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HERCA Multi-Stakeholder Workshop – Accidental and unintended exposures of individuals subject to medical exposure – notification and recording of significant events 24-26 October 2016, Paris

National approach – UK

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Background

Ionising Radiations Regulations 1985 largely addressed occupational and public exposures

BUT…..

Regulation 33 included requirements relating to the installation and maintenance of medical equipment including a requirement to:

“notify the Health and Safety Executive when an incident occurs involving a malfunction or defect in any “radiation equipment” which gives rise to a medical exposure that is much greater than intended”

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Background

Guidance relating to this requirement was first issued in 1992 -

Guidance Note PM77 - Fitness of equipment used for medical exposure to ionising radiation

Second edition was issued in 1998

NB regulations addressing medical exposures did not include a requirement for notification of exposures much greater than intended resulting from other failures

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Notification levels

Types of diagnostic examination	Guideline multiplying factor
Barium enemas, IVUs, angiography and other fluoroscopy, CT	3
Nuclear medicine >5mSv	3
Lumbar spine, abdomen, pelvis, mammography and others not included in this table	10
Nuclear medicine <5mSv but >0.5mSv	10
Extremities, skull, chest, dental and other simple examinations	20
Nuclear medicine<0.5mSv	20

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Notification levels

Type of treatment	Guideline multiplying factor
Beam therapy, brachytherapy, malignant, non-malignant (including palliative treatment)	1.1 (whole course) or 1.2 (any fraction)
Radionuclide therapy	1.2 (any administration)

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Background

Guidance included a statement that other incidents may warrant attention from HSE but fall outside these guidelines.

“These could include, for example, incidents involving a group of individuals each of whom receives a relatively small exposure additional to that intended as a result of an equipment fault.”

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Current Regulations in Great Britain

GB regulates medical exposures largely through two sets of Regulations

- Ionising Radiations Regulations 1999 – IRR1999
- Ionising Radiation (Medical Exposure) Regulations 2000 – IR(ME)R 2000

IRR1999 largely addresses occupational and public exposures - enforced by Health and Safety Executive

IR(ME)R 2000 largely addresses patient exposures – enforced by enforcement agencies of the UK Health Departments

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Current guidance on reporting levels

IRR 1999 (Health and Safety Executive)

Regulation 32(6) – notification of incidents as a result of malfunction of or defect in radiation equipment

Guidance Note PM77 (Third Edition) - Equipment used in connection with medical exposure – 2006

Includes similar statement relating to notification of incidents involving a group of individuals, each of whom receive a relatively small additional exposure as a result of equipment fault.

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Notification levels – IRR1999

Type of diagnostic examination	Guideline multiplying factor applied to intended dose
Interventional radiology, radiographic and fluoroscopic procedures involving contrast agents, nuclear medicine with intended dose >5mSv and CT	1.5
Mammography, nuclear medicine with intended E<5mSv but >0.5mSv, all other diagnostic examinations not referred to elsewhere in this table	10
Radiography of extremities, skull, dentition, shoulder, chest, elbow, knee, and nuclear medicine with intended E<0.5mSv	20
Type of treatment	**Guideline multiplying factor applied to intended dose**
Beam therapy, brachytherapy	1.1 (whole course) or 1.2 (any fraction)
Unsealed radionuclide therapy	1.2 (any administration)

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Current guidance on reporting levels

IR(ME)R 2000

Regulation 4(5) – notification of incidents other than those as a result of malfunction of or defect in radiation equipment

Number of working parties have considered reporting levels (2004 onwards….)

Recognise that PM77 is not ideal but should be used as a “signpost” for reporting of accidental and unintended exposures much greater than intended.

NB there is no requirement for reporting incidents involving doses much lower than intended.

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Current guidance on reporting levels

IR(ME)R 2000 (Health Departments and associated enforcement agencies)

"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 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."

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Current guidance on reporting levels

"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.

……

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."

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Current guidance on reporting levels

Type of diagnostic examination	Guideline multiplying factor applied to intended dose
Interventional and fluoroscopic procedures involving contrast agents, nuclear medicine with intended dose >5mSv and computed tomography examinations	1.5 “exclude reasonable repeat exposures when any repeat is for technical / optimisation purposes rather than a procedural error