



Department
of Health

Consultation on the transposition of European Council Directive 2013/59/Euratom (Medical Exposures)

Laying down basic safety standards for protection
against the dangers arising from exposure to
ionising radiation

Prepared by Emergency Preparedness and Health Protection Policy Directorate

July 2017

DH ID box
Title: Consultation on the transposition of European Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation – medical exposures.
Author: Global and public health/ Emergency preparedness and Health Protection/ EPHPP
Document Purpose: Consultation
Publication date: July 2017
Target audience: <ul style="list-style-type: none"> • Professional and representative bodies • Clinicians • Medical Physics Experts • Enforcement bodies • Employers who engage others to carry out, medical exposures or practical aspects, at a given radiological installation
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1. Introduction

The Department of Health is consulting on its proposals for Regulations to transpose and implement requirements of the European Council Directive 2013/59/Euratom with regard to medical exposures. This is consistent with an open and transparent approach to decision making and appropriate regulation in all matters relating to health.

This consultation relates to the transposition and implementation of the European Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. The Department of Health, in conjunction with the Health Departments of the Devolved Administrations in Wales and Scotland, proposes that the following regulations and order are repealed and replaced in order to transpose the Directive with respect to medical exposures;

The Ionising Radiation (Medical Exposure) Regulations 2000

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2011

and equivalent Northern Ireland Regulations, although this is the responsibility of the Northern Ireland Executive and out of scope of this consultation.

The Medicines (Administration of Radioactive Substances) Regulations 1978

The Medicines (Administration of Radioactive Substances) Order 1978

The Medicines (Administration of Radioactive Substances) Amendment Regulations 1995

The Medicines (Administration of Radioactive Substances) Amendment Regulations 2006

Other aspects of the Directive are the responsibility of other Government Departments, Devolved Administrations and Agencies and separate consultation processes will be conducted. The Department of Health continues to work with these other bodies to ensure comprehensive transposition and implementation of the Directive. As part of the requirements of the Euratom Treaty relating to the UK, separate regulations will be produced by Northern Ireland and Gibraltar.

The Department for Business, Energy and Industrial Strategy (BEIS) will address types or classes of practices, including those relating to medical exposure, in a separate consultation exercise.

This consultation invites your comments on the specific questions identified in section 5.

2. Background

EC Directive 2013/59/Euratom was developed in response to the recommendations of the International Commission on Radiological Protection, published in 2007.

The aim of the Directive is to update and consolidate five existing directives and one Commission recommendation relating to radiation protection into one Basic Safety Standards Directive (BSSD). These are:

- Basic Safety Standards Directive 96/29/Euratom
- Medical Exposure Directive 97/43/Euratom
- Outside Workers Directive 90/641/Euratom
- Control of High Activity Sealed Radioactive Sources and Orphan Sources Directive 2003/122/Euratom
- Public Information Directive 89/618/Euratom
- Indoor Exposure to Radon Recommendation 90/143/Euratom

The BSSD as a whole was negotiated by a range of Government Departments and Agencies reflecting the UK Government leads for occupational, public and medical exposures.

Development of approaches to transposition of the BSSD has followed a similar approach, with the Department of Health, in conjunction with Health Departments of the Devolved Administrations, leading for medical exposures. Co-ordination and overall responsibility for transposition of the BSSD lies with BEIS. The BSSD has a transposition date of 6 February 2018 and as a full member of the European Union, the UK is bound to comply with this requirement. This requirement is not affected by the decision that the UK will leave the European Union, following the referendum of 23 June 2016.

Structure of the BSSD

The BSSD includes ten Chapters and nineteen Annexes. The majority of the requirements relating to medical exposures are included within Chapter VII although other chapters address related and relevant requirements for medical exposures such as definitions, training, licensing, non-medical imaging and requirements relating to the Medical Physics Expert. These are all addressed within this consultation document.

Other chapters of the BSSD directly address occupational and public exposure. These are not considered as part of this consultation process because they are outside the scope of the Department's responsibility.

3. Legislative context

Current legislative provisions for medical exposure in Great Britain

The current GB regulations relating to medical exposures involving ionising radiation are listed in Section 2 and were based on previous European Council Directives made under the Euratom Treaty. The Medical Exposure Directive provides the basis for the Ionising Radiation (Medical Exposure) Regulations 2000 – known as IR(ME)R2000. Basic Safety Standards Directives, back to 1976, provide the basis for The Medicines (Administration of Radioactive Substances) Regulations 1978 – known as MARS1978.

