Guidance on Clinical Incidents in Nuclear Medicine resulting in exposures greater than intended

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Introduction

In Nuclear Medicine, errors can occur which result in the patient having to have a repeat radiopharmaceutical administration. For example; a patient might be given the wrong radiopharmaceutical, or the wrong amount. Where a repeat administration is required, the incidents should be reported locally through Trust incident reporting mechanisms. In addition, it may be necessary to report the incident to an external agency (the specific agency will depend upon the underlying reason behind the incident).

This guideline document outlines what you must do in the event of an incident. As soon as is feasible after the initial preliminary investigation, staff should consult the web pages listed in the Reference section. Partly for the useful guidance provided, (e.g. on conducting the detailed investigation), and partly to be sure of having up-to-date information.

Table 1. Instructions Following an Incident

Instructions	**Notes**
Organize on the same day an "Immediate preliminary investigation". Record an account of the incident from each of the staff involved.	The employer is responsible under IR(ME)R Reg 4(5), and under PM77 paragraph 45. Therefore you should involve management as soon as practicable, but do not delay the investigation. Refs: DoH and PM77
If the patient is still in the department, inform them of the incident in accordance with Trust policy. For a diagnostic dose (with the possible exception of a child receiving an adult dose) you may say that any harm from radiation is likely to be very small, and that physics staff will provide a proper assessment. If the patient has gone, do not contact them until a physicist has assessed the incident.	
Contact the MPE, or other physics staff. They will advise whether the incident is: a) Reportable to the Care Quality Commission (CQC) under IR(ME)R , or b) Reportable to the Health and Safety Executive (HSE) under IRR99. or c) Not reportable externally	See detailed advice in Table 2
If the incident is found to be reportable to the CQC, management should, with the help of the MPE, do this "forthwith", on behalf of the	Ref. CQC gives detailed instructions, indicating that the

employer, using the on-line IRMER Incident Report form	report should be submitted within 2 weeks, and gives a link to the on-line report form
If the incident is found to be reportable to the HSE, management should, with the help of the MPE and possibly the RPA, do this “forthwith”, on behalf of the employer	PM77 paragraph 53 specifies how to report an incident. This should be done “immediately” and not delayed pending a more detailed investigation
Whether the incident is externally reportable or not, the employer should carry out a full investigation, followed by the appropriate learning exercise and corrective actions, in accordance with Trust policy.	See guidance in refs PM77 and CQC
Only in the exceptionally rare event of a senior manager refusing to report on a serious error, would independent action by a member of staff be considered acceptable. Although all staff have the right to independently report errors under current legislation, before doing so, they should consult their Trust’s policy, and if possible express their concerns through their Trust’s radiation-safety or line-management systems.	Such an event would constitute a serious breach of IR(ME)R Regulation 4(5) or of IRR99. Regulation 32(6). The employer (e.g. the CEO), and not the manager concerned, would be the person responsible in law.

Table 2. Advice on Whether External Agencies must be notified

Key Information	**Notes**
Exposures ‘much greater than intended’ (MGTI), occurring a result of malfunction or defect in any radiation equipment are reportable to the HSE: Ancillary equipment, such as gamma cameras and imaging computers are not classed as “radiation equipment”.	Detailed advice: PM77 paragraphs 45-49 Examples reportable • Faulty Dose calibrator. • Faulty shutter on a Gd-153 line source. • Over-exposure due to a CT fault on PET-CT scan Example not reportable • Camera breakdown during dynamic acquisition
The MPE and/or RPA should assess the total dose and determine if it is MGTI.	HSE: The current PM77 (third edition) paragraph 54 requires the MPE and RPA to consult the Guideline Multiplying factors and other contents of PM77 Appendix 2,

If the total (including any repeat study) is greater than the intended dose times the Guideline Multiplying Factor, then the exposure is generally classed as MGTI	and make their own professional judgment. CQC: Ref DoH states that MGTI is under review, and …"the term much greater than intended … should be interpreted as in the HSE guidance PM77 second edition issued in 1998." See Table 3 for Guideline Multiplying Factors

Table 3. Guideline Multiplying Factors

Intended effective dose	For CQC notification, Mandatory: use the values in PM77 2nd edition (1998)	For HSE notification, Guideline: use the values in PM77 3rd edition (2006)
Diagnostic exam >5mSv	**3**	**1.5**
Diagnostic exam 0.5 - 5mSv	**10**	**10**
Diagnostic exam <0.5mSv	**20**	**20**
Unsealed radionuclide therapy (any administration)	**1.2**	**1.2**

References

CQC
Information on the reporting of incidents is given on the department of health website
http://www.cqc.org.uk/guidanceforallhealthcarestaff/managingrisk/useofionisingradiation/reportingincidents.cfm

DoH
The Ionising Radiation (Medical Exposure) Regulations 2000 (together with notes on good practice)
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007957

IRR99

The Ionising Radiations Regulations 1999
http://www.legislation.gov.uk/uksi/1999/3232/contents/made

PM77

HSE Guidance Note PM77, Equipment used in connection with medical exposure, third edition
http://www.hse.gov.uk/pubns/guidance/pm77.pdf

References

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