Authorisation under the Ionising Radiations Regulations 1999

Ionising Radiation Protection Series No 5

Introduction

This information sheet is aimed at all employers working with ionising radiation. It explains how a radiation employer can comply with the requirements in regulation 5 of the Ionising Radiations Regulations 1999 (IRR99)[1] for authorisation of certain practices. It also describes the system of generic authorisation under which radiation employers may be exempt from the requirement. Regulation 5 comes into effect on 13 May 2000.

What is prior authorisation?

Prior authorisation is written permission given by the competent authority, the Health and Safety Executive (HSE), to carry out a practice with electrical equipment capable of generating ionising radiations above 5 kV. The requirement for prior authorisation of the specified practices arises from a provision of the Basic Safety Standards Directive 96/29/Euratom.

Prior authorisation under IRR99 is not required where HSE has granted a generic authorisation for the type of practice and the conditions in the generic authorisation are met.

Practices that need authorisation

The only practices that are subject to the requirements for authorisation under IRR99 are as follows.

- **The use of electrical equipment intended to produce X-rays ('X-ray sets') for industrial radiography** - HSE interprets industrial radiography as involving non-destructive testing of welds or structural integrity.

- **The use of X-ray sets for processing of products** - this is regarded as inducing some physical, chemical or biological change in the material being processed.

- **The use of X-ray sets for research** - this includes industrial, academic, medical and veterinary uses, for example the use of an X-ray set to deliver high doses to laboratory animals in radiobiology research. Research covers creative work undertaken on a systematic basis in order to increase the stock of knowledge. It includes basic research, undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, and applied research (ie original investigation directed primarily towards a specific practical aim or objective). It is not seen as including the use of X-rays sets for analytical, diagnostic or investigation purposes where this is incidental to research. In the context of IRR99, research would not include exposures where there is a diagnostic or therapeutic benefit to the patient. Nor would it include medico-legal exposures or exposure as part of a well thought-out screening program. Proposals for research exposures would normally be vetted by a local ethical committee before proceeding.

- **The use of X-ray sets ('kilovoltage therapy equipment') for the exposure of persons for medical treatment** - 'medical' refers to the exposure of persons, therefore excludes veterinary exposures, and 'treatment' means therapeutic purposes.

- **The use of accelerators (other than electron microscopes)** - an accelerator is defined as an apparatus or installation in which particles are accelerated and which emits ionising radiation with an energy higher than 1 MeV. It includes all aspects of the use of such accelerators, eg beamlines or remote target stations. Uses include non-destructive testing, industrial, academic, medical and veterinary research and development, medical and veterinary diagnosis and treatment, and radioisotope manufacture.

Summarising the more detailed guidance above, the following practices which involve the use of accelerators or X-ray sets do not need authorisation under IRR99. This list is indicative rather than exhaustive.

- Use of electron microscopes

- Diagnostic use of X-ray sets in medical and dental practice

- Use of X-ray sets for routine analytical, diagnostic or investigation purposes

- Use of X-ray sets in baggage, postal or food screening

- Use of X-ray gauging and detection systems in measurement processes

- Diagnostic or therapeutic use of X-ray sets for veterinary purposes

How will the generic authorisation system work?

HSE has developed two certificates of generic authorisation that together cover all the practices that need authorisation under IRR99. Each certificate contains conditions which are basic requirements for that use of ionising radiation; compliance with the conditions will not be sufficient to achieve full compliance with IRR99.

Radiation employers who plan to carry out practices subject to authorisation under regulation 5 of IRR99 should consider the conditions specified in the relevant generic authorisation, if appropriate seeking advice from their radiation protection adviser (RPA). Those who can meet the conditions are exempt from prior authorisation and need take no further action in this respect. They may, however, wish to document their assessment of this compliance for reference, or for when an HSE inspector visits.

Most radiation employers will be able to comply with the conditions attached to the relevant certificate of generic authorisation. Radiation employers who cannot comply will need to apply to HSE for an individual authorisation.

How can I get a copy of the generic authorisations?

Excerpts from both generic authorisations are included in this document. The certificates themselves can be found at HSE's website (www.hse.gov.uk) or may be obtained through HSE's InfoLine (08701 545500). Radiation employers may also contact their local HSE office (these are listed under Health and Safety Executive in telephone directories).

What if I need an individual prior authorisation?

A radiation employer who believes that an individual prior authorisation is necessary may wish to discuss the matter with the local HSE inspector who will, if appropriate, provide guidance on how to apply. All applications for individual authorisations should be made to the local HSE office.