IR(ME)R2000 includes regulations on justification and optimisation, which are the two fundamental radiation protection principles that apply to medical exposures. The Regulations also provide a framework for radiation protection by identifying and placing responsibilities on duty holders – the employer, the practitioner, the operator and the referrer. In addition, the Regulations address clinical audit, expert advice, equipment and training. IR(ME)R2000 are made under the section 2(2) of the European Communities Act 1972 and the provisions of the regulations are enforced as if they were health and safety regulations made under section 15 of the Health and safety at Work etc Act 1974.

MARS1978 provides a system of certification for doctors and dentists who wish to administer radioactive substances to humans for the purpose of diagnosis, treatment or research. This is in response to an original requirement for a system of prior authorisation required under a Basic Safety Standards Directive from 1976, since repeated in subsequent Directives up to 1996. MARS1978 are made under section 60 of the Medicines Act 1968 and enforced under the same Act.

Need for new Regulations

The BSSD introduces new requirements relating to medical exposure. BSSD implementation offers an opportunity to update the existing Regulations (IR(ME)R2000 and MARS1978) and consolidate them into a single set of Regulations – The Ionising Radiation (Medical Exposure) Regulations 2018 (IR(ME)R2018).

IR(ME)R2018 will also include requirements that may have been addressed previously through administrative means. This is in line with the European Commission preference and the UK Government's approach to transposition.

IR(ME)R2018 are intended to add clarity but do not seek to go further than the BSSD requires. This should minimise costs to stakeholders while still providing enhancement protection against radiation to people who are subject to medical exposure.

Previous stakeholder engagement

Prior to this consultation, the Department of Health's proposal for IR(ME)R2018 have been informed through meetings with professional bodies and associations and the Medical Exposure Working Group (MEWG) – a multi-stakeholder working group established under similar principles to those by other Government Departments and Agencies for occupational and public exposures.

Throughout the process of developing these proposals, the Department of Health has engaged with the Health Departments of the Devolved Administrations, their enforcement bodies and the Health and Safety Executive.

Equalities and Health Inequalities

The Government is committed to equal treatment and equality of opportunity. The Public Sector Equality Duty (PSED) is a key lever for ensuring that public bodies take into account equality when conducting their day-to-day work in shaping policy and delivering services. Under Section 149, public bodies are required to have regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations when making policy decisions and delivering services.

In developing the proposals contained in this consultation, the Department has taken into account the PSED as set out in the Equality Act 2010, and where relevant the Secretary of State's duties under the NHS Act 2006, including the duty to have regard to the need to reduce inequalities relating to the health service.

The Department has developed its proposals so as not to have an unjustifiable adverse impact on any protected groups, and would welcome your views on how to ensure this is done as effectively as possible.

4. Key features of IR(ME)R2018

The major additions within Chapter VII of the BSSD include new requirements for accidental and unintended exposures (Article 63) and additional requirements relating to equipment (Article 60). These are addressed in IR(ME)R2018 by Regulations 8-9 and 15-17 respectively. Other Articles are enhanced and specific requirements of IR(ME)R 2000 have been amended to reflect this.

While IR(ME)R2000 included a specific Regulation (Regulation 9) on the need for expert advice and the involvement and availability of the Medical Physics Expert, it did not address criteria for or methods of recognition of MPEs. The BSSD also describes in greater detail the role of the MPE, and IR(ME)R2018 addresses this, the need for national recognition and the role of the MPE in providing the employer with advice on compliance with the Regulations. These are included in an expanded Regulation 14 and a new Schedule (3) to the Regulations.

Exposure of carers and comforters is included within the BSSD definition of medical exposure. Although carers and comforters were previously addressed by HSE in the Ionising Radiation Regulations 1999, it is proposed that BSSD requirements for carers and comforters, including a new requirement for justification of individual exposures of carers and comforters, are included within IR(ME)R2018.

Although the BSSD includes some new requirements for equipment, those relating to quality assurance programmes and performance testing for medical equipment are largely unchanged. It is proposed that these requirements of Article 60, along with new requirements, are included within IR(ME)R2018, rather than as previously within the HSE's Ionising Radiations Regulations 1999. The intention is to consolidate into IR(ME)R2018 all requirements of the BSSD that are intended to provide protection for those undergoing medical exposures. This will also provide better synergy with the requirements relating to Medical Physics Experts (MPEs). All requirements relating to MPEs were included previously in IR(ME)R2000 and it is intended that this approach is continued within IR(ME)R2018.

