

Ionising Radiations Regulations (Northern Ireland) 2017 – Guidance for Notifications, Registrations and Consents

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Introduction

- 1. This guidance advises employers on how to comply with regulations 5, 6 and 7 of the Ionising Radiations Regulations 2017 (IRR(NI)17) in Northern Ireland.
- 2. These regulations provide a framework for ensuring that exposures to ionising radiation arising from work activities are kept as low as reasonably practicable and do not exceed specified dose limits.

What is the graded approach?

- 3. Included within this legal framework is a 'graded approach' this is where regulatory control over practices is proportionate to the size and likelihood of exposures resulting from work.
- 4. The graded approach aspects of IRR(NI)17 refer to:
 - regulation 5 notification of certain work involving ionising radiation to HSENI;
 - regulation 6 registration of certain work practices involving ionising radiation to HSENI;
 - regulation 7 consent from HSENI to perform specific work practices.
- 5. The introduction of the graded approach represents a change from the previous system of notifications and prior authorisations in the previous lonising Radiations Regulations (IRR(NI)2000).
- 6. Employers will notify or apply for registrations and consents using an online HSENI application system.
- 7. This guidance document explains:
 - what the different tiers of the graded approach apply to;
 - which questions HSENI will be asking of employers who apply through the online system;
 - what employers can expect from HSENI after applying through the online system;
 - procedures for revocations and appeals.
- 8. This guidance will help employers understand the new process and HSENI strongly advises that they talk to their radiation protection adviser (RPA) before applying through the online system.
- 9. HSENI's implementation of the graded approach does not apply to any work performed on nuclear premises.
- 10. Any employer who wishes to carry out work with ionising radiation on nuclear premises that requires notification, registration or a consent will need to obtain



the relevant notifications, registration and/or consents from the Office for Nuclear Regulation (ONR): http://www.onr.org.uk/.

Who should apply

- 11. HSENI requires information from the employer in order to process any notifications or applications for registrations or consents. Third parties can advise on the application process, but the onus is on the employer to submit any application.
- 12. A duly authorised employee should submit any graded approach applications for the employer.



What work and sites does the graded approach apply to?

Type of work

- 13. The graded approach applies to all employers working with ionising radiation. This could be work with the following:
 - radioactive material:
 - o artificial radionuclides and/or naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties;
 - naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties;
 - radiation generators, such as X-ray devices;
 - work in an atmosphere containing radon assessed to be above an annual average concentration of 300 Bq m⁻³.
- 14. There are three tiers within the graded approach:
 - notification;
 - registration;
 - consent.
- 15. Depending on the work being performed, an employer may be required to notify or to hold registrations and consents at the same time.

Sites

16. Notifications, registrations and consents are not site-specific – they apply to the overall employer and will apply to all fixed sites under the employer's direct control. As part of a single application, employers will provide numbers of all their fixed sites where the work with ionising radiation is under their direct control (see paragraphs 103-104).

What does the graded approach not apply to?

17. The graded approach does not apply where the work with ionising radiation is one of the practices identified in Schedule 1 of IRR(NI)17. Generally speaking, these are work with very small amounts or concentrations of radioactive substance, apparatus of a type approved by HSE, and the operation of some electrical devices.

IRR(NI)17 - Schedule 1 (excerpt) - Work not required to be notified under regulation 5 (notification)

- 1. Work with ionising radiation is not required to be notified in accordance with regulation 5 when the only such work being carried out is in one or more of the following categories
 - a) where the concentration of activity per unit mass of a radioactive substance does not exceed the concentration specified in column 2 of Part 1 of Schedule 7 (for artificial radionuclides and naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties) or column 2 of Part



- 2 of Schedule 7 (for naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties);
- b) where the quantity of radioactive substance involved does not exceed the quantity specified in column 3 of Part 1 of Schedule 7 (for artificial radionuclides and naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties) or column 3 of Part 2 of Schedule 7 (for naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties);
- c) where the concentration of activity per unit mass or quantity of a radioactive substance does not exceed values which may be approved by the appropriate authority for specific types of work and where such work satisfies the exemption criteria set out in paragraphs 2 and 3 below;
- d) where apparatus contains radioactive substances in a quantity exceeding the values specified in sub-paragraphs (a) and (b) provided that—
 - (i) the apparatus is of a type approved by the Executive;
 - (ii) the apparatus is constructed in the form of a sealed source;
 - (iii) the apparatus does not under normal operating conditions cause a dose rate of more than 1 μ Svh⁻¹ at a distance of 0.1 m from any accessible surface; and
 - (iv) conditions for the disposal of the apparatus have been specified by the relevant environmental body;
- e) the operation of any electrical apparatus to which these Regulations apply other than apparatus referred to in sub-paragraph (f) provided that—
 - (i) the apparatus is of a type approved by the Executive; and
 - (ii) the apparatus does not under normal operating conditions cause a dose rate of more than 1 μ Svh⁻¹ at a distance of 0.1 m from any accessible surface;
- f) the operation of—
 - (i) any cathode ray tube intended for the display of visual images; or
 - (ii) any other electrical apparatus operating at a potential difference not exceeding 30kV,

provided that the operation of the tube or apparatus does not under normal operating conditions cause a dose rate of more than 1 μ Svh⁻¹ at a distance of 0.1 m from any accessible surface; or

- g) where the work involves contaminated material resulting from authorised releases which the relevant environmental body has declared not to be subject to further control.
- **2.** The criteria for the exemption from notification of work with ionising radiation are as follows:
 - a) the radiological risks to individuals caused by such work are sufficiently low as to be of no regulatory concern;
 - b) work of such type has been found to be justified; and
 - c) such work is inherently safe.
- 3. Work with ionising radiation only meets the requirements of paragraph 2(a) if
 - a) in relation to an employee, the effective dose caused by such work does not exceed 1 mSv in a calendar year; and



- b) (b)in relation to any other person, the following requirements are met in all circumstances where it is reasonably practicable to do so—
 - (i) the effective dose caused by such work from radionuclides which are not naturally occurring radionuclides does not exceed 10 μ Sv in a calendar year; and
 - (ii) the effective dose caused by such work from naturally occurring radionuclides does not exceed 1 mSv in a calendar year.



What are the key differences from the previous IRR(NI)2000 approach?

- 18. Under IRR(NI)2000, any relevant work with ionising radiation had to be notified to HSENI at least 28 days in advance of that work beginning. Certain work was also subject to prior authorisation, as well as notification.
- 19. Prior authorisation is no longer required, and forms no part of the graded approach.
- 20. What was previously notified under IRR(NI)2000 now requires, depending on what work is being carried out and prior to the work commencing:
 - notification;
 - registration;
 - consent from HSENI.
- 21. It is important to note that notification under IRR(NI)17 uses different activity concentration and quantity levels than notification under IRR(NI)2000.

What is the timescale for transition to IRR(NI)17?

