Evolution of the System of Regulation

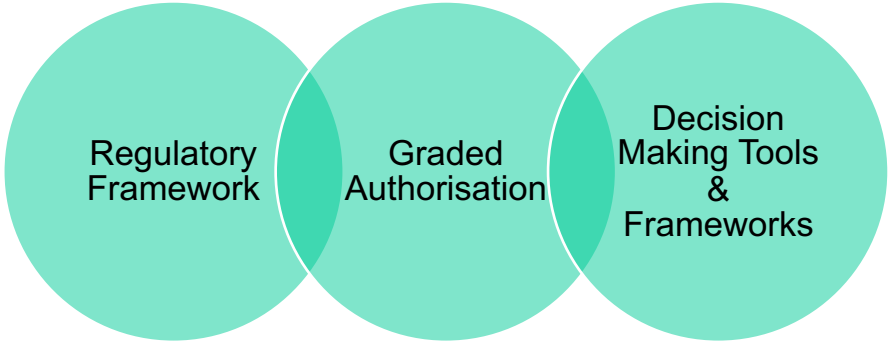
Ireland

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

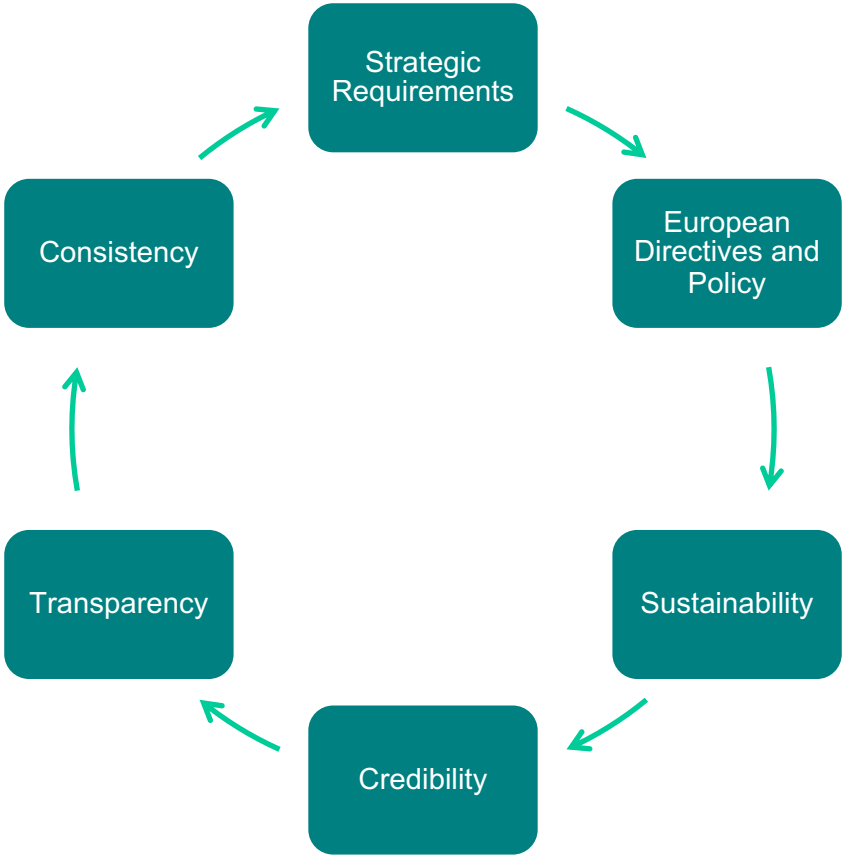


- Further Work
  - Focus on going Beyond Compliance – promoting ALARA
  - Innovation

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

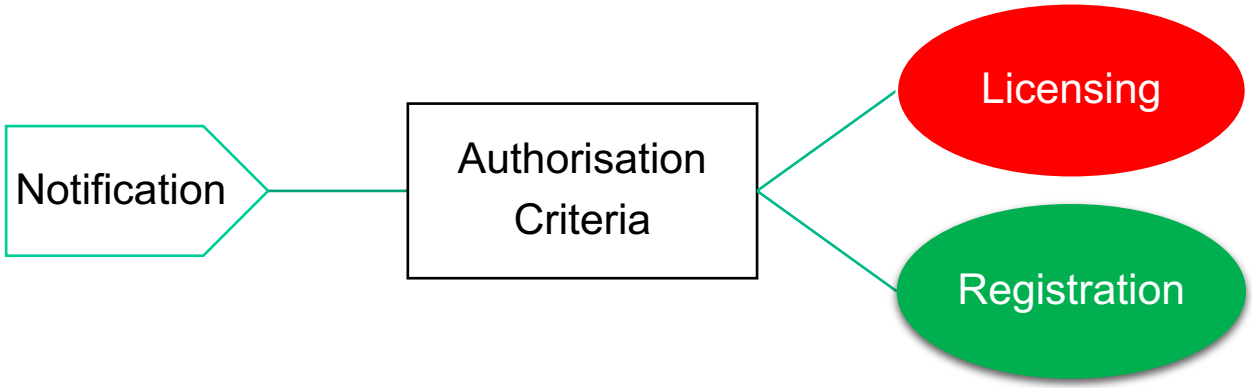
Drivers for Regulatory Reform



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

October | 12

Proposals for a Graded Authorisation Model for the use of Ionising Radiation in Ireland

