Environmental Protection Agency

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulatory Framework and Inspections in Ireland

HERCA MedInspector Workshop 6-8 November 2018 Stockholm

Environmental Protection Agency

Agenda

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- Legislative Background & Competent Authorities in Ireland
- Occupational and Public Exposures
  - BSS Transposition – Key Aspects for Nuclear Medicine
  - Regulatory Framework
  - Inspections
  - New Issues
- Patient Exposures
  - New Regulatory Body
  - Approach to Regulatory Oversight
- Beyond the BSS Transposition …The Future

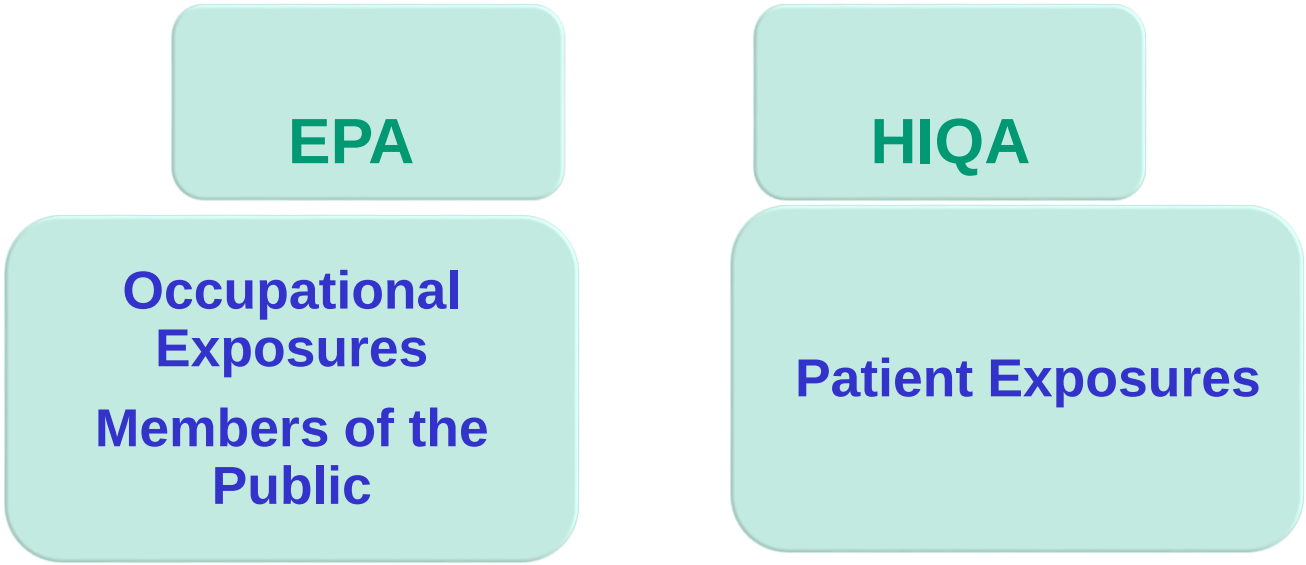
Legislative Background

Responsibility	Public and workers	Patients
Drafting Legislation	Department of Environment (DCCAE)	Department of Health (DoH)
Competent Authorities	EPA	HIQA