22. Those who have previously notified HSENI under IRR(NI)2000 requirements have until 5 February 2018 to notify or apply for the relevant registration or consents.



What is notification?

- 23. Notification is the lowest tier of the graded approach, and applies to certain work with radioactive material and work in an atmosphere containing radon assessed to be above an annual average of 300Bg m⁻³.
- 24. There are three categories of work that you can notify to HSENI:
 - a. working with artificial radionuclides and/or naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties
 - b. working with naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties
 - c. working in an atmosphere containing radon above an annual concentration of 300 Bq m⁻³
- 25. HSENI issues notifications under IRR(NI)17. These primarily relate to restricting occupational exposures incurred from the practice.

Working with artificial radionuclides and/or naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties

- 26. Work with radioactive material containing artificial radionuclides and/or radioactive material containing naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties requires notification where:
 - a. There is 1000kg or less of radioactive material; and
 - b. the concentration of the radioactive substance is above the value in column 2, but does not exceed column 4 of Schedule 7, Part 1; and
 - c. the quantity of radioactivity exceeds the value in column 3 of Schedule 7, Part 1.
- 27. HSENI believes that the vast majority of working practices with radioactive material containing artificial radionuclides and/or radioactive material containing naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties will require registration as most of this work will usually exceed the values identified in paragraph 26 b. and c. above.

Working with naturally occurring radionuclides which are <u>not</u> processed for their radioactive, fissile or fertile properties

- 28. Work with radioactive material containing naturally occurring radionuclides which are not being processed for their radioactive, fissile or fertile properties requires notification if:
 - a. there is 1000kg or less of radioactive material; and
 - b. the concentration is above the value in column 2, but does not exceed column 4 of Schedule 7, Part 2; and
 - c. the quantity of radioactivity exceeds the value in column 3 of Schedule 7, Part 2



29. HSENI believes that the vast majority of working practices with naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties will require registration as most of this work will usually exceed the values identified in paragraph 28 b. and c. above.

Working in an atmosphere containing radon above an annual average concentration of 300 Bg m⁻³

- 30. Radon is a naturally occurring radioactive gas that can seep out of the ground and build up in houses and indoor workplaces. Radon (more properly known as radon-222) comes from uranium which occurs naturally in many rocks and soils.
- 31. Any workplace where a radon concentration assessed to be above an annual average of 300 Bq m⁻³ should be notified to HSENI. If multiple measurements have been undertaken, the highest measurement is the one that should be notified to HSENI.
- 32. Risk assessments for workplaces should include employees' exposure to radon for:
 - all below ground workplaces
 - all workplaces located in radon affected areas
- 33. Radon concentration measurements undertaken as a result of these risk assessments should provide a result capable of providing an annual average in units of Bq m⁻³.
- 34. For more information, visit HSENI's webpages on radon http://www.hseni.gov.uk/articles/radiation or also HSE's webpages http://www.hse.gov.uk/radiation/ionising/radon.htm

Examples of working in an atmosphere containing radon above an annual concentration of 300 Bq m⁻³

- i. You work in a school in a radon affected area and have radon concentration measurements above the 300 Bq m⁻³ level.
- ii. You work in a shop in a radon affected area and have radon concentration measurements above the 300 Bg m⁻³ level.
- iii. You work in a hospital basement not in a radon affected area and have radon concentration measurements above the 300 Bg m⁻³ level.
- iv. You work underground (e.g. show cave or a mine) and have radon concentration measurements above the 300 Bq m⁻³ level.
- v. You have performed multiple measurements in your workplace, with some providing results under an annual average of 300 Bq m⁻³, but with one or more results above.

Notifications over multiple sites



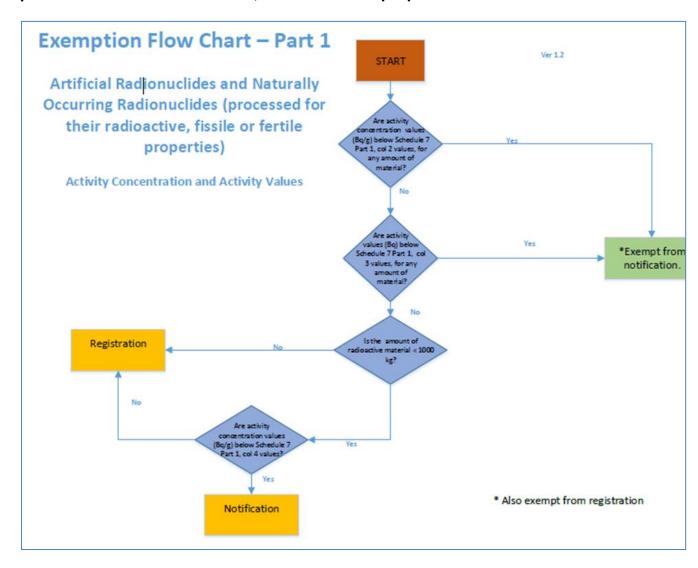
- 35. When notifying the relevant work to HSENI, the employer only needs to notify this work once for all sites that are under their control where they carry out work with ionising radiation.
- 36. For example, if an employer has five different sites all working with notifiable levels of naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties, they should only notify HSENI once, for all the relevant sites. Notifications for each site are not required.

What to expect?

- 37. No fee will be charged for a notification.
- 38. You will be required to download the questionnaire document from the HSENI website, input your data and email the information you have provided to mail@hseni.gov.uk.

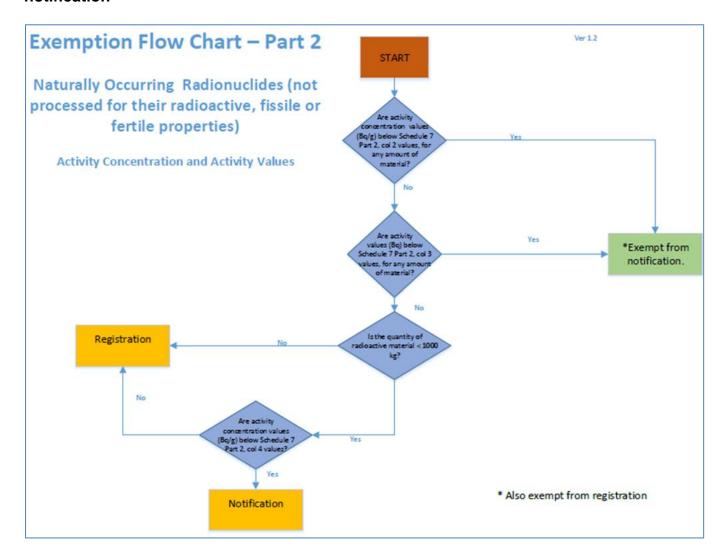


Flowchart showing which level of the graded approach applies for work with artificial radionuclides and/or naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties





Flowchart showing which level of the graded approach applies for work with artificial radionuclides and naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties that require notification





What is registration?