Outside Chapter VII, Article 22 addresses practices involving the deliberate exposure of humans for non-medical imaging purposes. Further detail is provided at Annex V of the BSSD. The BSSD differentiates between those procedures that use medical radiological equipment and others that do not. It is proposed that the former are included within IR(ME)R2018 to ensure the same regulatory framework and level of protection are provided to those subject to such exposures. Some of these exposures were previously dealt with by IR(ME)R2000 as medico-legal exposures.

Article 28(a) of the BSSD introduces requirements for licensing of the deliberate administration of radioactive substances to persons for diagnosis, treatment of research. This, along with Annex IX of the Directive, provides detailed requirements for licensing as compared to prior-authorisation in previous Basic Safety Standards Directives. To implement this, it is proposed that IR(ME)R2018 includes a requirement for licensing of practitioners and employers who wish to administer radioactive substances for these purposes. This will enable MARS1978 to be revoked entirely, and responsibilities relating to such administrations to be consistent with those of other medical exposures.

Employers who provide services involving the administration of radioactive substances would need to hold an appropriate licence at each site.

- Each licence may be granted indefinitely or for a fixed term

Individuals who act as IR(ME)R2018 practitioners for the administration of radioactive substances would need to hold an appropriate licence.

- Each practitioner will only require one licence, regardless of the number of sites where they work
- Each licence would be granted for a fixed term

Applications for employer and practitioner licences will be managed by Public Health England (PHE) on behalf of the Secretary of State for Health and assessed by the Administration of Radioactive Substances Advisory Committee (ARSAC).

PHE will develop a new IT system to allow applicants to submit their applications online. PHE proposes to charge fees for some types of applications to cost recover for the design, operation and maintenance of this system. The total cost of the new IT system has not been finalised and therefore the fees included within IR(ME)R2018 are subject to final confirmation.

Further information on application processes will be provided in guidance which will be available later this year.

Potential impact of the BSSD and new Regulations on the Great Britain legal regime

The requirements within the BSSD for medical exposure (largely Chapter VII of the BSSD) are similar in structure and content to those included in the previous Medical Exposure Directive, with articles addressing justification, optimisation, responsibilities, procedures, training (and recognition), equipment, special practices, pregnancy and breastfeeding and estimates of population doses. These articles are enhanced, but many of these changes are already addressed within existing UK legislation, administrative processes and good practice within healthcare. The impact of the BSSD and IR(ME)R2018 on stakeholders is likely to be low.

A Regulatory Triage Assessment (RTA) has been carried out and this is provided at Annex II. Most of the additional costs to stakeholders relate to recognition of Medical Physics Experts and licensing requirements relating to the administration of radioactive substances to humans for the purposes of diagnosis, treatment and research.

5. Consultation Proposals and Questions

We are seeking your views and comments on a number of provisions which we intend to include in the new Regulations to reflect the new requirements introduced by the BSSD. The areas of interest are:

1. Duties of the employer with regard to accidental and unintended exposures

IR(ME)R2018 will expand requirements for reporting of incidents. This will require the Competent Authority to define significant events (in effect as now) but does not require it to define clinically significant accidental or unintended exposures.

1.1 Do you support reporting of significant events under IR(ME)R2018, regardless of whether these result from equipment or procedural failure?

1.2 Do you agree that the definition of clinically significant exposures should be the responsibility of professional scientific and medical societies rather than the Competent Authority?

1.3 Do you support the view that any such exposure should however be considered as a significant event and reported to the Competent Authority?

1.4 Do you support the reporting of significant events in radiotherapy where doses are less than intended?

2. Duties of the employer with regard to quality assurance programmes for equipment when used in medical exposures

IR(ME)R2018 offers an opportunity to include in one set of Regulations requirements relating to medical exposure (rather than occupational or public exposure) associated with medical radiological equipment, including inventories, surveillance and quality assurance programmes.

2.1 Do you support inclusion of these requirements within IR(ME)R2018?

3. Medical physics experts

The BSSD is more prescriptive about the role of the medical physics expert.