Radiation employers who have to obtain individual authorisation under IRR99 will need to tell HSE if the work they do changes to such an extent that the particulars relating to the authorisation become wrong or out of date.

Does authorisation replace notification?

No. Radiation employers must also notify HSE of their intention to work with ionising radiation 28 days in advance of actually starting that work, in accordance with regulation 6 of IRR99. Guidance on notification is given in paragraphs 18 to 26 of the regulatory guidance in the Approved Code of Practice.[2]

Other types of authorisation

Some radiation employers, for example those who use both X-ray sets and radioactive sources/substances for industrial radiography, such as use of an X-ray pipeline crawler that has a radioisotope control source, will also need to comply with requirements for registration and/or authorisation under the Radioactive Substances Act 1993 (RSA93) for the keeping and disposal of radioactive substances. The guidance in this document relates only to authorisation under IRR99. Advice on registration and authorisation under RSA93 should be sought from the Environment Agency, in England and Wales, or the Scottish Environment Protection Agency (in Scotland).

Prior authorisation for the use of accelerators (other than electron microscopes)

This is an excerpt from the generic authorisation. For details of how to obtain the certificate please see 'How can I get a copy of the generic authorisations?' earlier in this information sheet.

The Health and Safety Executive authorises the use of accelerators (other than electron microscopes) as specified in regulation 5(2) of the Ionising Radiations Regulations (IRR99) subject to the conditions shown below.

NB: The scope covers all uses of accelerators (other than electron microscopes), including medical and veterinary purposes (an accelerator is an apparatus or installation in which particles are accelerated and which emits ionising radiation with an energy higher than 1 MeV).

The conditions for the use of accelerators are that the radiation employer shall:

1 as part of satisfying the general requirement in regulation 8 of IRR99 to keep exposure as low as reasonably practicable, take specific steps before starting the work to provide engineering controls, design features, safety devices and warning devices which include at least the following:

(a) where the work is to be carried out in a room, purpose made structure, other enclosure or a cabinet:

(i) adequate shielding as far as reasonably practicable; and

(ii) interlocks or trapped key systems or other appropriate safety devices in order to prevent access to high dose rate areas (eg in which employed persons could receive an effective dose greater than 20 mSv or an equivalent dose in excess of a dose limit within several minutes when radiation emission is underway). The control system for such safety devices should comply with paragraph 4;

(b) in other cases, adequate local shielding as far as reasonably practicable and, in the case of site radiography, a suitable system for ensuring that:

(i) persons other than those directly involved in the exposure are excluded from the area by means of a barrier or other suitable means;

(ii) where employees of another employer may be present in the same workplace, there is co-operation and co-ordination with the other employer(s) for the purposes of restricting access to the controlled area;

(iii) warning notices are displayed at the perimeter of the controlled area; and

(iv) radiation levels are monitored to establish that controlled areas have been properly designated;

(c) suitable means to minimise exposure so far as is reasonably practicable from substances that have been activated by the accelerator;

(d) a suitable assessment of the hazards arising from the production of adventitious radiation;

(e) where there is a risk of significant exposure arising from unauthorised or malicious operation, equipment which has been fitted with locking-off arrangements to prevent its uncontrolled use;

(f) initiation of exposures under key control, or some equally effective means, so as to prevent unintended or accidental emission of a radiation beam; and

(g) suitable warning devices which indicate when the accelerator is preparing to produce radiation and give a signal when the radiation is about to be produced and a distinguishable signal when the emission is underway, unless this is impracticable;

2 arrange for adequate and suitable personal protective equipment to be provided where appropriate;

3 arrange for suitable maintenance and testing schedules for the control measures selected; and

4 provide safety devices, as referred to in 1(a), which should be configured so that the control system will ensure that an exposure:

(a) cannot commence while any relevant access door, access hatch, cover or appropriate barrier is open, or safety device is triggered;

(b) is interrupted if the access door, access hatch, cover or barrier is opened; and

(c) does not re-commence on the mere act of closing a door, access hatch, cover or barrier.

Notes:

(a) The use of accelerators, subject to the conditions in paragraphs 1 to 4, does not need individual prior authorisation as required by regulation 5(1) of IRR99.

(b) This authorisation is without prejudice to the requirements or prohibitions imposed by any other enactment, in particular, the Health and Safety at Work etc Act 1974 and IRR99 and to the provisions of the Approved Code of Practice IRR99.