- 39. Registration is the middle tier of the graded approach and applies to certain work with radioactive material and work with radiation generators.
- 40. There are three categories of work that you can register with HSENI:
 - a. working with radiation generators
 - b. working with artificial radionuclides and/or naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties
 - c. working with naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties
- 41. HSENI issues registrations under IRR(NI)17. These primarily relate to restricting occupational exposures incurred from the practice.

Working with radiation generators

42. A radiation generator is defined in regulation 2 of IRR(NI)17 as:

"radiation generator" means a device capable of generating ionising radiation such as x-rays, neutrons, electrons or other charged particles;

- 43. Working with a radiation generator will require a registration unless:
 - it is used for a practice requiring consent, such as the operation of an accelerator, industrial radiography, or industrial irradiation;
 - it is specifically exempted by Schedule 1.
- 44. In the vast majority of cases, an X-ray device is a radiation generator, and will require registration.

Examples of working with radiation generators

- i. You work in a dental practice which has at least one dental X-ray device
- ii. You work in a veterinary practice which has at least one X-ray device
- iii. You work in an airport that has an X-ray device to scan baggage
- iv. You work in a post room for an office building that has an X-ray device to scan incoming packages
- v. You work in a port or dock that has an X-ray device to scan incoming or outgoing cargo
- vi. Your work involves the use of a handheld X-ray Fluorescence (XRF) device to determine the metallurgic content of metal
- vii. You work in a chiropractic practice which has at least one X-ray device
- viii. You work in an NHS Trust that has X-ray devices on its sites
- ix. You work in industry and use X-rays in a cabinet that cannot be entered to examine products

Working with artificial radionuclides and/or naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties



- 45. Work with 1000 kg or less of radioactive material containing artificial radionuclides and/or radioactive material containing naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties requires registration if:
 - a. the concentration is above the value in column 4 of Schedule 7, Part 1; and
 - b. the quantity of radioactivity exceeds the value in column 3 of Schedule 7, Part 1;
- 46. Work with over 1000 kg of radioactive material containing artificial radionuclides or radioactive material containing naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties requires registration if:
 - a. the concentration is above the value in column 2 of Schedule 7, Part 1;
 and
 - b. the quantity of radioactivity exceeds the value in column 3 of Schedule 7, Part 1;

Examples of working with artificial radionuclides and/or naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties that require registration

- i. You work in a school or university that uses radioactive material as a teaching source
- ii. You work with a sealed source that is not a high activity sealed source
- iii. You work with nuclear density gauges
- iv. You transport or store radioactive substances (unless explicitly included within a consentable practice)
- v. You work in a museum that holds articles containing radium

Working with naturally occurring radionuclides which are <u>not</u> processed for their radioactive, fissile or fertile properties

- 47. Work with 1000 kg or less of radioactive material containing naturally occurring radionuclides which are not being processed for their radioactive, fissile or fertile properties requires registration if:
 - a. the concentration is above the value in column 4 of Schedule 7, Part 2; and
 - b. the quantity of radioactivity exceeds the value in column 3 of Schedule 7, Part 2
- 48. Work with over 1000 kg of radioactive material containing naturally occurring radionuclides which are not being processed for their radioactive, fissile or fertile properties requires registration if:
 - a. the concentration is above the value in column 2 of Schedule 7, Part 2; and
 - b. the quantity of radioactivity exceeds the value in column 3 of Schedule 7, Part 2



Example of working with naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties that require registration

Example - foundry and zircon sand

A foundry has 10 x 20 kg bags of zircon sand. The information provided at point of sale says that it contains Th-232 at 1 Bq/g and U-238 at 4 Bq/g.

Quantity

- Total quantity of Th-232 is therefore 10 x 20 x 1000 x 1 Bq = 2×10^5
- Total quantity of U-238 is therefore $10 \times 20 \times 1000 \times 4 \text{ Bq} = 8 \times 10^5$

Concentration

- Th-232 at 1 Bq/g
- U-238 at 4 Bq/g

Ratios for more than one radionuclide

Regulation 2(4) of IRR(NI)17 requires that if more than one radionuclide is involved, the quantity or concentration ratio calculation outlined in Schedule 7, Part 3 must be used. If the ratio is greater than 1, then it must be treated as exceeding the levels stated for single radionuclides in Schedule 7, Parts 1 and 2. Since this material is naturally occurring, Schedule 7, Part 2 values should be used.

Schedule 7, Part 3 states that:

- 1. For the purpose of Regulation 2(4)—
 - (a) the quantity ratio for more than one radionuclide is the sum of the quotients of the quantity of a radionuclide present Q_p divided by the quantity of that radionuclide specified in the appropriate entry in Parts 1, 2 or 4 of this Schedule Q_{lim} , namely—

$$\sum \frac{Q_p}{Q_{lim}}$$

(b) the concentration ratio for more than one radionuclide is the sum of the quotients of the concentration of a radionuclide present C_p divided by the concentration of that radionuclide specified in the appropriate entry in Parts 1 or 2 of this Schedule C_{lim} , namely—

$$\sum \frac{c_p}{c_{lim}}$$

- The concentration ratio (1/1 + 4/1) = 5, which is more than 1.
- The quantity ratio is $(2 \times 10^5 + 8 \times 10^5) / 10^3 = 1 \times 10^3$ which is more than 1

Both ratios exceed 1. The concentration and quantity ratios are exceeded, therefore the foundry must register this work.

Registrations over multiple sites



- 49. When registering the relevant work to HSENI, the employer only needs to register this work once for all sites that are under their control where they carry out work with ionising radiation.
- 50. For example, if an employer has five different sites all working with X-ray devices (radiation generators), the employer should only register with HSENI once, for all the relevant sites. Registrations for each site are not required.
- 51. Only one registration is required per employer, no matter how many categories of work that require registration are being performed.

Changes to an existing registration

52. If your registration is only for one of the categories of registrable work, you can make amendments to the registration if you start work with another category of work requiring registration.

What to expect?

- 53. No fee will be charged by HSENI for registration within Northern Ireland.
- 54. Registration applications submitted to HSENI that can confirm a series of statements relating to work requiring registration (see paragraphs 108-110) will receive a certificate from HSENI.
- 55. The certificate will grant the applicant HSENI's permission for the work identified in the application. The certificate will also come with some conditions attached (see paragraphs 126 and 133-135).
- 56. You will be required to download the questionnaire document from the HSENI website, input your data and email the information you have provided to mail@hseni.gov.uk. The certificate will be emailed to you.



What is consent?

- 57. In IRR(NI)17, there are nine specific work practices involving ionising radiation that require consent from HSENI before the work can be carried out. If an employer is carrying out more than one work practice that requires consent from HSENI, the employer will need to apply for a separate consent for each relevant work practice.
- 58. HSENI issues consents under IRR(NI)17. These primarily relate to restricting occupational exposures incurred from the practice.
- 59. The nine specific work practices are listed in regulation 7(1) of IRR(NI)17 and are as follows:

Consent to carry out specified practices

- 7.—(1) In this regulation a "specified practice" means any of the following practices—
- (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;
- (f) industrial irradiation;
- (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 people or animals for medical or veterinary diagnosis, treatment or research

60. If radioactive substances are administered to persons for medical purposes, or to animals for veterinary purposes, the employer will need consent from HSENI for this practice. This consent will apply to all fixed sites operated by the employer where this practice is carried out.

