

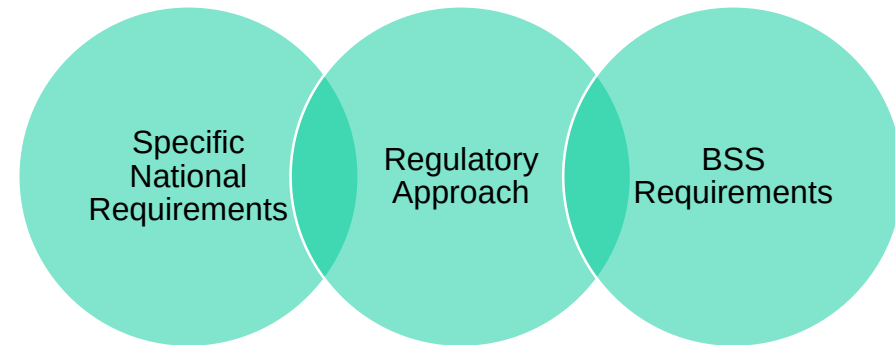
Evolution of the System of Regulation

Ireland

Tanya Kenny

Agenda

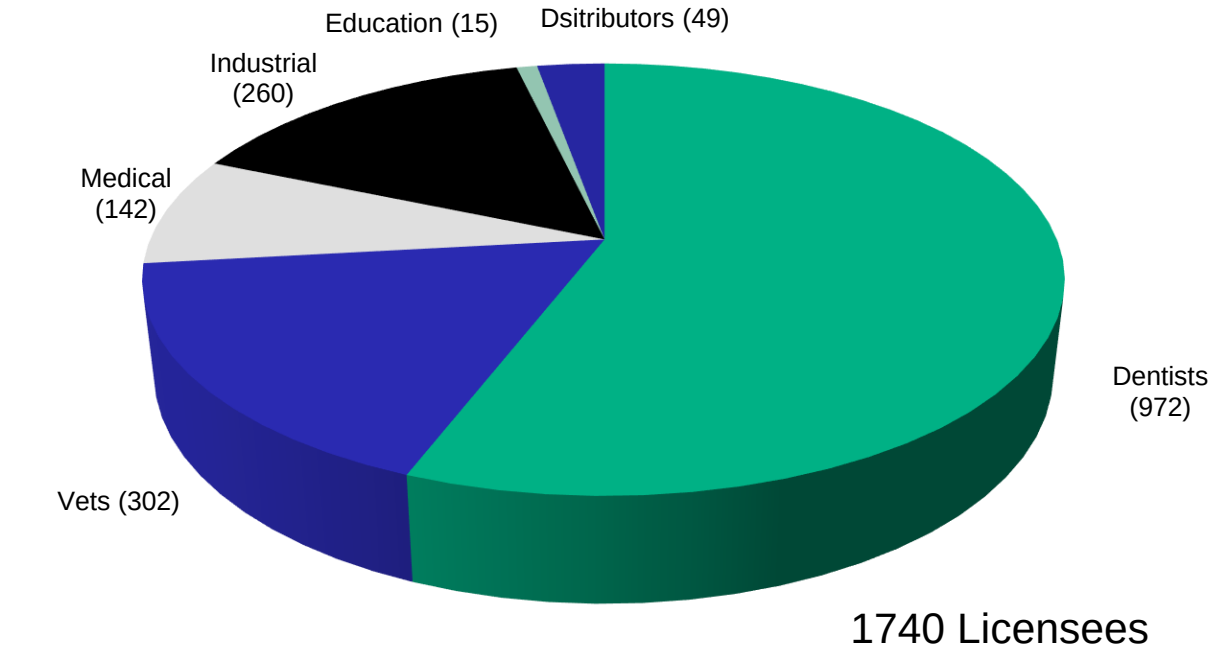
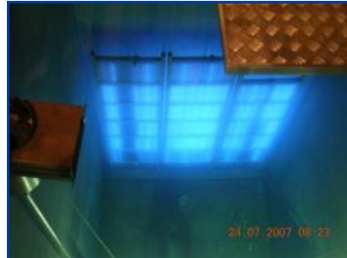
- Current system
- New Regulations
- Changing Regulatory Context
- Regulatory Approach
- Development of Graded Authorisation Model
- Implementation Graded Authorisation
 - Critical Success Factors
 - IT Development – GAMIS
 - Codes of Practice
- Implications of Graded Authorisation



Ireland's Current Regulatory Framework

- Radiological Protection Act, 1991
 - Licensing system
 - Appointment of inspectors
 - Offences & enforcement powers
- Regulate all users of ionising radiation
 - To ensure safety of workers and members of the public
 - Authorisation (Licensing), Inspection, Enforcement and Guidance
- Currently one size fits all model
- All users of a radiation in Ireland require a **Licence**

Who do we regulate?



How do the new Regulations differ?

