

The Ionising Radiation (Medical Exposure) Regulations Enforcement in Scotland

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Inspector warranted by the Scottish Ministers for
the Ionising Radiation (Medical Exposure)
Regulations



The Scottish Government
Riaghaltas na h-Alba

European Directive 97/43/Euratom

IR(ME)R came into force on 13th May 2000 to implement the European Directive 97/43/Euratom (The Medical Exposures Directive).

- The 2006 amendment changed “registered medical practitioner, dental practitioner or other health professional” to “registered health care professional”;

“registered health care professional” means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002.”.



The Need for Inspections

- *Article 13: Member States shall ensure that a system of inspection as defined in Article 2 enforces the provisions introduced in compliance with this Directive.*
- *Inspection is an investigation by any competent authority to verify compliance with national provisions on radiological protection for medical radiological procedures, equipment in use or radiological installations.*



Enforcement of IR(ME)R in Scotland

Enforcement

12. - (1) The provisions of these Regulations shall be enforced as if they were health and safety regulations made under section 15 of the Health and Safety at Work etc. Act 1974^[5] and, except as provided in paragraph (2), the provisions of that Act, as regards enforcement and offences, shall apply for the purposes of these Regulations.

(2) The enforcing authority for the purposes of these Regulations shall be the appropriate authority.



Enforcement

Section 21:

The power to serve improvement notices

Section 22:

The power to serve prohibition notices.

- Two improvement notices have been served in Scotland for the IRMER, one on an NHS Hospital, and one on a chiropractor.



Inspections in Scotland

- Between 2000 and 2004, the Secretary of State's Inspectorate for the Medical Exposure Regulations carried out proactive inspections in all Scottish NHS Boards except Borders, Western Isles, and Orkney.
- In 2005 members of the Inspectorate moved to the HPA and ceased to have a warrant for Scotland.
- In 2006 and 2007 all radiotherapy centres were inspected.
- In 2008, inspections were temporarily suspended in favour of dialogue with the NHS Boards on compliance structures.
- All NHS Boards were inspected in May, June, and July 2009, and again between November 2010 and May 2011.