Examples of the deliberate administration of radioactive substances to people or animals for medical or veterinary diagnosis, treatment or research



- i. You work in an NHS Trust administering radioactive substances to patients, through either the injection, ingestion or inhalation of radioactive substances
- ii. You work in an NHS Trust administering radioactive substances to patients in the form of a sealed source (brachytherapy) (NB. HASS used for brachytherapy is covered by the working with HASS practices)
- iii. You work in a veterinary practice administering radioactive substances to animals, through either the injection, ingestion or inhalation of radioactive substances

The exploitation and closure of uranium mines;

61. There are no active uranium mines in Northern Ireland. This will not appear as an option for applying for consents.

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

- 62. If the employer is manufacturing or producing products that have radioactive substances deliberately added to them, they will need consent from HSENI 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.
- 63. The deliberate addition of radioactive substances in the production or manufacture of any consumer product will require justification under the Justification of Practices Involving Ionising Radiation 2004 http://www.legislation.gov.uk/uksi/2004/1769/contents/made

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

- i. You work in an NHS Trust radiopharmacy
- ii. You work in the radiopharmaceutical industry
- iii. You work in a research facility that adds radioactive substances to make tracers

Operation of an accelerator (except when operated for the practices of industrial radiography or industrial irradiation and except an electron microscope)

64. Accelerator is defined in regulation 2 of IRR(NI)17 as:

"accelerator" means an apparatus or installation in which particles are accelerated and which emits ionising radiation with energy higher than 1 MeV;

65. If the employer is working with an apparatus or installation that meets this definition, they will need consent from HSENI for this practice, unless they are



working with an electron microscope (industrial radiography and/or industrial irradiation which uses an accelerator will require a consent under the specific categories below). This consent will apply to all fixed sites operated by the employer where this practice is carried out.

Examples of the operation of an accelerator

- i. You work in an NHS Trust using an accelerator to perform radiotherapy
- ii. You work with a particle accelerator for the purposes of research

Industrial radiography;

66. Industrial radiography is defined in regulation 2 of IRR(NI)17 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 which is carried out in a cabinet which a person cannot enter);

- 67. If the employer is performing work defined as industrial radiography using either radioactive sources (e.g. HASS), accelerators or radiation generators, they will need consent from HSENI for this practice. This consent will apply to industrial radiography in enclosures on all fixed sites operated by the employer where this practice is carried out; sites where the employer is performing site radiography in line with the conditions associated with this consent; and the transport of the radiation sources use for the purposes of industrial radiography between sites.
- 68. HSENI does not consider the use of X-rays for the inspection of mail, packages or baggage, or for security purposes as industrial radiography.

Examples of industrial radiography

- i. You use ionising radiation to inspect welds on a variety of structures at fixed locations you are responsible for
- ii. You inspect welds on a variety of structures at sites you are not responsible for (site radiography)

Industrial irradiation;

69. Industrial irradiation is defined in regulation 2 of IRR(NI)17 as:

"industrial irradiation" means the use of ionising radiation to sterilise, process or alter the structure of products or materials;

70. If the employer is performing work defined as industrial irradiation using either radioactive sources (e.g HASS), accelerators or radiation generators, they will need consent from HSENI for this practice. This consent will apply to all fixed sites operated by the employer where this practice is carried out.

Examples of industrial irradiation

- i. You work with a particle accelerator to perform ion implantation
- ii. You use ionising radiation to sterilise articles or food
- iii. You use neutrons to activate materials



Working with a high-activity sealed source (HASS) (except for industrial radiography or industrial irradiation purposes)

71. A high activity sealed source is defined in regulation 2 of IRR(NI)17 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:

72. If the employer is either performing work with sealed sources that are defined as high activity sealed sources, or if they are transporting HASS, they will need consent from HSENI for this practice, unless they are performing the specified practices of industrial radiography and/or industrial irradiation and have consent for these. This consent will apply to all fixed sites operated by the employer where this practice is carried out.

Examples of working with high activity sealed sources

- i. You work in an NHS Trust using HASS for brachytherapy or radiotherapy
- ii. You supply HASS to other operators
- iii. You work in a research facility and irradiate biological materials with HASS

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

73. HSENI considers 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 Northern Ireland. This will only appear as an option to the dutyholders responsible for these sites.

Examples of working on any facility for the long-term storage of radioactive waste or disposal of radioactive waste

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 facility
- ii. 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

74. If the employer discharging radioactive material with airborne or liquid effluent into the environment expects the quantities of radioactive material, in a single discharge, to exceed the quantities specified in column 5 of Part 1 of Schedule 7, the employer will need consent from HSENI. This consent will apply to all fixed sites operated by the employer where this practice is carried out.



Consents over multiple sites

- 75. For each consent that HSENI issues for a practice, the employer only needs to apply for the consent once for all sites that are under their control where they carry out work with ionising radiation.
- 76. For an example, if an NHS Trust is deliberately administering radioactive substances to a person for the purposes of medical diagnosis, treatment or research across multiple sites under its control, the employer (NHS Trust) should only apply for one consent, for all the relevant sites. Consents for each site are not required.

What to expect?

- 77. No fee will be charged by HSENT for a consent within Northern Ireland.
- 78. Consent applications submitted to HSENI that can confirm a series of statements and provide satisfactory answers to the questions relating to work requiring consent (see paragraphs 111-122) will receive a certificate from HSENI.
- 79. The certificate will grant the applicant HSENI's permission for the work identified in the application. The certificate will also come with some conditions attached (see paragraphs 127-142).
- 80. You will be required to download the questionnaire document from the HSENI website, input your data and email the information you have provided to mail@hseni.gov.uk. The certificate will be emailed to you.



How long do notifications/registrations/consents last for?

- 81. Unless a material change is notified to HSENI (see paragraphs 83-87), all notifications, registrations and consents that the employer has applied for will not need to be renewed.
- 82. If an employer stops working with ionising radiation and therefore no longer needs the relevant HSENI registration or consent or to notify HSENI, they should tell HSENI about this change.

What is a material change?

- 83.IRR(NI)17 requires that any material changes to a notification, registration or consent are notified to HSENI.
- 84. Broadly speaking, material changes are significant changes to the information you have provided during the application process, such as a change of address or if you begin to carry out work with portable radiation sources at sites other than your own.
- 85. Any registrations or 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 HSENI of this change.
- 86. You are expected to use your judgement as to what else amounts to a significant change to the information you have provided. You will be able to access your existing information and amend it where necessary.
- 87. A name change to your employer will require a notification of cessation of work for the old employer and a brand new application in the name of the new employer.

