



Radiological Protection Institute of Ireland
An Institiúid Éireannach um Chosaint Raideolaíoch

Training of an Inspector under ISO 17020

Stephen Fennell

ERPAN Meeting - 27th May 2009

New Inspector

- **Scientific Officer/Inspector - Nov 2007**
- **Diploma in applied physics (2001)**
- **BSc – physics & physics technology (2003)**
- **Field service engineer, research assistant**
- **MSc Medical Physics (2007)**
- **Warrant issued – Sept 2008**
- **Training complete – Jan 2009**



Pre-Accreditation

- No formal programme
- Shadowed experienced inspector
- Training courses – whenever opportunity arose
- No formal assessment of competency/sign off
- Issue of warrant - subjective
- Understanding of “big picture”?
- No on-going review mechanism



ISO 17020 Training Requirements

Section 8: Personnel

- Staff responsible for inspections shall have **appropriate** qualifications, training, experience and a **satisfactory** knowledge of the requirements of the inspections to be carried out
- The inspection body shall establish a **documented** training system to ensure that the training [of inspectors] is **kept up-to-date**
- The training shall depend upon the **ability, qualifications and experience** of persons involved
- Training shall include:
 - **Induction period**
 - **Supervised** working period with **experienced** inspectors
 - **Continuation** training ... to keep pace with developing technology
- The inspection body shall provide **guidance on conduct**



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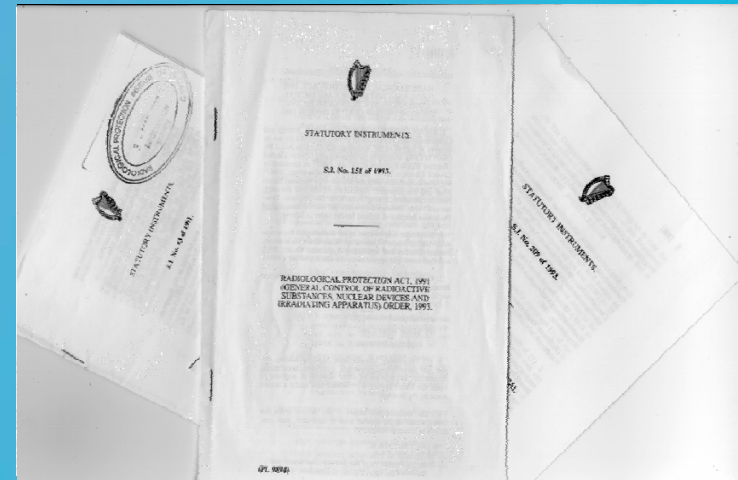
Training Programme

- **Introduction to RPII**
 - Relationship with/to government
 - Internal structures
- **Introduction to regulatory responsibilities**
 - Licensing
 - Inspection
 - Enforcement
 - Guidance
- **RPII staff handbook**
 - Code of business conduct
 - Inspector's code of conduct
 - IT usage policy



Training Programme

- **Health and Safety**
 - RPII H&S manual
 - Manual handling course
 - Safepass course
 - Fire safety
- **ISO 17020 QMS**
 - Quality manual
 - Quality procedures
- **Legislation**
 - Radiological Protection Act, 1991
 - S.I. No. 125 of 2000
 - Legal workshop



Training Programme

- Database & IT servers
- Equipment
 - PPE
 - Radiation monitors
 - Personal dosimetry
- Use of radiation monitors
- Inspection procedures
- Inspections
 - Observation (20)
 - Lead under supervision (5)
 - Competency assessment (4)



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Training Programme

- **Court experience & protocols**
- **Incident investigation**
 - Accidents
 - High dose investigations
- **Business planning**
 - RPII three year strategic plan
 - Annual business planning
 - Performance Management Development System (PMDS)
 - Training
 - Formal courses
 - Technical meetings
 - Conferences



Quality Procedures

- QP01 Corrective Action Procedure
- QP02 Document Control Procedure
- QP03 Management Review Procedure
- QP04 Audit Procedure
- **QP05 Annual Inspection Programme**
- **QP06 Pre- Inspection Procedure**
- **QP07 Inspection Procedure**
- **QP08 Post- Inspection Procedure**
- **QP09 Inspectors Meetings**
- QP10 Training Programme Procedure
- QP11 Equipment Procedure