Key Interface

2 New Statutory Instruments (Regulations)

Competent Authorities



Two Regulatory Bodies for Radiation Protection

EPA
Regulatory Framework and Inspections

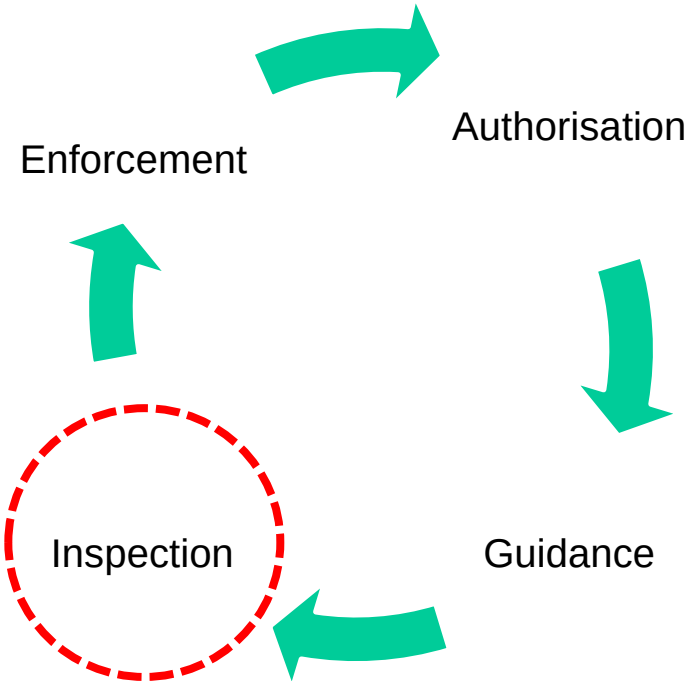
Occupational and Public Exposures

Tanya Kenny
Collette O'Connor

BSS Transposition - *Key Points for Nuclear Medicine*
Regulations Strengthened

- Requirement to designate on site Radiation Protection Officer
  - Increases profile as now statutory role
  - Increases ownership of operational radiation protection
  - Regulatory Body to set minimum training requirements
- Service Level Agreement
  - Between undertaking and qualified expert
  - Submitted to Regulatory Body
- Education and Training in Radiation Protection
  - More specific - to cover all relevant ancillary staff
  - High Activity Sealed Sources (HASS)
  - Refresher Training in RP
  - Requirement for staff input to Risk Assessments

Regulatory Framework – Key Components



Workers

Members of the Public

Justification and Optimisation

Inspections Focus

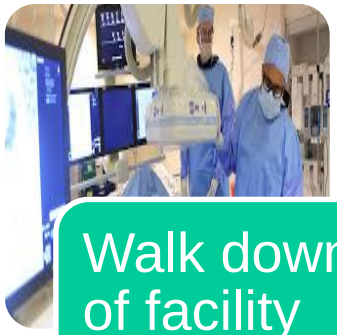
- Assess compliance with legislation and licence conditions
- Assess how radiation protection is implemented in practice
- Assess the organisational culture and commitment to radiation protection
- Promote good practice
- Provide an opportunity for licensees to raise issues with the regulatory authority
- Nuclear Medicine inspection frequency currently every 3 years

Inspector Competence
ISO Accreditation for Inspection Activities

- Inspectors warranted
- Structured Inspector training programme
  - Observation Period
  - Supervisory Period
  - Competency sign off
- Inspection Witnessing
  - All inspectors witnessed once every two years by technical manager
  - Assists consistency of approach

Inspection Method

Entrance Meeting



Walk down of facility

- Observe procedures

Review relevant records

Inspectors Private Discussion

Close out Meeting - Senior Management Presence Important

Inspection Process

Challenges

- Access Issues - Key personnel or records
- Consent - observing patient procedure
- Data protection

What works well?

- Multiple inspectors - Enabler of discussion to determine any underlying issues
- Observing procedures underway - yields great insight into radiation protection practice
- Positive message of being on site to staff – *the regulator cares*

Some Effective Regulatory/Compliance Tools Utilised

- Licensing embargos
- Licensing restrictions – equipment taken out of operation
- Increased regulatory surveillance
- Increased reporting requirements – quarterly, six monthly

New and Topical Issues

- The growth of Nuclear Medicine Procedures
- Governance and Responsibilities
  - Targeted Nuclear Medicine and Radiotherapy
  - Outsourcing of nuclear medicine services to third party
- Topical recent authorisations
  - Xofigo Ra- 223 – waste issues
  - Lu -177
  - Generation of Gallium – 68
- Robustness of Patient instruction information for discharge
  - Recent incidents
    - Iodine Seeds
    - Emergency Surgery

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HERCA Nuclear Medicine MedInspector Workshop

6–8 November 2018, Stockholm, Sweden

John Tuffy – Regional Manager (Ionising Radiation)
Health Information and Quality Authority(HIQA)
Ireland

Introduction to HIQA

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- HIQA is an independent authority that exists to improve health and social care services for the people of Ireland.