Examples of material change

- Change in employer address (see paragraphs 89-97)
- Change in expected doses for a practice requiring consent (see paragraphs 115-116)
- Change in answers to questions relating to radiation emergencies (see paragraphs 117-122)
- Additions/deletions to the categories of work undertaken in a registration (see paragraphs 39-48)
- Change in the use of portable radiation sources on sites other than the employers' (see paragraph 102).



Questions for ionising radiation applications

88. Before any notifications are confirmed, or registrations and consents are issued, the online system will ask the employer a series of questions about their work in Northern Ireland.

Details about the employer (all applicants)

89. Some questions will be asked of every applicant to ensure HSENI has a basic level of information on all employers working with ionising radiation, and that any registration and/or consent certificates are issued to the correct legal organisation. These questions will only be asked once per employer, regardless of the number of notifications, registrations or consents that are being applied for.

Which of the following best describes your employer?

- A limited company
- A public limited company (plc)
- Partnership
- Sole Trader
- Limited liability partnership
- Education (including schools, sixth form and further education colleges and universities)
- Charity
- Government body
- Statutory body
- Local authority
- Healthcare provider
- Veterinary practice
- Other
- 90. 'Your employer' means the organisation on whose behalf you're completing this application.

Does your employer have a company registration, school or charity number?

- Yes
- No
- 91. This will help HSENI identify your employer. If you have one but don't know it, it is fine to select 'no'.

What is your company registration, school or charity number?

92. This will need to be input by you, if it is available to you.



Help us find you What is your:

- Organisation name
- Address
- Postcode
- 93. This information will need to be input by you. This may not be the same address as where the work with ionising radiation takes place.
- 94. These details will be used on all documentation we issue
- 95. We can't match your employer to our database, you must provide us with your employer's name and address. Certificates cannot be issued automatically.
- 96. You will still be able to continue with your application while we take these additional steps, but you will not receive any certificates until we have taken these additional steps. We will get in touch once you've completed your application.
- 97. HSENI requests that you apply in good time before you start working with ionising radiation to avoid any delays.

How many employees (in Northern Ireland) does your employer have?

- 0-9
- 10–49
- 50-249
- 250+
- 98. This is the total number of people employed. You don't need to count contractors, suppliers, independent or outside workers (they will need to apply separately).

How many are classified radiation employees?

- 0
- 1–5
- 6–10
- 11–25
- 26+
- 99. Classified radiation employees are higher-risk radiation workers whose doses are required to be monitored. Your radiation risk assessment should identify any employees likely to be defined as a classified radiation worker.

Do you transport radioactive substances either as your main work or in connection with it? (This doesn't apply to X-ray devices.)

Yes



- No
- 100. If you physically move radioactive substances by road, or through another public place, or by rail, inland waterway, sea or air then it is likely you 'transport' radioactive substances.

101. Transport is defined in regulation 2 of IRR(NI)17 as

"transport" means, in relation to a radioactive substance, carriage of that substance on a road within the meaning of Article 2(2) of the Road Traffic (Northern Ireland) Order 1995(a) or through another public place (whether on a conveyance or not), or by rail, inland waterway, sea or air and, in the case of transport on a conveyance, a substance is deemed as being transported from the time that it is loaded onto the conveyance for the purpose of transporting it until it is unloaded from that conveyance, but a substance is not to be considered as being transported if—

- (a) it is transported by means of a pipeline or similar means; or
- (b) it forms an integral part of a conveyance and is used in connection with the operation of that conveyance;

Examples where you are transporting radioactive substances

- i. You offer various testing and analytical services, and have a mobile gauge containing radioactive sources which you use occasionally. You package the gauge, and prepare the associated paperwork then you move it by road to a remote site for use before returning back to your normal premises. You are transporting radioactive substances according to IRR(NI)17.
- ii. You are a courier company and you transport packages containing radioactive material from a radiopharmacy by road to various hospitals. You are transporting radioactive substances according to IRR(NI)17.

Examples where you are <u>not</u> transporting radioactive substances

- i. You prepare a package containing radioactive material and associated paperwork. You use a third party to physically move the material to its final destination at a location 20 miles away. You do not transport radioactive substances according to IRR(NI)17.
- ii. You are a biomedical research facility and take delivery of supplies of radioactive substances only. You are not involved in transport according to IRR(NI)17.

Does your employer carry out work with portable ionising radiation sources (this includes X-ray devices) at sites belonging to other employers?

- Yes
- No
- 102. "Radiation source" is a term that captures all sources of ionising radiation, whether they emit ionising radiation or release radioactive material.



This includes all of the following – radioactive source; radiation generator, accelerator.

How many fixed sites (in Northern Ireland) is your employer responsible for where they carry out work with ionising radiation?

- 1
- 2-5
- 6–10
- 11–25
- 26+
- 103. If more than one tier of work with ionising radiation (notifications; registration; consents) is being applied for, the answer to this question will be the total number of fixed sites where there is work with ionising radiation.
- 104. In general terms, HSENI would consider places with different postcodes to be different sites.



Details of radon assessments (radon notifications only)

105. If you have selected working in an atmosphere containing radon above an annual concentration of 300 Bq m⁻³ as a category of your work with ionising radiation, you will be asked a further question.

Please provide details of the most recent radon concentration assessment.

- 300-499 Bq m⁻³ annual average
- 500–699 Bq m⁻³ annual average
- 700–999 Bq m⁻³ annual average
- 1000+ Bq m⁻³ annual average
- 106. If multiple assessments have been taken for one site, or taken across multiple sites, you should notify the highest to HSENI.
- 107. You don't need to notify HSENI if your assessment is below 300 Bq m⁻³ annual average.



Registration questions

- 108. If the work with ionising radiation requires registration with HSENI, then you will be asked to confirm a series of statements during the application process that relate to the working practices being registered.
- 109. Applicants need to confirm that they understand their regulatory requirements under IRR(NI)17 before a registration will be granted. Applicants can further their understanding of these regulatory requirements by referring to the HSENI publication L121 Working with ionising radiation Ionising Radiations Regulations 2017 Approved Code of Practice and guidance http://www.HSENI.gov.uk/pubns/books/I121.htm.
- 110. Some of these statements may refer to regulatory requirements that do not apply to the work you are registering. For example your work may not require any supervised or controlled areas. These statements contain the phrase "where required", so, if they are not required, it is correct to confirm that you have performed the regulatory requirement.

You must be able to confirm, on behalf of the employer, the following:

A risk assessment has been completed which identifies the main radiological risks associated with the work with ionising radiation and identifies any reasonably foreseeable radiation accident (regulation 8 and associated Approved Code of Practice (ACOP) of IRR(NI)17).

Steps have been taken to measure or estimate employees' exposure to ionising radiation and appropriate action taken (regulation 8 and associated ACOP of IRR(NI)17).

Actions identified in your radiation risk assessment that will restrict employees' and other persons' exposure to ionising radiation so far as is reasonably practicable have been completed (regulation 9 of IRR(NI)17).