(c) Electron microscopes are not covered by the authorisation as they do not need to be authorised under IRR99.

Prior authorisation for the use of electrical equipment intended to produce X-rays

This is an excerpt from the generic authorisation. For details of how to obtain the certificate please see ‘How can I get a copy of the generic authorisations?’ earlier in this information sheet.

The Health and Safety Executive authorises the use of electrical equipment intended to produce X-rays (‘X-ray sets’) for: industrial radiography; processing of products; research; or exposure of persons for medical treatment as specified in regulation 5(2) of the Ionising Radiations Regulations 1999 (IRR99), subject to the conditions shown below.

The conditions for the use of ‘X-ray sets’ for: industrial radiography; processing of products; research; or exposure of persons for medical treatment are that the radiation employer shall:

1 as part of satisfying the general requirement in regulation 8 of IRR99 to keep exposure as low as reasonably practicable, take specific steps before starting the work to provide engineering controls, design features, safety devices and warning devices which include at least the following:

(a) where the work is to be carried out in a room, purpose made structure, other enclosure or a cabinet,

(i) adequate shielding as far as reasonably practicable; and

(ii) except in the use of X-ray sets for radiotherapy at or below 50kV, interlocks or trapped key systems or other appropriate safety devices in order to prevent access to high dose rate areas (eg in which employed

persons could receive an effective dose greater than 20 mSv or an equivalent dose in excess of a dose limit within several minutes when radiation emission is underway). The control system for such safety devices should comply with paragraphs 4 or 5;

(b) in other cases, adequate local shielding as far as reasonably practicable and, in the case of site radiography, a suitable system for ensuring that:

(i) persons other than those directly involved in the exposure are excluded from the area by means of a barrier or other suitable means;

(ii) where employees of another employer may be present in the same workplace, there is co-operation and co-ordination with the other employer(s) for the purposes of restricting access to the controlled area;

(iii) warning notices are displayed at the perimeter of the controlled area; and

(iv) radiation levels are monitored to establish that controlled areas have been properly designated;

(c) where there is a risk of significant exposure arising from unauthorised or malicious operation, equipment which has been fitted with locking-off arrangements to prevent its uncontrolled use;

(d) initiation of exposures under key control, or some equally effective means, so as to prevent unintended or accidental emission of a radiation beam; and

(e) suitable warning devices which indicate when the tube is in a state of readiness to emit radiation and, except for diagnostic radiology equipment, give a signal when the useful beam is about to be emitted and a distinguishable signal when the emission is underway, unless this is impracticable;

2 arrange for adequate and suitable personal protective equipment to be provided where appropriate;

3 arrange for suitable maintenance and testing schedules for the control measures selected; and

4 provide safety devices, as referred to in 1(a), which for routine operations should be configured so that the control system will ensure that an exposure:

(a) cannot commence while any relevant access door, access hatch, cover or appropriate barrier is open, or safety device is triggered;

(b) is interrupted if the access door, access hatch, cover or barrier is opened; and

(c) does not re-commence on the mere act of closing a door, access hatch, cover or barrier; or

5 for non-routine operations such as setting up or aligning equipment, where the safeguards for routine operation are not in use, provide a procedure for an alternative method of working that affords equivalent protection from the risk of exposure which should be documented and incorporated into the local rules.

Notes:

(a) The use of 'X-ray sets' for: industrial radiography; processing of products; research; or exposure of persons for medical treatment, subject to the conditions shown, does not need individual prior authorisation as required by regulation 5(1) of IRR99.

(b) This authorisation is without prejudice to the requirements or prohibitions imposed by any other enactment, in particular, the Health and Safety at Work etc Act 1974 and IRR99, and to the provisions of the Approved Code of Practice on IRR99.

References

1 *Ionising Radiations Regulations 1999* SI 1999/3232 Stationery Office 2000

2 *Work with ionising radiation. Ionising Radiations Regulations 1999. Approved Code of Practice and guidance* L121 HSE Books 2000 ISBN 0 7176 1746 7

Further information

HSE priced and free publications are available by mail order from HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA. Tel: 01787 881165 Fax: 01787 313995 Website: www.hsebooks.co.uk

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For other enquiries ring HSE's InfoLine Tel: 08701 545500 or write to HSE's Information Centre, Broad Lane, Sheffield S3 7HQ. Website: www.hse.gov.uk

This leaflet contains notes on good practice which are not compulsory but which you may find helpful in considering what you need to do.

Printed and published by the Health and Safety Executive 04/00 IRIS5 C80