

WELSH HEALTH CIRCULAR



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Welsh Government

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Title: Ionising Radiation – Requirements for NHS organisations in Wales from February 2018

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For Action by:

Chief Executives; Medical Directors; and
Directors of Therapies and Health Sciences
of Health Boards and NHS Trusts

For information:

Chairs, Nurse Directors and Board
Secretaries of Health Boards and NHS Trusts
DG/Chief Executive NHS Wales
Deputy Chief Executive NHS Wales
Operations Team – Health and Social
Services Group, Welsh Government
Communications Team – Health and Social
Services Group, Welsh Government
Chief Medical Officer
Deputy Chief Medical Officer
Chief Executive, Healthcare Inspectorate
Wales
Health and Safety Executive Wales
Chief Dental Officer

Action required by: With immediate effect

Sender: Dr Rob Orford, Chief Scientific Adviser, Health and Social Services Group, Welsh Government

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Enclosure(s):

None

Dear Colleagues,

IONISING RADIATION – REQUIREMENTS FOR NHS ORGANISATIONS IN WALES FROM FEBRUARY 2018

1. From early February, NHS organisations in Wales must ensure compliance with the requirements of new Regulations relating to Ionising Radiation.

Background

2. These Regulations, in part, implement the provisions of Council Directive 2013/59/Euratom dated 5 December 2013 (known as the Basic Safety Standards Directive, or BSSD). The BSSD lays down the basic safety standards for protection against the dangers from exposure to ionising radiation. In particular, the Regulations address the radiation protection of employees, members of the public, persons undergoing medical exposure and non-medical imaging exposure using medical radiological equipment. The BSSD will be transposed into UK law in early February.
3. This Welsh Health Circular reminds NHS organisations in Wales of their obligations and highlights the main requirements of the two new sets of Regulations, namely:
 - The Ionising Radiation Regulations 2017 (IRR2017)¹ and
 - The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R2017)²
4. The Welsh Health Circular should be read in conjunction with the Regulations and supporting guidance documents³.

The Ionising Radiation Regulations 2017 (IRR2017)

5. IRR2017 applies to all employers working with ionising radiation including those who work with:
 - radioactive substances: artificial radionuclides and 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;
 - particle accelerators; and
 - work in an atmosphere containing radon above an annual average

¹ <http://www.legislation.gov.uk/uksi/2017/1075/contents/made>

² <http://www.legislation.gov.uk/uksi/2017/1322/contents/made>.

³ <https://services.hse.gov.uk/bssd/>

concentration of 300Bq m⁻³.

6. Under IRR2017, employers must register with or gain consent from the Health and Safety Executive (HSE) for certain work they do with ionising radiation. This is known as the 'graded approach'. Depending on the level of risk (size and likelihood of exposure) of the ionising radiation work you do you may need to:
 - Notify;
 - Register;
 - Obtain a consent;
 - or a number of the above.
7. The application must be made by the employer or by an employee authorised by the employer. It cannot be submitted by a third party but they can advise you on your application. You must apply before you start new work and by **5 February 2018** if you have previously notified HSE of the work. Notification made under the IRR99 are not valid under the IRR17.

The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R2017)

8. IR(ME)R2017 comes into force on 6 February 2018, revoking and replacing the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R2000), the Medicines (Administration of Radioactive Substances) Regulations 1978 and the Medicines (Radioactive Substances) Order 1978.
9. From 6 February, most provision related to medical equipment included in previous Ionising Radiation Regulations will be transferred to IR(ME)R2017. In Wales the regulatory powers related to medical equipment will move from the Health and Safety Executive to Healthcare Inspectorate Wales.
10. IR(ME)R2017 follows a format similar to that of the IR(M)R2000. The employer is identified as a duty holder and provides a framework of procedures and protocols under which professionals, also as duty holders, undertake a range of activities, including the justification and optimisation of exposures.
11. IR(ME)R2017 includes requirements for a number of topics which either were not addressed or addressed to a lesser degree in IR(ME)R2000. These include:
 - Licensing for nuclear medicine;
 - Non-medical imaging using medical radiological equipment;
 - Carers and comforters and
 - Medical Physics Experts.
12. The BSSD requires that all exposures to ionising radiation must be justified prior to the exposure being made. The Directive refers to two levels of justification; justification of types of practice for all practices and justification of individual exposures for medical and non-medical imaging purposes

where medical radiological equipment is used. IR(ME)R2017 applies only to individual exposures.