Contingency plans have been drawn up for all reasonably foreseeable radiation accidents identified in the radiation risk assessment and, where appropriate, rehearsals will be carried out at suitable intervals (regulation 13 of IRR(NI)17).

A suitable radiation protection adviser (RPA) has been appointed and consulted (regulation 14 of IRR(NI)17).

Appropriate training, information and instruction is provided to all employees engaged in or affected by work with ionising radiation and will be repeated at appropriate intervals (regulation 15 of IRR(NI)17).



Controlled and/or supervised areas have been correctly designated and demarcated (where required) (regulations 17 and 19 of IRR(NI)17).

Written local rules have been drawn up, where required, and radiation protection supervisor(s) are appointed for all your work in controlled areas and, where appropriate, supervised areas (regulation 18 of IRR(NI)17).



Consent questions

- 111. If the work with ionising radiation requires a consent from HSENI, then you will be asked to confirm a series of statements and answer some questions during the application process that specifically relate to the working practice requiring consent.
- 112. Those who undertake several working practices that require consent will need to answer these questions for each specific working practice.
- 113. Applicants need to confirm that they understand their regulatory requirements under IRR(NI)17 before a consent will be granted. Applicants can further their understanding of these regulatory requirements by referring to the HSENI publication L121 Working with ionising radiation Ionising Radiations Regulations 2017 Approved Code of Practice and guidance http://www.HSENI.gov.uk/pubns/books/I121.htm.
- 114. Some of these statements may refer to regulatory requirements that do not apply to the work you are applying for consent for. For example your work may not involve radioactive waste. These statements contain the phrase "where appropriate", so, if they are not appropriate to your work, it is correct to confirm that you have performed the regulatory requirement.

You must be able to confirm, on behalf of the employer, the following:

An appropriate programme of monitoring or auditing of arrangements will be in place to check compliance with IRR(NI)17 (regulation 8 and associated Approved Code of Practice (ACOP) of IRR(NI)17).

A person(s) with appropriate authority has been identified and named as having responsibility for radiological protection for this (regulation 8 and associated ACOP of IRR(NI)17)?

A radiation risk assessment has been completed (under regulation 8 of IRR(NI)17) that has identified, where relevant:

- ways in which reasonably foreseeable radiation accidents could occur and the likelihood and potential severity of them;
- engineering control measures and design features in place, or planned;
- planned systems of work;
- estimated radiation dose rates to which anyone can be exposed and the action needed to keep doses as low as reasonably practicable.



Where appropriate, the management of any radiation source no longer used will ensure that exposures to employees will be restricted so far as is reasonably practicable (regulations 8 and 9 of IRR(NI)17).

Where appropriate, the management of any radioactive waste will ensure that exposures to employees will be restricted so far as is reasonably practicable (regulations 8 and 9 of IRR(NI)17).

The engineering controls, design features and safety features of the facility and/or radiation sources will restrict exposures to ionising radiation so far as is reasonably practicable (regulation 9 of IRR(NI)17).

The engineering controls, design features and safety features of the facility and/or radiation sources will be properly maintained and, where appropriate, thorough examinations and tests of these will be carried out at suitable intervals (regulation 11 of IRR(NI)17).

Contingency plans for all reasonably foreseeable radiation accidents identified in the radiation risk assessment have been drawn up and, where appropriate, rehearsals will be at suitable intervals (regulation 13 of IRR(NI)17).

A suitable Radiation Protection Adviser (RPA) has been appointed and consulted (regulation 14 of IRR(NI)17).

Employees engaged in this: (under regulation 15 of IRR(NI)17):

- have received appropriate training in radiological protection.
- have been informed and instructed regarding the radiological risks to their health from the practice and the precautions that should be taken.
- will receive updates/refresher training in radiological protection at appropriate intervals.

Employees not engaged in this, but who are likely to be affected by it, have received appropriate training, information and instruction in radiological protection and this will be repeated at appropriate intervals (regulation 15 of IRR(NI)17).

Where appropriate, suitable and sufficient quality assurance programmes will be in place for equipment used for medical exposure (regulation 33 of IRR(NI)17).

Expected dose questions

What is the maximum anticipated total annual effective (whole body) dose (in mSv) to an employee engaged in the practice?

0–1 mSv



- 1.1-5.9 mSv
- 6–9.9 mSv
- 10–14.9 mSv
- 15–20 mSv

What is the maximum expected total annual dose equivalent (in mSv) to an employee engaged in the practice for the lens of the eye?

- 0–1 mSv
- 1.1–5.9 mSv
- 6–9.9 mSv
- 10-14.9 mSv
- 15–20 mSv

What is the maximum expected total annual dose equivalent (in mSv) to an employee engaged in the practice for the extremities (a person's hands, forearms, feet and ankles)?

- 0-49.9 mSv
- 50-149.9 mSv
- 150–249.9 mSv
- 250–349.9 mSv
- 350-500 mSv

What is the maximum expected total annual dose equivalent (in mSv) to an employee engaged in the practice for the skin?

- 0-49.9 mSv
- 50-149.9 mSv
- 150-249.9 mSv
- 250–349.9 mSv
- 350–500 mSv

What is the maximum expected total annual effective (whole body) dose (in mSv) to an employee not directly engaged in the practice?

- 0-0.3 mSv
- 0.31–0.49 mSv
- 0.5–1 mSv

What is the maximum expected total annual effective (whole body) dose (in mSv) to a member of the public?

- 0-0.3 mSv
- 0.31-0.49 mSv
- 0.5–1 mSv
- 115. Employers may already be working with ionising radiation and monitoring the actual doses received. If it is appropriate to use the results of this monitoring to answer these questions, employers can do so.



116. If estimates or actual measurements provide a detailed result that fits between the ranges provided, e.g. 1.05 mSv whole body dose, then the result should be rounded up or down, as appropriate.

Radiation emergencies

In relation to potential radiation emergencies, have you considered if the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR) apply?

- Yes
- No
- 117. Within REPPIR, a 'radiation emergency' is an event that is likely to result in a member of the public receiving an effective dose of 5 mSv during the year immediately following the emergency.
- 118. REPPIR applies to work with radioactive substances above certain thresholds. It does not apply to work with radiation generators such as accelerators, or to special form sources that have a current special form certificate or to radioactive sources that can be demonstrated to be non-dispersible or to radioactive substances where the activity concentration is less than 100 Bq/g (except for the transport of such substances).
- 119. To decide if REPPIR applies, operators or transporters (but not those using standard forms of transport such as road, rail, inland waterway, sea, air, or through a pipeline) will need to identify the quantities of radionuclides or fissile material present or transported and compare them with threshold quantities in REPPIR. If the threshold amounts are exceeded, there may be the potential for a radiation emergency, so regulations 4–6 of REPPIR will apply.
- 120. Further information can be found on HSENI's website http://www.hseni.gov.uk/articles/ionising-radiation or also HSE's website http://www.hse.gov.uk/radiation/ionising/reppir.htm

Does REPPIR apply to you? Is a hazard identification and risk evaluation (HIRE) required (regulation 4 of REPPIR)?