- In Healthcare, we inspect public acute hospitals, talk to hospital patients, staff and managers to determine if hospitals are meeting nationally agreed Standards of care. National Standards describe what patients and people using services should expect when they experience a healthcare service

- Directorates within HIQA
  - Regulation
  - Health Technology Assessment
  - Health Information and Standards

There are four distinct pillars delivering programmes of regulation

- Disability Services (Adults and Children)
- Older People's Services
- Children's Services
- Healthcare (envisaged there will be an amendment off primary legislation to include Ionising Radiation which will allow access to public and private facilities)

How we currently monitor and report in Healthcare

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- Receipt of information – business intelligence/data surveillance
- Self-assessment
- Thematic inspection
  - Announced and unannounced inspection (usually one day, with a team of one to two staff for larger Healthcare facilities)
  - If announced, usually request pre-onsite information
- Investigation or large service review
- We then publish the findings of our inspection reports on our website.

Oversight of Ionising Radiation legislation in Ireland

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- Up to this point, the EPA have been the sole formal regulator from the point of view of environmental and occupational exposures.
- There has been a gap in formal regulation of the medical exposure.
- Until enactment of new legislation, the Department of Health is the competent authority for medical exposures and MERU will maintain current functions.
- It is anticipated the legislation will transfer the competent authority and regulatory functions for patient radiation protection from the DOH and MERU to the Health Information and Quality Authority (HIQA).
- It is anticipated that relevant Justification and Optimisation regulations will remain true to the BSS Directive without further requirements.

Preparations for the transfer in function to HIQA

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- Stakeholder engagement –engage fully with relevant professionals involved in medical exposures post commencement. We have convened an Expert Advisory Group to advise at key stages of regulatory programme.

- Recruitment of specialist inspectors from clinical/regulatory backgrounds.

- Certified training of non specialist inspectors in radiation protection.

- HIQA has vast experience in formal regulation in adult and social care-Internal training in proportionate regulation is transferrable to new area of medical exposures.

Expert Advisory Group

Health Service Executive Acute Hospitals Division
Quality Assurance and Verification Division Health Service Executive
Environmental Protection Agency
Faculty of Radiologists (Radiology)
Irish Institute of Radiographers and Radiation Therapists
Irish Association Physicists in Medicine
Irish Dental Association
Private Hospitals Association
Faculty of Radiologists (Radiation Oncology)
Irish Cancer Society
Public Health England
Health Products Regulatory Authority

Proposed initial regulatory activity

- After commencement and handover of incident reporting has been completed, HIQA plan to produce guidance on the regulations as an aid to undertakings.
- HIQA also plan to issue an online self assessment to be completed by undertakings.
- Each undertaking will use this opportunity to self determine their compliance with regulations.
- The returned information will help HIQA get a baseline assessment of adherence to regulations in each undertaking.
- Each undertaking can use their own information as a quality improvement process.