For the Regulatory Service of the Radiological Protection Institute of Ireland

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.

https://www.epa.ie/pubs/advice/radiation/RPII_Proposal_Graded_Authorisation_Model_Radiation_2012.pdf

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

EU BSS Directive

Mandatory licensing for certain practices

IAEA Categorisation of Sources

Based on Risk

Implement IAEA categorisation of sources

IAEA Regulatory Control

Suggested Criteria for Registration (IAEA BSS)

Risk Assessment

- Analyse Risk associated with the practice
- Apply Regulatory Experience

- Identification of the practices that are suitable for registration

Identifying lower risk practices

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)

Registered Practices (Medical)

Dental cone beam CT	Registration
Dental radiography using an intra/extra oral unit (except handheld)	Registration
Bone densitometry giving rise to a medical exposure	Registration
General radiography giving rise to a medical exposure in a medical radiological installation	Registration
Mammography giving rise to a medical exposure	Registration
Specimen radiography for medical purposes	Registration

Licensed Practices (Medical)

Dental radiography using handheld intra oral unit	Licence
CT giving rise to a medical exposure in a medical radiological installation	Licence
Fluoroscopy giving rise to a medical exposure in a medical radiological installation	Licence
Interventional radiology giving rise to a medical exposure in a medical radiological installation	Licence
Mobile radiography/fluoro giving rise to a medical exposure in a medical radiological installation	Licence

Licensed Practices (Medical)

Nuclear Medicine giving rise to a medical exposure in a medical radiological installation	Licence
PET/CT giving rise to a medical exposure in a medical radiological installation	Licence
Radiotherapy using a LINAC in a medical radiological installation	Licence
Radiotherapy using brachytherapy in a medical radiological installation	Licence
Radiotherapy using X-Ray in a medical radiological installation	Licence

Implementing Graded Authorisation

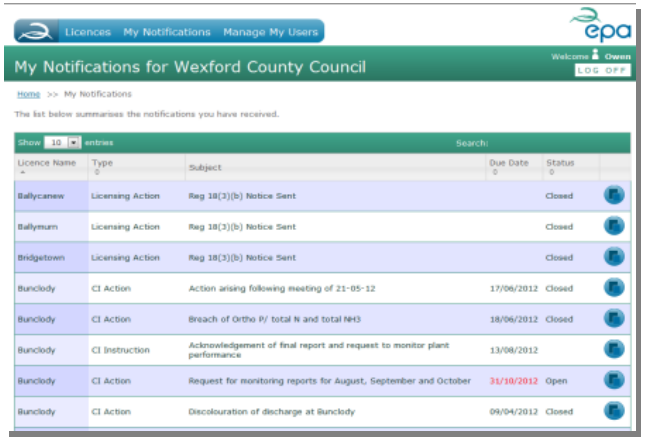
Enabling Legislation

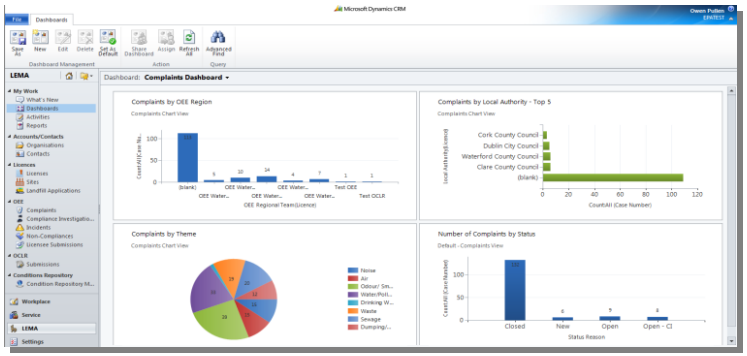
- New Regulations introduced two forms of authorisation:
  - registration and licensing
- The Regulations list practices, which must be licensed (nuclear medicine, incorporation in consumer products, HASS, etc.)
- For other practices the decision on registration or licensing rests with the regulatory 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