- Yes
- No
- 121. In a lot of circumstances (eg those who only use radiation generators, such as an accelerator, or to those who use special form sources) it will be appropriate to answer NO to this question. If the answer to this question is NO, you do not need to answer further radiation emergencies questions.



If required, have you completed a HIRE and sent the report to HSENI (regulation 6 of REPPIR)?

- Yes
- No

Are emergency plans required as a result of the HIRE indicating that a radiation emergency is reasonably foreseeable (regulations 7–9 of REPPIR)?

- Yes
- No
- 122. If a radiation emergency is not reasonably foreseeable, it will be appropriate to answer NO to this question. If the answer to this question is NO, you do not need to answer further radiation emergencies questions.

If required, are appropriate emergency plans in place (regulations 7-9 of REPPIR)?

- Yes
- No



What to expect in a registration or consent certificate

- 123. Every registration and every consent certificate will be issued by HSENI on the basis of the answers to the relevant registration/consent questions that the employer provides.
- 124. Every registration and every consent certificate will have conditions associated with them. Unless there are exceptional circumstances (see paragraphs 160-161), these conditions will be standardised.
- 125. There are three different types of certificate that HSENI will issue:
 - registration;
 - consent;
 - consent for industrial radiography.

Registration certificates

- 126. A registration certificate will contain the following:
 - employer's name (see paragraphs 89-97);
 - employer's address (see paragraphs 89-97);
 - details of all relevant categories of work registered with HSENI (see paragraphs 39-48);
 - conditions associated with the registration:
 - notification to HSENI of material changes to, or cessation of, the registered work;
 - o compliance with IRR(NI)17 can be demonstrated;
 - certificate does not apply to work carried out on nuclear premises;
 - Confirmation of statements relating to the registration application

Consent certificates

- 127. A consent certificate will contain the following:
- 128. employer's name (see paragraphs 89-97);
- 129. employer's address (see paragraphs 89-97);
 - the specific practice being consented by HSENI (see paragraphs 57-74);
 - conditions associated with the consent:
 - notification to HSENI of material changes to, or cessation of, the consented work;
 - o compliance with IRR(NI)17 can be demonstrated;
 - certificate does not apply to work carried out on nuclear premises;



 Confirmation of statements relating to the consent application and details of the employer's answers to the consent questions for this practice.

Consent for industrial radiography certificates

- 130. A consent certificate will contain the following:
- 131. employer's name (see paragraphs 89-97);
- 132. employer's address (see paragraphs 89-97);
 - the specific practice of industrial radiography is being consented by HSENI (see paragraphs 66-68);
 - conditions associated with the consent:
 - o notification to HSENI of material changes to, or cessation of, the consented work:
 - o compliance with IRR(NI)17 can be demonstrated;
 - o certificate does not apply to work carried out on nuclear premises;
 - No site radiography will take place without the consent holder receiving at least seven days' written notice from the client commissioning the site radiography work on each and every occasion the work is carried out, or written HSENI agreement to waive this requirement;
 - o if directed by HSENI, written confirmation provided to HSENI before site radiography begins and any further information regarding the site radiography work as specified
 - Confirmation of statements relating to the consent application and details of the employer's answers to the consent questions for this practice.

Registration and consent conditions

Notification to HSENI of material changes to, or cessation of, the registered or consented work

133. HSENI expects the certificate holder to notify HSENI of a material change or if the work is stopped. If a material change has not been notified to HSENI, the certificate that the employer holds may not be valid.

Compliance with IRR(NI)17 can be demonstrated

134. HSENI expects employers to be able to demonstrate how they comply with IRR(NI)17. If non-compliance with IRR(NI)17 is found, we will consider enforcement action proportionate to the health and safety risks and the seriousness of the breach. In certain circumstances, we will consider the revocation of the registration and/or consent (see paragraph 143).



Certificate does not apply to work carried out on nuclear premises

- 135. All certificates issued by HSENI do not apply to any work performed on nuclear premises. These are defined in IRR(NI)17 as:
- (a) a GB nuclear site (within the meaning given by section 68 of the Energy Act 2013);
- (b) an authorised defence site;
- (c) a new nuclear build site; or
- (d) a nuclear warship site;
- 136. Any employer who wishes to carry out work with ionising radiation that requires registration or a consent on nuclear premises will need to obtain the relevant registration and/or consents from the Office for Nuclear Regulation (ONR): http://www.onr.org.uk/.

No site radiography will take place without the consent holder receiving at least seven days' written notice from the client commissioning the site radiography work on each and every occasion the work is carried out, or written HSENI agreement to waive this requirement (consents for industrial radiography only)

- 137. Site radiography must not be performed without seven days' written notice from the client to the radiography employer on each and every occasion the work is carried out, unless a waiver is granted by HSENI. Where work continues at one site with no significant change, one notification, covering a period not exceeding one calendar month, from the client to the radiography employer for a series of radiography operations is acceptable. There is no requirement under this condition to send the written notice to HSENI.
- 138. HSENI may consider the waiving of this seven day notification requirement in the following circumstances:
 - a) genuinely unforeseen work and emergency work which it is not reasonably practicable to delay;
 - b) where site radiography work is "embedded" on a site under a longterm contract, HSENI may agree to one notification from the client to the radiography employer for periods longer than a month.
- 139. If you are considering requesting a waiver from HSENI, further guidance and information is available from HSENI's website http://www.hseni.gov.uk/articles/ionising-radiation. Only HSENI can grant waivers for site radiography work being carried out in Northern Ireland. General information can also be obtained from HSE's industrial radiography webpage http://www.HSENI.gov.uk/radiation/ionising/indradiography.htm.
- 140. Failure to demonstrate that seven days' written notice has been provided, or suitably waived by HSENI, for any site radiography work will be considered as a lack of compliance with the conditions of the consent. Enforcement action proportionate to the health and safety risks and the



seriousness of the breach will be considered. In certain circumstances, HSENI will consider revoking the consent (see paragraph 143).

If directed by HSENI, written confirmation is provided to HSENI before site radiography begins and any further information regarding the site radiography work as specified (consents for industrial radiography only)

- 141. HSENI may choose to direct the employer to notify HSENI before any site radiography is performed and request further information regarding the site radiography.
- 142. If HSENI directs employers to do so, HSENI will provide a justification for this requirement.

