Evolution of the System of Regulation

Ireland

Decision aiding tools in Developing a Graded Approach to Authorisation

19th EAN WORKSHOP “INNOVATIVE ALARA TOOLS” JOINTLY ORGANISED WITH THE PODIUM (Personal Online DosImetry Using computational Methods) PROJECT
Agenda

- Regulatory Control of Ionising Radiation
- Transforming Regulatory Regime
- Graded Approach to Authorisation
  - Development
  - Implementation
  - Implications
- Further Work
  - Focus on going Beyond Compliance – promoting ALARA
  - Innovation
Regulatory Control of Ionising Radiation

- **Public value Proposition**
  - To manage the risks associated with the beneficial use of ionising radiation

- **Regulate all users of ionising radiation**
  - To ensure safety of workers and members of the public
Drivers for Regulatory Reform

- Strategic Requirements
- Consistency
- European Directives and Policy
- Transparency
- Sustainability
- Credibility

Decision to Develop Graded Approach to Regulation
What is graded authorisation?

- Graded authorisation is one element of a system of risk based regulation.
- Regulatory effort focused according to risk.
- Authorisation by **registration** or **licensing**:
  - magnitude and likelihood of any exposures;
  - the impact of the regulatory control.

Moving from one size fits all system where all practices licensed.
Developing Graded Authorisation Model for Ireland
Development of a Proposed Model for Graded Authorisation

A more graded approach to regulation in place based on the risk associated with the use of ionising radiation; delivering a more efficient use of resources without compromising on safety.

Some fundamentals

- No compromise to safety or security
- Related to justified practices
- Licensing and registration will be different processes
- The model will be dynamic and evidenced based
- Stakeholder engagement and peer review
- Public value
Model Development Phases

- Identification of drivers and principles underlying change
- Investigation of international guidance
- Development of criteria for deciding the level of authorisation
- Development of models for registration and licensing
- Interpretation in Irish context (for existing licensee base)
- Gathering evidence on practical implications and risks
Flow of Decision Criteria For Registration Candidates

1. **EU BSS Directive**
   - Mandatory licensing for certain practices

2. **IAEA Categorisation of Sources**
   - Based on Risk
   - Implement IAEA categorisation of sources

3. **IAEA Regulatory Control**
   - Suggested Criteria for Registration (IAEA BSS)

4. **Risk Assessment**
   - Analyse Risk associated with the practice
   - Apply Regulatory Experience

5. **Identifying lower risk practices**
   - Identification of the practices that are suitable for registration
Refer to IAEA

- Does the facility or equipment design ensure safety?
- Are operating procedures simple to follow?
- Are safety training requirements minimal?
- Is there a history of few problems with safety in operation?
- Is safety largely/significantly independent of human activity?
- What are the security considerations?
- What is the likelihood and possible consequences of, and the level of risk associated with, a loss of control.
Risk analysis for the practice:
Could the application be addressed in generic risk assessment?

- Identify the risks associated with the practice – e.g security screening X-ray
- Who are the groups exposed to radiation?
- Magnitude and likelihood of exposures;
  - Control measures in place to minimise risk (room design, training, PPE)
  - Possibility and probability of accidental exposures
- Availability of Standard Radiation Safety procedures/Regulatory Decisions/guidance
- Historical data and personnel dosimetry if available
- Effectiveness of regulatory control (does more stringent regulatory control reduce exposures further or improve safety of installations)

Informing Decision to authorise by Registration
<table>
<thead>
<tr>
<th>Registered Practices (Medical)</th>
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<tr>
<td>Dental cone beam CT</td>
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<tr>
<td>Registration</td>
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<tr>
<td>Dental radiography using an intra/extra oral unit (except handheld)</td>
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<tr>
<td>Registration</td>
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<tr>
<td>Bone densitometry giving rise to a medical exposure</td>
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<tr>
<td>Registration</td>
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<tr>
<td>General radiography giving rise to a medical exposure in a medical radiological installation</td>
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<td>Registration</td>
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<td>Mammography giving rise to a medical exposure</td>
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<td>Registration</td>
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<td>Specimen radiography for medical purposes</td>
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<td>Licensed Practices (Medical)</td>
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<tr>
<td>Dental radiography using handheld intra oral unit</td>
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<td>CT giving rise to a medical exposure in a medical radiological installation</td>
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<td>Fluoroscopy giving rise to a medical exposure in a medical radiological installation</td>
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<td>Interventional radiology giving rise to a medical exposure in a medical radiological installation</td>
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<td>Mobile radiography/fluoro giving rise to a medical exposure in a medical radiological installation</td>
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<td>Licensed Practices (Medical)</td>
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<tr>
<td>Nuclear Medicine giving rise to a medical exposure in a medical radiological installation</td>
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<td>PET/CT giving rise to a medical exposure in a medical radiological installation</td>
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<td>Radiotherapy using a LINAC in a medical radiological installation</td>
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<td>Radiotherapy using brachytherapy in a medical radiological installation</td>
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<tr>
<td>Radiotherapy using X-Ray in a medical radiological installation</td>
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Implementing Graded Authorisation
Enabling Legislation

• New Regulations introduced two forms of authorisation:
  ➢ registration and licensing

• The Regulations list practices, which must be licensed (nuclear medicine, incorporation in consumer products, HASS, etc.)