13. NHS organisations in Wales should be aware of the requirements of IR(MER)2017 as follows:

- Employers must hold a licence at each medical radiological installation, such as a hospital or mobile imaging service, where radioactive substances will be administered for diagnosis, treatment or research - this licence will define the range of services that can be delivered at that location. A fee is payable for the licence.
- Practitioners, such as nuclear medicine physicians, must hold a licence to clinically justify exposures involving the administration of radioactive substances for diagnosis, treatment or research; a practitioner's licence is valid anywhere they are entitled under IR(ME)R 2017 to act as a practitioner. There is no fee payable for a practitioner licence.
- A practitioner will only require one licence, regardless of how many employers they work for; the scope of the licence will reflect the individual's training and experience.
- Any exposure involving the administration of radioactive substances at a medical radiological installation must be justified by a licensed practitioner whose employer holds an appropriate licence for that exposure, at that installation.
- Entitled operators can continue authorising exposures in line with justification guidelines issued by a licensed practitioner entitled at that medical radiological installation.
- Any current Administration of Radioactive Substances Advisory Committee (ARSAC) certificates due to expire after the new Regulations come into force will remain valid and be considered as equal to a licence for both the practitioner and the employer until the expiry date. Application Forms for licences under IR(ME)R2017 are available, via ARSAC website.⁴

iRefer

14. To facilitate appropriate referrals to radiology departments, and since 1989, the Royal College of Radiologists (RCR) has published RCR iRefer Guidelines: *Making the best use of clinical radiology (iRefer)*⁵. iRefer is

⁴ <https://www.gov.uk/government/publications/arsac-notes-for-guidance/> / <https://www.gov.uk/government/publications/arsac-application-forms>

⁵ <https://www.irefer.org.uk/>

now widely accepted as a major tool to promote evidence-based imaging. The eighth edition of the guidelines was published in May 2017. The guidelines are aimed at clinicians, radiologists, radiographers and other healthcare professionals to determine the most appropriate imaging procedures for a wide range of clinical problems and to help clinicians to meet their obligations under the IR(ME)R 2017. The guideline methodology has been accredited by NICE Evidence, managed by the National Institute for Health and Care Excellence (NICE). A national licence has been procured by NHS Wales Informatics Service and a follow up communication will be issued with the live link when it is available.

Actions for NHS organisations in Wales

ISSUE	ACTION
General policy governing ionising radiation	Ensure organisation's radiation policy reflects IRR2017 and IR(ME)R2017
Notifying staff	Ensure all staff either working with, or referring to, departments using ionising radiation are made aware of the changes
IRR2017	
Notification, registration or consent from HSE under IRR17 ⁶	The individual completing the online website is individually responsible for ensuring the answers given are correct; it is recommended that this should be completed at Executive level within an organisation
Appointment of officers	New appointment letters required for Radiation Protection Advisers (RPA) and Radiation Protection Supervisors (RPS)
Local rules governing ionising radiation	Department Local Rules to be revised in line with new IRR2017
Cooperation of employers	Revise and communicate arrangements
Outside workers	Consider new definition for outside workers e.g. students, locums, agency
Radiation dose monitoring	Ensure staff monitoring is in line with IRR2017. In particular careful consideration must be given to the new eye dose level

⁶ <https://services.hse.gov.uk/bssd/>

Training	Ensure RPAs and RPSs are appropriately trained
IR(ME)R2017	
Duty holder entitlement	Ensure that all duty holders are formally entitled under IR(ME)R 2017
Staff register	Update register (matrix) for Practitioners and Operators
Policies and procedures, protocol and technique files	Revise existing IR(ME)R2000 procedures to ensure they meet the requirements of IR(ME)R2017 and develop the additional procedures required by Schedule 2 IR(ME)R2017
Appointment of officers	Medical Physics Experts (MPE). Ensure MPEs are involved with exposures e.g. through image optimisation teams
Nuclear medicine licensing arrangements	The timing of applications for employer and practitioner licences will depend on the status of any ARSAC certificates currently held for a particular site since the transitional arrangements allow such certificates to be considered licences until their expiry. Employers will thus need to review expiry dates and clinical practices covered by current ARSAC certificates to ensure applications are submitted when required. Note that the application for the employer license will need to be signed off at Executive level within an organisation.
Risk benefit information	Develop suitable information for patients prior to examination (see paragraph 15 below)
Carers and comforters	Develop suitable information and dose constraints. Guidance as part of Employer's Procedures is a new requirement (see paragraph 15 below)
Equipment	Ensure equipment installed after 6 February 2018 meets new IR(ME)R2017 specification
Training (Referrer)	Ensure all duty holders are appropriately trained and made aware of the changes required by IR(ME)R 2017

15. The Radiation Protection Specialist Standing Advisory Group (RPSSAG) is working with other Welsh Scientific Advisory Committee groups to develop 'once for Wales' guidance related to 'carers and comforters' and 'risk benefits information for patients'. We would encourage NHS organisations to work with RPSSAG to ensure consistency in approaches. A second RPSSAG workshop will be held in the spring 2018 to further develop guidance and information to support NHS organizations in implementing IRR 2017 and IR(ME)R 2017.

16. For further information please contact:

Information relating to IRR2017 – contact Health and Safety Executive
<http://www.hse.gov.uk/contact/information-advice.htm>

Information relating to IR(ME)R2017 - contact Health Inspectorate Wales
<http://hiw.org.uk/contactus/?lang=en>

Information relating to Radiation Protection Specialist Standing Advisory Group
healthcarescienceandtherapies@gov.wales or Julian.MacDonald@wales.nhs.uk

Acknowledgements

17. This Welsh Health Circular has been developed with the kind support of colleagues from Betsi Cadwaladr University Health Board - Helen Hughes, Julian MacDonald and Peter Hiles.

Yours sincerely



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