EPA Staff





Web
Portal

Internal Platform
(CRM System)

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

Records regulatory decisions on authorisation and inspections

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

Environmental Protection Agency

Licence

L2145-06

The Environmental Protection Agency, in accordance with the terms of the Radiological Protection Act, 1991 (Ionising Radiation) Regulations 2019, hereby authorises the Undertaking

Galway Clinic Doughiska Ltd
Galway Clinic,
Doughiska,
Galway

to carry out the practice(s) listed in Table 1 using the Radiation Sources/Accelerators listed in Schedule 2 for the purposes therein at the authorised premises listed in Schedule 4 subject to the conditions listed in Schedule 1 of this Authorisation. These conditions may be amended at the discretion of the Environmental Protection Agency.

This authorisation does not exempt the Undertaking from compliance with other regulations or statutory requirements.

Signed Tanya Kenny Date 02 April 2019

On behalf of the Environmental Protection Agency

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/.

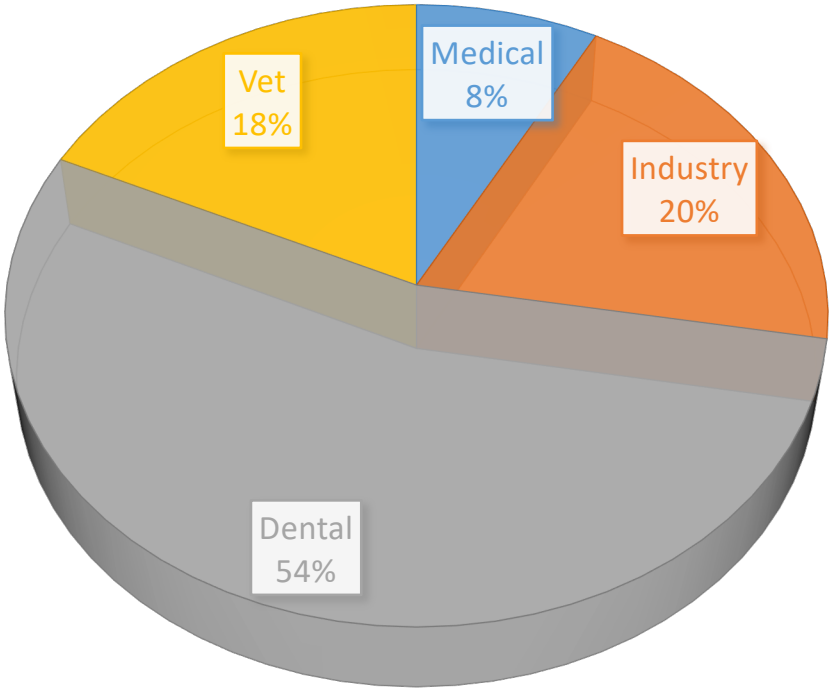
Save

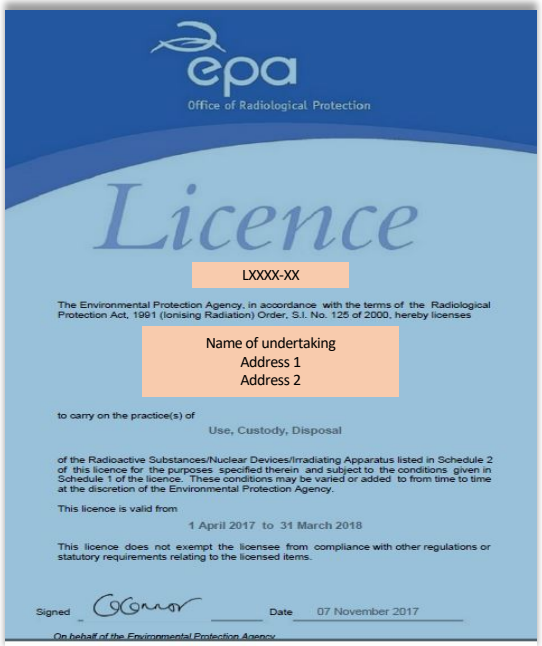
Go to Complete | Premises >

Implications of Graded Authorisation for Ireland

Previous Regulatory Framework

LICENSEES UNDER LEGISLATION OF 2000





epa
Office of Radiological Protection

Licence

LXXXX-XX

The Environmental Protection Agency, in accordance with the terms of the Radiological Protection Act, 1991 (Ionising Radiation) Order, S.I. No. 125 of 2000, hereby licenses

Name of undertaking
Address 1
Address 2

to carry on the practice(s) of

Use, Custody, Disposal

of the Radioactive Substances/Nuclear Devices/Irradiating Apparatus listed in Schedule 2 of this licence for the purposes specified therein and subject to the conditions given in Schedule 1 of the licence. These conditions may be varied or added to from time to time at the discretion of the Environmental Protection Agency.