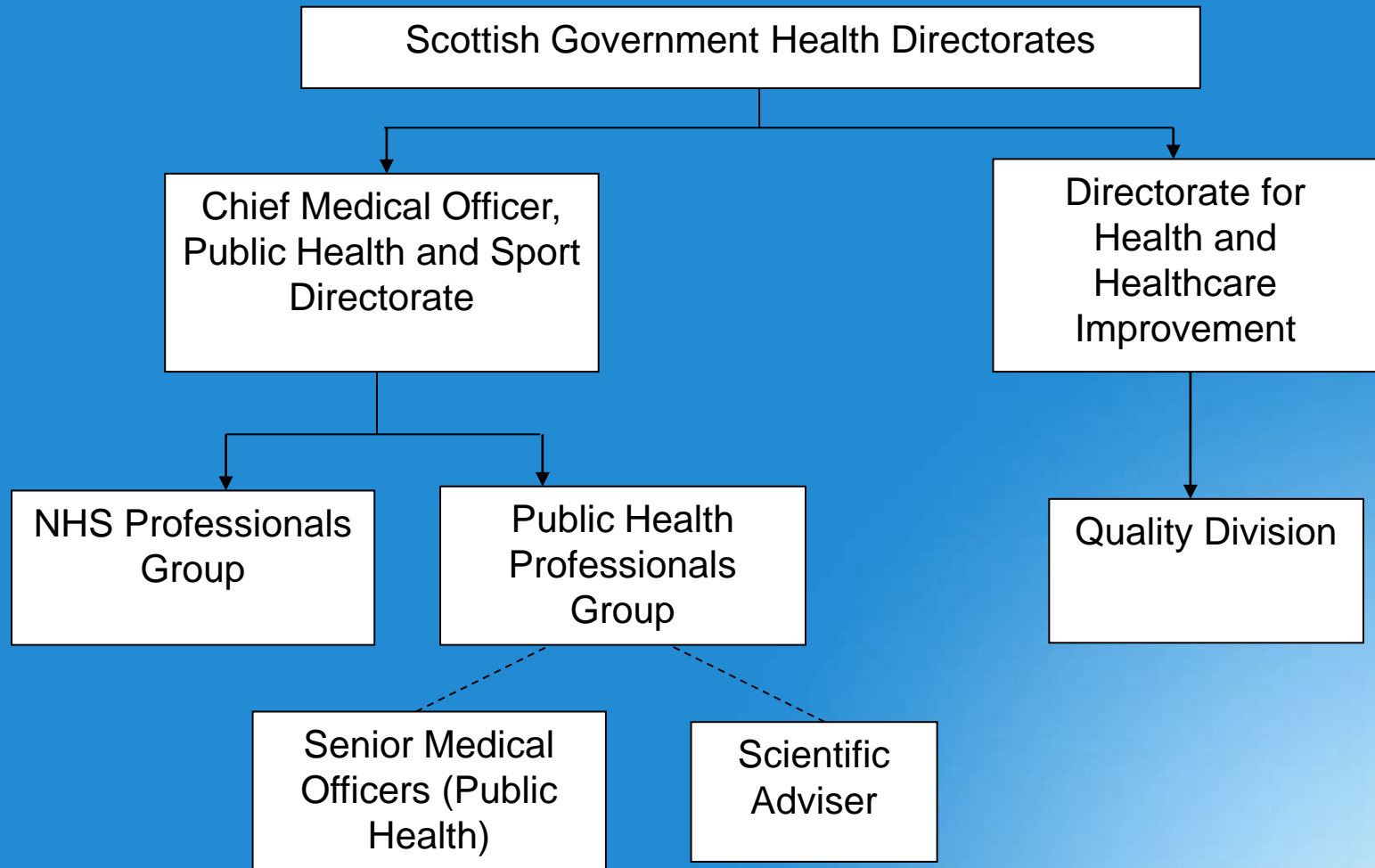


Support for Scottish Employers

- Scottish Government funding is currently in place to support HPA visits.
- Additional Scottish Government on-going funding in place for HPA training for Scottish NHS Board staff in all aspects of radiation safety.
- Sharing of good practice among Scottish NHS Boards through the 'Radiation (or IRMER) Leads'.



Scottish Government



Inspection process

- Proactive inspections will be ‘announced’.
- A focus on the employer’s duties under the Regulations (Written Procedures, Entitlement of Duty Holders, training records, etc..)
- Detailed scrutiny of Employer’s Written Procedures and Protocols (usually about 4 hours).
- Formal report to the employer will identify non-compliances and recommendations for improvement.
- Agree a timescale to address non-compliances and recommendations



Notification of incidents

- Regulation 4(5): Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation to an extent *much greater than intended*, he shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.



‘Much greater than intended’

- HSE PM77 ‘Equipment used in connection with medical exposure to ionising radiation.’

Type of diagnostic examination intended dose	Guideline multiplying factor applied to intended dose
Radiography of extremities, skull, dentition , shoulder, chest, elbow, knee, and nuclear medicine with intended $E < 0.5 \text{mSv}$	20



Making a notification

- By letter to :

Dr Arthur Johnston
Warranted Inspector for the Medical Exposure Regulations
Chief Medical Officer Directorate
Public Health Professionals Group
St Andrew's House
Regent Road
Edinburgh EH1 3DG

What happened

Why did it happen

What was the dose to the patient

Was the patient informed

What has been done to minimize the possibility of recurrence.

- Reply by letter, either closing the incident or requesting further information, or a reactive visit.



Summary of Scottish notifications

Year	Number	Therapy	Diagnosis	Wrong patient
2000	2	0	2	2
2001	8	2	6	2
2002	13	1	12	4
2003	15	4	11	7
2004	21	6	15	9
2005	8	3	5	3
2006	17	4	13	9
2007	35	3	32	20
2008	56	6	50	30
2009	65	2	63	53
2010	60	2	58	36
2011	51 (so far)	4	47	33
Total	351	37	314	208(66%)



Enforcement in the England

England: Care Quality Commission.

Notifications to the CQC in 2010, were:

- 410 from diagnostic radiology.
- 26 from nuclear medicine,
- 58 from radiotherapy.

Inspection reports are published on the internet

‘We estimate that around half of notifications from diagnostic radiology involve the 'wrong patient' – whether they were referred incorrectly or whether operators failed to follow the established patient identification procedure and X-rayed the incorrect patient.’

‘We have noticed an increasing proportion of notifications arising from errors made in computed tomography (CT) scanning since 2008.’



Radiographer competences

1. Competent for all plain film exposure procedures (except mammography) using any fixed, authorized X-ray equipment in this NHS Board area.
2. Competent for all plain film mammography exposure procedures using authorized X-ray equipment in this NHS Board area.
3. Competent for fluoroscopy exposure procedures using any fixed, authorized fluoroscopy equipment in this NHS Board area.
4. Competent for CT scanning exposure procedures using any fixed, authorized CT equipment in this NHS Board area.