Revocations and Appeals

Revocation

- 143. HSENI has the power, under IRR(NI)17, to revoke registrations (regulation 6(5)) or consents (regulation 7(4)) where it considers it appropriate to do so. HSENI will consider revocation if, for example:
 - a) it can be demonstrated that the registration or consent was obtained through a false declaration;
 - b) where a pattern of poor performance has emerged, demonstrating evidence of poor radiological protection. This may have resulted in enforcement action (eg conviction(s) for Ionising Radiations Regulations offences, enforcement notices for ionising radiation-related deficiencies, notifications of contraventions etc);
 - c) 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;
 - d) if the employer been found guilty of health and safety offences.
- 144. When revocation is identified as appropriate, HSENI will proceed as speedily as possible with revocation action, even if there are outstanding criminal, or notice appeal, proceedings against the registration/consent holder concerned. The revoking of a licence is a very serious step, which could affect the livelihood of the licence holder and his employees. HSENI will consider each case on its merits in line with our Enforcement Policy.
- 145. Where HSENI is the consenting and enforcing authority for the working practice covered by the registration or consent, the process outlined below will be followed. Where HSENI is the consenting authority but not the enforcing authority, HSENI will implement the recommendations from the relevant enforcing authority with regards to any revocation decisions.



- 146. Where HSENI is considering whether to revoke, we will prepare a revocation file:
 - a) this will provide detail of all interventions, including all correspondence;
 - b) each intervention must be clearly identified in the file so it can be referenced in a matrix of 'revocation evidence';
 - c) HSENI will produce a summary of why it is considered appropriate to revoke the registration/consent;
 - d) where appropriate, HSENI will liaise with other regulators and consider any relevant information and evidence they provide;
 - e) all relevant evidence will be used.
- 147. The revocation file will form the basis of the discussion at the formal revocation meeting.
- 148. Depending on the individual circumstances of each case, HSENI has the option of:
 - a) recommending a complete revocation; or
 - b) recommending a revocation followed up immediately by a new registration or consent with added further conditions at the discretion of HSENI, which may include a limit of time.
- 149. HSENI will write to the registration and/or consent holder and explain the reason(s) for the proposed action. A copy of the revocation file will be provided. The registration and/or consent holder will be asked for a written response which will be considered by HSENI. This reply must be received by HSENI no later than the date specified in the letter and will be added to the revocation file. If the registration and/or consent holder does not respond, then the revocation process will continue, but without the benefit of HSENI being able to consider any comments/information the registration and/or consent holder might have provided.
- 150. HSENI's Radiation Team (RT) will consider any response carefully. If HSENI considers it is appropriate to continue with the revocation process, HSENI will write and inform the registration and/or consent holder, and assign an appropriate HSENI inspector.
- 151. This letter will also state that they will be contacted by an appropriate member of HSENI to arrange a formal meeting. The formal meeting is not about investigating the alleged breaches of ionising radiations-related legislation; to assess the registration and/or consent holder's ability to work with ionising radiation safely in the future, it is necessary to address the evidence, as detailed in the revocation file, which gave rise to the revocation proceedings. The object of the formal meeting is to give the registration and/or consent holder the opportunity to demonstrate that they have robust and reliable management arrangements and procedures in place to maintain sustained compliance with current ionising radiations legislation.



HSENI action

- 152. HSENI will contact the registration and/or consent holder to arrange the formal meeting. This will be at a mutually convenient time. The registration and/or consent holder will be given time to prepare their case, but as they will already be aware of the proposal to revoke the registration and/or consent, the meeting will be arranged promptly. This will normally be within two weeks of HSENI contacting the registration and/or consent holder to arrange the formal meeting.
- 153. In cases where the registration and/or consent holder refuses to attend the meeting, HSENI should write again to the registration and/or consent holder, inviting them to make written representations within 14 days of receipt of the letter. The letter should explain that if the registration and/or consent holder does not respond, then the revocation process will continue, but without the benefit of HSENI being able to consider any information the registration and/or consent holder might have provided.
- 154. The formal meeting is between HSENI and the registration and/or consent holder to discuss the revocation. The registration and/or consent holder may bring their legal representative or another relevant third party, such as a radiation protection adviser to the meeting. As the meeting is between HSENI and the registration and/or consent holder, any contribution made by a third party may not be taken into account.

Record of meeting

155. A record of the meeting must be made and supplied to the registration and/or consent holder, including any documents provided by the registration and/or consent holder and their responses at the meeting.

Recommendation and decision

- 156. All documents prepared by HSENI or provided by the registration and/or consent holder must be added to the revocation file. The appropriate HSENI inspector will make a recommendation based on the evidence contained in the revocation file.
- 157. The Head of RT will consider the recommendation, discuss as is appropriate with HSENI colleagues concerned and reach a decision.
- 158. The final decision is made by the Head of RT. This will be done by considering all the evidence justifying revocation including any written representation made by the registration and/or consent holder. The decision will be made in writing with a signed and dated explanation.
- 159. The Head of RT will write to the registration and/or consent holder and inform them of the decision. This will specify the date of the revocation, and, if appropriate, what further conditions will be added to a new registration or consent certificate. If the decision is for a complete revocation, it will be illegal



to carry out the work identified in the revocation decision after that date. Where appropriate, HSENI will inform other ionising radiation regulators of the decision.

Regaining revoked registrations and/or consents

- 160. If a consent or registration has been revoked, HSENI 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. HSENI will liaise closely with the employer before agreeing that a registration or consent can be re-applied for.
- 161. In circumstances such as these, HSENI may decide that registration or consent with further conditions is appropriate.

Appeals Procedure

- 162. The decision made by the head of RT on behalf of HSENI will remain in place until the outcome of any appeals process. If after considering the reasons provided to explain the decision, the registration/consent holder wishes to challenge the decision, there are three options available:
 - have an informal (verbal) discussion with the head of RT to discuss the decision and the explanation of the reasons for it
 - a request to HSENI to review the decision made. This will be by way of a review board (RB) with members who were not involved with the decision made.
 - a formal appeal against the decision made under regulation 6(7) or regulation 7(6) (as appropriate) of IRR(NI)2017.

Review Board review

- 163. The RB may consist of the following members:
 - a member of the HSENI Deputy Chief Executive with overall responsibility for RT:
 - a radiation specialist inspector not involved with the decision being reviewed; and
 - a principal inspector who is not involved with ionising radiation work.
- 164. The members of the RB are chosen to ensure that they have not been involved in the decision made.
- 165. Any request for an RB review should be made to HSENI setting out the reasons for requesting the review. The SCS member of the RB will inform the applicant of the date of the RB and the date for any further submissions to be considered.
- 166. The applicant will be informed of the RB's decision immediately following the meeting.



- 167. Any person who is aggrieved by a decision of HSENI has the right to make representations to Department for the Economy (DfE) against this decision (per Article 41 of the Health and Safety at Work (Northern Ireland) Order 1978). The aggrieved person must be given a written notice explaining how, where, within what period and on what grounds, an appeal may be brought, and whether the enforcement action would be stayed while the appeal were pending.
- 168. The aggrieved person must send a notice of appeal to the Registrar so that it is received not later than the end of the period of twenty eight days beginning with the date on which the Review Board have made their decision.
- 169. DfE will then initiate the formal appeals mechanism as per the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997.



HSENI would like to acknowledge the assistance of the Health and Safety Executive (HSE) in Great Britain.