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Section 1: Infection prevention and control programme			
1.1.1	The hospital has a formalised governance structure for infection prevention and control.	Yes	No
1.1.2	An annual infection prevention and control risk assessment is performed which takes into consideration potential risks for infection, contamination, and infection-related exposures in the hospital in addition to local and national antimicrobial resistance trends.	Yes	No
1.1.3	The hospital develops an annual infection prevention and control programme plan which includes priorities based on identified risks and the demographic profile of the population served by the hospital.	Yes	No
1.1.4	An annual infection prevention and control report is produced.	Yes	No
1.1.5	The hospital provides financial and human resource support for maintaining the infection prevention and control programme.	Yes	No
1.1.6	Written infection prevention and control policies, procedures and guidelines available in each clinical area are current, and are based on evidence-based best practice guidelines and national standards and safety alerts including those from the National Clinical Effectiveness Committee, the Health Protection Surveillance Centre, the Health Service Executive, HIQA and others as applicable.	Yes	No
1.1.7	The performance of the service in relation to the prevention and control of healthcare-associated infection is continuously monitored within the hospital. There is measurement of performance indicators and targets that are relevant to the service.	Yes	No
1.1.8	There is reporting in relation to prevention and control of healthcare-associated infection performance through formalised governance structures.	Yes	No
1.1.9	Written reports are prepared following significant outbreaks of infection to identify opportunities for improvement.	Yes	No
1.1.10	Information about infection prevention and control is provided to patients and their carers and or visitors.	Yes	No

Formal Regulatory site visits

- After review of self assessment responses , HIQA will commence a risk based approach to regulation.
- Will involve on site inspections across a range of services(dental,nuclear medicine, radiology, radiotherapy etc.)
- Information used to devise this approach will include
    - Self assessment results
    - Incident reporting
    - Unsolicited information
    - The types of services provided
    - Size and scale of activities

- Guides to be issued in advance.
    - Guide to inspection programme
    - Assessment framework on how our regulatory decisions are based

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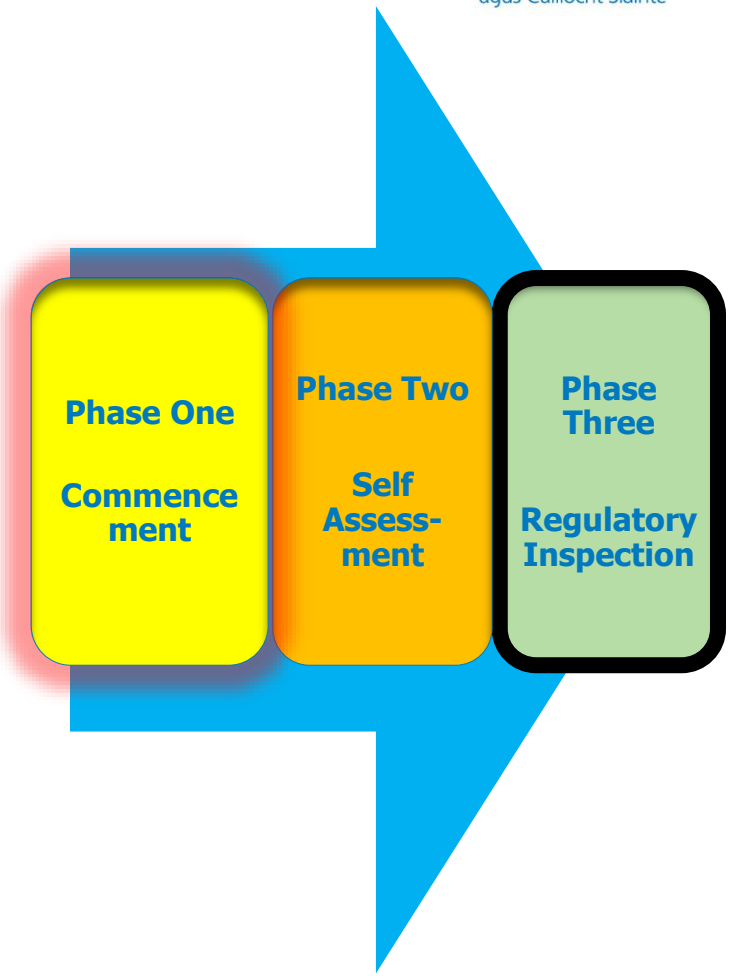

Beyond the BSS Transposition
Ongoing and Future Work

- Collaborative working between the two regulators
- Data Sharing
- Memorandum of Understanding
- Coherent Approach to regulating Radiation Protection
- Combine Patient/ Occupational/ Public Protection during inspections

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Thank you

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