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Formal Courses

- **“How to inspect” – a foundation course in non-technical aspects of inspection, Irish Medicines Board (Dublin)**
- **Quality customer services, RPII (Dublin)**
- **Auditor training, RPII (Dublin)**
- **A course in radiotherapy physics, Royal Marsden Hospital (London)**
- **WHO Co-ordination Meeting - Radiation Safety in Healthcare Settings, WHO (Geneva)**
- **Presentation skills course, Irish Times (Dublin)**



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Formal Courses

- **Radiation protection in nuclear medicine, IPEM (London)**
- **Madiera Course - Radiation Physics for Nuclear Medicine, EC funded (Milan)**
- **ICRP Seminar, ICRP (Dublin Castle)**
- **ADR basic training, Dublin**
- **ADR Class 7 specialisation course, One Photon Consultancy (Louth)**
- **3 week placement in Royal Surrey County Hospital, Guildford, UK**
- **Radiological Protection Summer School 2009, IBC Global Academy, Cambridge**



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On-the-job Training

- Inspection audit forms
- Template for inspection reports
- Observer (20)
 - Diagnostic radiology (14)
 - Nuclear medicine (1)
 - Radiotherapy (4)
 - Dental (4)
 - Vet – diagnostic/nuclear medicine (3)
 - Distributor (1)
- Supervised (5)
 - Diagnostic radiology (4)
 - Dental (2)



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Reference		Report Page	
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Licensee		Inspection Date	
Blackrock Clinic		25/02/09	
Contact Name		Issue date	
Mr Bryan Harty		06/03/09	
Address		Inspection Location - if different	
Rock Road Blackrock Co Dublin			
Personnel in Attendance			
Inspector(s)		Dr Stephen Fennell and Ms Noeleen Cunningham	
Licensee Representatives		Mr Bryan Harty (CEO), Dr George Duffy (Hospital Director), Dr Michael Casey (RPA), Dr Christine Jennings (RSC Chairperson), Dr Lorraine Wilson (Nuclear Medicine Clinician), Dr Julie Lucy (RSO), Ms Nancy Manning (RSM) and Ms Leanne McNamara (Physicist)	
Audit Protocol		Hospital Level 4 (Nuclear Medicine)	
Scope of Inspection		Nuclear Medicine and Waste Store	
Omissions from Scope		None	
Test Equipment		Rotem Ram Gene-1 (s/n 12506-020)	
Regulatory/Licensing Requirements			
Radiological Protection Act, 1991 (No. 9 of 1991) and Orders/Regulations made there under			
Radiological Protection (Amendment) Act, 2002 (No. 3 of 2002)			
Carriage of Dangerous Goods by Road Regulations, 2007 (S.I. No 288/289 of 2007)			
Conditions of Licence No 0380-0331-08 (version 5.0)			
Statements			
This Inspection Report and its findings only relate to the scope of the inspection as identified above.			
This Inspection Report shall not be reproduced without prior approval of both the Regulatory Services Division and the licensee.			
A reply, informing the Regulatory Services Division of the response to the attached inspection findings, is required by 3rd April 2009 .			
Signature: 			
3 Clonsillaugh Square, Clonsillaugh Road, Dublin 14. T: +353-1-2697766 F: +353-1-2697437 E: rpi@rpi.ie W: www.rpi.ie Chairperson: Prof Eugene Kennedy Chief Executive: Dr Ann McGarry			

Competency Assessment

- **Assessment by technical manager**
 - Diagnostic radiology (2)
 - Dental (1)
 - Vet (1)
- **Technical Manager cannot be “directly” involved in training**



Inspection Witnessing

- Core requirement of ISO standard
- Matrix of inspection category types
 - Distributors
 - Diagnostic radiology
 - Nuclear medicine
 - Radiotherapy
 - Cabinet/baggage X-ray, distributors
 - Gauges, education & research
 - Non-destructive testing
 - Industrial irradiators
- Inspector witnessed performing a minimum of one inspection type annually
- Each inspector witnessed in every category once every 3 years



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Inspection Witnessing

- Technical managers witness each other
- Included in annual training programme
- Standard template developed
- Ensures consistency between inspectors & inspections
- Interview between technical manager/inspector



Microsoft Word
Document



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