• For other practices the decision on registration or licensing rests with the regulatory authority (EPA)
  ➢ Designed as dynamic system
  ➢ Can modify categories based on experience & advances in technology

• Regulatory Body publish on its website the list of justified practices which are subject to registration and licensing
Enabling IT System
On-line services, two perspectives

Licensees
Inbuilt decision making to guide applicant to appropriate authorisation level based on risk

EPA Staff
Records regulatory decisions on authorisation and inspections

Web Portal
Internal Platform (CRM System)
Online application – Registration

- IT Intelligence guides applicant
- Inbuilt Decision Making
- No inspector input/sign off
- Assumption of compliance
- Onus on applicant to comply
- Certificate of Registration Issued

Critical Supports
- Self declaration
- Code of practice to aid compliance
- Compliance Assurance Methods
  - Sampling – QA of applications
  - Questionnaires
  - Inspections where necessary

Reduced administrative burden
**Self Declaration on Application**

I confirm that, prior to the commencement of any registered practice, I have, in accordance with the provisions of Ionising Radiation Regulations 2019 (IRR19)

| Completed a risk assessment to assess the nature and magnitude of the risks of exposure to ionising radiation arising from the practice or from potential exposures resulting from the practice for workers and members of the public who may be affected, and to identify the protective measures needed to restrict exposures to ionising radiation (regulation 31 and associated EPA guidance). | ☐ |
| Have implemented the protective measures identified in the radiation risk assessment that will restrict my employees’ and other persons’ exposure to ionising radiation (regulation 32 and associated EPA guidance) | ☐ |
| Will consult with a suitable Radiation Protection Adviser (RPA) as appropriate (regulation 33 and associated EPA guidance) | ☐ |
| Have designated a Radiation Protection Officer (RPO) to supervise or perform radiation protection tasks (regulations 34 and 80 and associated EPA guidance) | ☐ |
| Will provide appropriate training, information and instruction to any of my employees engaged in work with ionising radiation, and those likely to be affected by that work, and such training will be repeated at appropriate intervals (regulation 35 and associated EPA guidance) | ☐ |
| Have, where required, correctly classified and demarcated any controlled and/or supervised areas (regulations 36 and 37 and associated EPA guidance) | ☐ |
| Have drawn up procedures to be followed in the event of a reasonably foreseeable incident liable to have radiation safety implications as identified in the risk assessment (regulation 32 and associated EPA guidance) | ☐ |
Online application – Licensing

- IT system will direct applicant to licensing
  - Dependent on the practice
  - Complete details and submit documentation

- Inspector Review and assessment

- Compliance Assurance Methods
  - Inspections
  - Questionnaires
  - Sectoral Analysis
Licence Application Process – Information required

- Legal entity & address
- Contact person (CEO/GM)
- Source details and locations
- RPO and RPA details
- Licence fee
- Risk assessment
- Radiation safety procedures
- Shielding requirements
- Emergency plans
- Intervention plans

Safety Assessment (IAEA BSS)
Radiological Protection Licence

Please note that changes made to any records on your licence (Licence Details, Premises, Personnel, Inventory) will not be forwarded to the EPA for approval until you navigate to the COMPLETE step and select the SUBMIT button. Documents to support any changes may be uploaded in the DOCUMENTS step and will only be forwarded to the EPA when the request is submitted.

Licence Details for ACME Radiological Services

Welcome to the Radiological Protection licence amendment process. Any changes to the nature of activities or licensed practices detailed below should be included in the Background Information box on the Complete step.

- **Type of radiological practice:** Industrial
- **Nature of activities:** Cabinet style X-ray
- **Licensed practices:** Custody, Use
- **Your approved dosimetry service provider:** GE Healthcare Ltd

Details of approved dosimetry service providers are available on [http://www.epa.ie/radiation/lic/dosimetry/](http://www.epa.ie/radiation/lic/dosimetry/).
Implications of Graded Authorisation for Ireland
Previous Regulatory Framework

LICENSEES UNDER LEGISLATION OF 2000

- Dental: 54%
- Industry: 20%
- Medical: 8%
- Vet: 18%

One size fits all

1759 Licensees
New Regulatory Framework
2019 Legislation

CERTIFICATE OF REGISTRATION
- Vet: 16%
- Medical: 1%
- Industry: 16%
- Dental: 67%

LICENCE
- Vet: 27%
- Medical: 33%
- Industry: 33%
- Dental: 7%

Total 1396
Total 363
Implications of New Regulatory Regime

- Represents the transformational change to our system of regulatory control in 30 years
- Enables better deployment of resources
- Allows rebalancing and targeting of regulatory effort where we can have the highest regulatory impact
  - Focus on higher risk practices
- For registered practices
  - Reduced administrative burden – leverage IT systems
  - Streamlined processes
  - Reduced fees
- Strengthened regulatory framework
- Improved radiation safety
Further Work

- Focus on going ‘Beyond Compliance’ – driving ALARA
- Communications key in driving behaviours
- Codes of Practice
- Exploring Role of Social Media in regulatory approach
- Recognising Innovation can be evolution not revolution
  - Incremental improvements important
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