This licence is valid from

1 April 2017 to 31 March 2018

This licence does not exempt the licensee from compliance with other regulations or statutory requirements relating to the licensed items.

Signed _____ Date 07 November 2017

On behalf of the Environmental Protection Agency

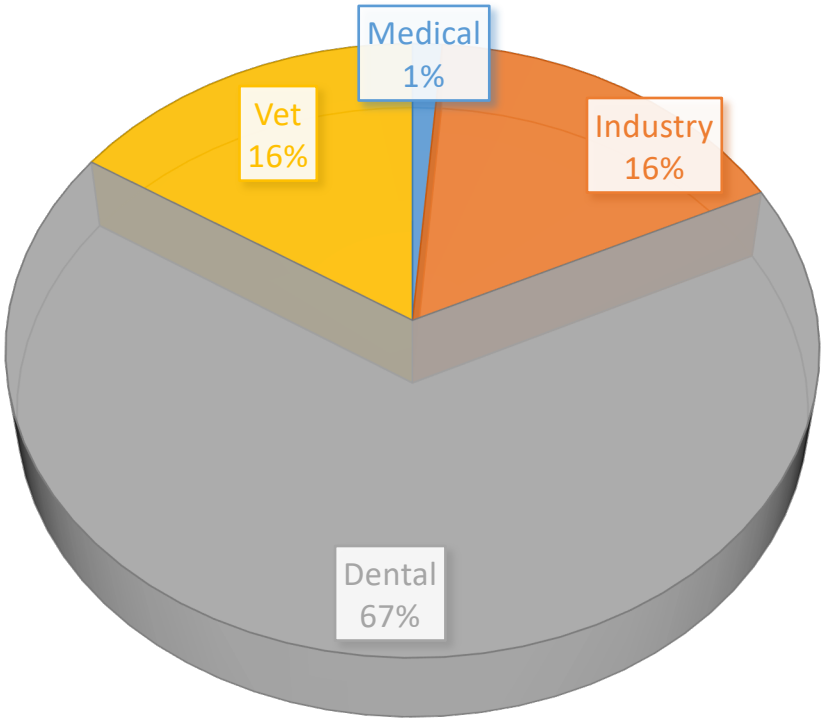
One size fits all

1759 Licensees

New Regulatory Framework

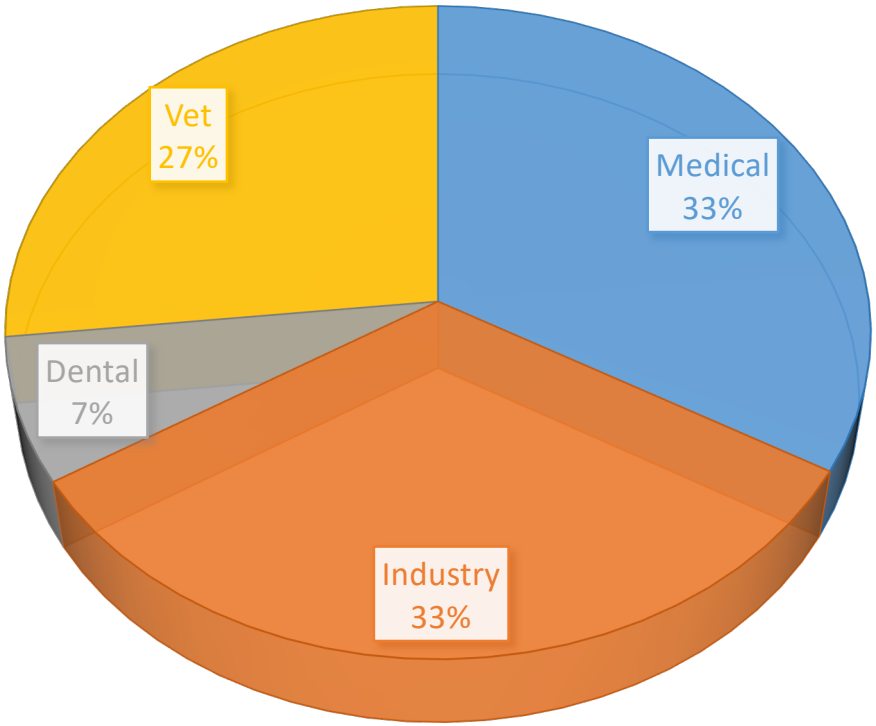
2019 Legislation

CERTIFICATE OF REGISTRATION



Total 1396

LICENCE



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
- T.Kenny@epa.ie