action has occurred.

1. When revocation is identified as appropriate, ONR will consider revocation action, irrespective of other potential enforcement action under Health and Safety at Work Act 1974 and, if revocation is undertaken, clearly explain to the consented employer the basis for revocation. Employers may appeal to the regulator.
2. If an employer applies for a consent after they have had a consent revoked, ONR will need to be assured of the demonstrable improvements and sustainable performance that have been taken by the employer to address the original reasons for the revocation.

## Appeals procedure

1. If a consent is not granted or revoked, then the applicant/consent holder may appeal to the appropriate regulator. The decision made by regulator will remain in place until the outcome of any appeals process.