3.1 Do you object to medical physics experts advising employers on compliance?

3.2 Do you think the Regulations should require employers to appoint MPEs?

4. Carers and comforters

The BSSD defines medical exposure as including exposures made to carers and comforters and requires that such exposures are justified individually and subject to dose constraints.

4.1 Do you support the inclusion of requirements for carers and comforters within IR(ME)R2018?

5. Non-medical imaging

The BSSD has introduced non-medical imaging as a new type of exposure and categorises these exposures as those resulting from the use of medical radiological equipment and those that do not.

5.1 Do you support the inclusion of non-medical imaging using medical radiological equipment within IR(ME)R2018?

5.2 Do you think dose constraints or dose limits should be applied to such exposures?

6. Licensing for the administration of radioactive substances

IR(ME)R2000 and MARS1978 (and associated amending regulations) will be replaced by IR(ME)R2018. A dual licensing system will be introduced to satisfy more stringent requirements of the BSSD and charges for licences will need to be made on a cost recovery basis.

6.1 Do you agree that charges should not be levied on practitioners who wish to hold a licence?

6.2 Do you think licences for employers should be for a fixed period or reviewed only when amendments are sought?

6.3 Do you support a single licence for practitioners?

7. Diagnostic reference levels (DRLs)

The BSSD extends requirements for DRLs but retains the requirement that DRLs should have regard to European DRLs where available

7.1 Do you support extending requirements in IR(ME)R2018 to having regard to National DRLs as well as European values?

8. Adequate training

Training requirements for practitioners and operators are listed in Schedule 4.

8.1 Please provide comments on Schedule 4 – amendments and deletions - noting that the intention of the Schedule is not to replace or replicate the detail of established training programmes.

6. How to Respond to the Consultation

Responding to the consultation

The Department welcomes responses to all of the questions above. Please submit your responses to the questions by 31 July 2017.

The preferred method of receiving your response is via the on-line consultation questionnaire, which can be found on CitizenSpace:

<https://consultations.dh.gov.uk/health-protection/medical-exposures-to-ionising-radiation>

Please use this to record your responses. Alternatively, you may wish to complete the response form and e-mail it to us at:

HealthProtectionTeamPQsandGeneral@dh.gsi.gov.uk

If you do not have internet or e-mail access, then please write to:

Emergency Preparedness and Health Protection Policy Directorate

Department of Health, Richmond House

79 Whitehall, SW1A 2NS

A paper copy of this consultation document, and the corresponding response form, is available on request, using the e-mail address. If you have any questions about the content of this consultation then please send them to:

HealthProtectionTeamPQsandGeneral@dh.gsi.gov.uk

If you wish to do so, you can request that your name and/or organisation be kept confidential and excluded from the published summary of responses.

Please note that we may use your details to contact you about your responses or to send you information about our future work. We do not intend to send responses to each individual respondent. However, we will analyse responses carefully and give clear feedback on how we have developed the implementation plan as a result.

Comments on the consultation process

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator

Department of Health

2E26 Quarry House

Leeds

LS2 7UE

e-mail: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

Any information received, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information you have provided we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding by the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Annex I - Draft IR(ME)R 2018 Regulations

Annex II – Regulatory Triage Assessment

Consultation letter:

Consultation on the transposition of European Council Directive 2013/59/Euratom (Medical Exposures)

Laying down basic safety standards for protection against the dangers arising from medical exposure to ionising radiation

Dear Colleague

I am pleased to say that I am writing to you today to give notice of the publication of a consultation on draft regulations to transpose and implement requirements of the European Council Directive 2013/59/Euratom with regard to medical exposures.

The aim of the Directive is to update and consolidate five existing directives and one Commission recommendation relating to radiation protection into one Basic Safety Standards Directive (BSSD).

Section 5 of the consultation therefore focuses on specific questions related to Chapter VII of the BSSD including:

- New requirements for accidental and unintended exposures
- Additional requirements relating to Medical Physics Experts
- Additional requirements for licensing of the deliberate administration of radioactive substances to persons for diagnosis, treatment or research - A dual licensing system will be introduced to satisfy more stringent requirements of the BSSD and charges for licences will need to be made on a cost recovery basis.

This consultation continues the collaborative approach we have taken throughout the transposition of this Directive and seeks views on specific elements of the regulations that are due to come into force on 6 February 2018.

You will be able to find further information, including the full suite of consultation documents and ways of responding at the consultation website here:

Your response is requested by 31 July 2017.

Yours faithfully,