Medical Exposures - Regulatory Background

The Ionising Radiation (Medical Exposure) Regulations 2000, (IR(ME)R 2000), came into force on 13 May 2000 IRMER 2000 to implement the European Directive 97/43/Euratom (The Medical Exposures Directive). The regulations replaced the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988 (POPUMET) which have been repealed.

On 1 April 2009, the Care Quality Commission (CQC) assumed responsibility from the Healthcare Commission for the inspection and enforcement for incidents in England under Ionising Radiation (Medical Exposure) Regulations 2000. Further information is available on the CQC website.

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, SI 2006/2523 (‘the Regulations’) amend the 2000 Regulations IRMER 2006. They passed the enforcement powers under the 2000 Regulations to the “appropriate authority”. In England, the current “appropriate authority” is the Care Quality Commission. The Amendment Regulations also make amendments to certain definitions in the 2000 Regulations in order to clarify:

• their meaning
• reflect changes to terminology used in the 2000 Regulations
• make transitional provision for incomplete matters or matters not finally disposed of before the Regulations came into force on 1 November 2006

The Ionising Radiation (Medical Exposure)(Amendment) Regulations 2011 amend the IRMER 2000. A minor amendment was made to Regulation 3(a) IRMER 2011.

Diagnostic Reference levels

The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R 2000), which partially implements Council Directive 97/43/Euratom, require employers undertaking medical exposures to establish diagnostic reference levels (DRLs) and to undertake appropriate reviews if these are consistently exceeded.

Link to Diagnostic Reference Levels

Reporting Medical Exposures “Much Greater Than Intended”

Currently, there is no specific guidance issued by the Department of Health regarding the reporting of incidents resulting from a person undergoing a medical exposure as required by The Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) Regulation 4(5). The Department wishes to update any previous advice with immediate effect and advise employers that the reporting of exposures much greater than intended as defined in IRMER shall be as set out in the “Guidance on Reporting” section below until further notice.

In March 2006, the Health and Safety Executive (HSE) made available the third edition of PM77 (V3) ‘Equipment used in connection with medical exposure’ on their website. PM77 (V3) currently addresses the requirement for reporting of incidents to the Health and Safety Executive where a radiation employer suspects or has been informed that a person,
while undergoing a medical exposure and as a result of a malfunction or defect in radiation equipment, was exposed to ionising radiation to an extent much greater than intended - the Ionising Radiations Regulations 1999, Regulation 32(6). In the short-term, to clarify what should be currently reported to IRMER Enforcement Authorities, we have added a small amendment to the HSE document PM77 (V3) in Appendix 2 (Table 1). This amendment is detailed below for clarity in bold italics after the 1.5 multiplier.

<table>
<thead>
<tr>
<th>Type of diagnostic examination</th>
<th>Guideline multiplying factor applied to intended dose</th>
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<tbody>
<tr>
<td>Interventional and fluoroscopic procedures involving contrast agents, nuclear medicine with intended dose &gt;5mSv and computed tomography examinations</td>
<td>1.5 “exclude reasonable repeat exposures when any repeat is for technical / optimisation purposes rather than a procedural error”</td>
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Contrary to previous information, DH can now confirm that it is not producing joint guidance with HSE and instead will be producing guidance relevant to IRMER and intends to publish this new guidance on this page in the near future.

In England, notifications of radiation incidents can be reported in the strictest confidence through the CQC website relating to ‘Reporting incidents’

Employers in Devolved Administrations should report such incidents to their respective IRMER Enforcement Authorities.

Read more about the Ionising Radiation (Medical Exposure) Regulations 2000 on the [Care Quality Commission website](http://www.cqc.org.uk).