Radiation safety requirements

Justification strengthened
Strengthened requirements on non-medical human imaging
Eye dose
Disposal of unsealed sources
Training requirements
Radon (Evolution rather than revolution)

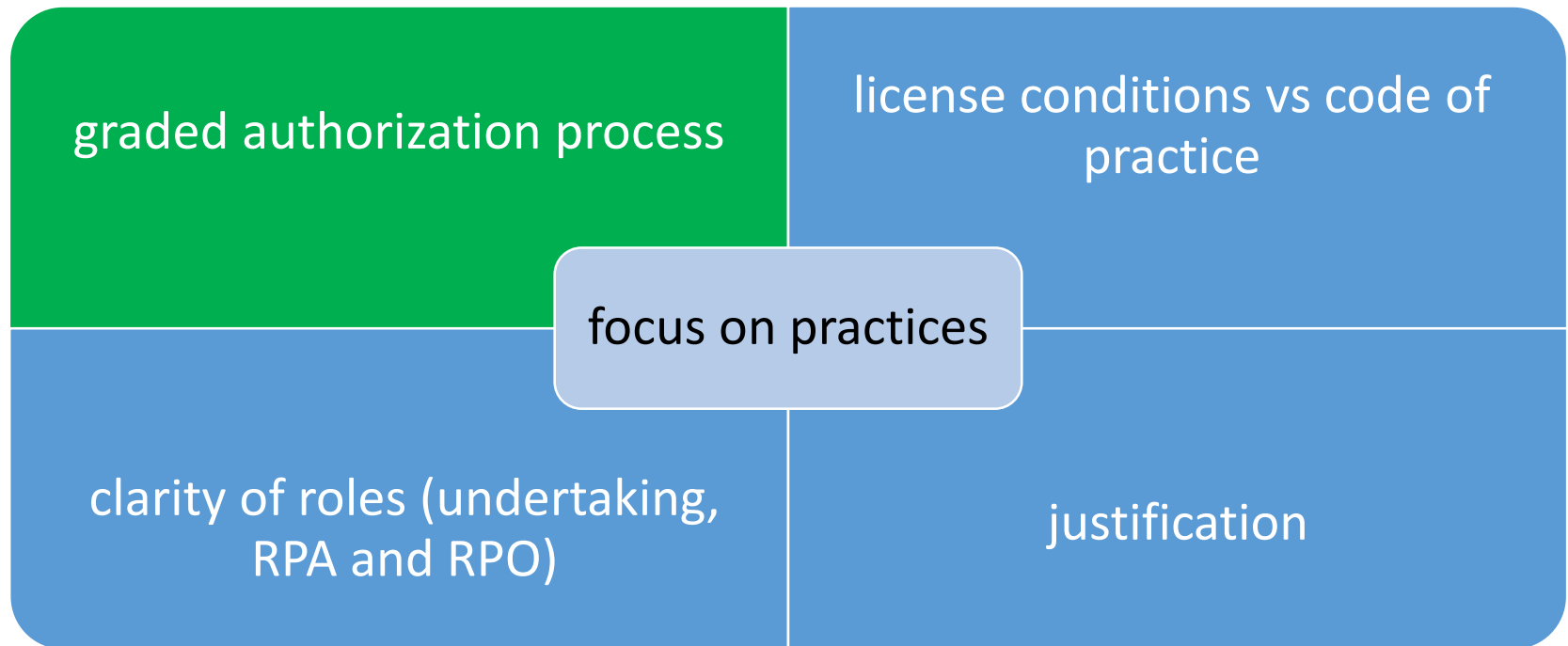
System of Regulation

2 Regulators
Graded authorisation
Further consolidation of the risk based approach
Responsibilities of RPA, RPO, MPE, undertaking, etc.
(Relatively significant change)

Our changing regulatory context

- New regulatory will be take over responsibility patient protection regulation.
- Old licensing health care paradigm: undertaking owns & operates equipment, employs own staff and often employs its own RPA. Now we are seeing greater range and complexity of delivery models.
- Accelerating rate of technological change and increasing complexity of applications across all sectors.
- Move to towards greater use of centres of excellence and increasing specialism.
- Improving economy is resulting increased activity across all sectors.

Regulatory approach - Changes



What do we mean by a practice (examples):

- Dental radiography in a risk assessed clinic.
- Nuclear medicine giving rise to a medical exposure in a medical radiological installation.
- Use of sealed sources in industrial process control.
- Security screening of baggage, cargo or parcels using X-ray within shielded enclosure.

Developing Graded Authorisation – New Regulations

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.

Some fundamentals

- No compromise to safety or security
- Related to justified practices
- Stakeholder engagement and peer review
- Public value



Implement IAEA categorisation of sources

Suggested Criteria for Registration (IAEA BSS)

- Analyse Risk associated with the practice
- Apply Regulatory Experience

- 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 units

Then ask the following:

- Who are the groups exposed to radiation?
- Magnitude and likelihood of exposures;
 - Control measures in place to minimise risk (room design, training, PPE, etc)
 - Possibility and probability of accidental exposures
- Availability of Standard Radiation Safety procedures/Regulatory Decisions/other 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).

Implementing Graded Authorisation – New Regulations

Authorisation

- The Regulations introduce 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)
 - can be changed relatively easily based on experience, advances in technology, etc.
- The EPA will publish on its website lists of justified practices which are subject to registration and licensing.

GAMIS

(Graded Authorisation Management Information System)

- **LEMA - Licensing Enforcement Management Application**
 - System Developed within LEMA on EPA IT platform
- **EDEN – Environmental Data Exchange Network**
 - EPA Web Portal – interface with licensees, applicants for online interaction
 - Primary communication tool with licensees
- **CRM – Customer Relation Management**
 - ORP Interface for processing licensing functions, managing inspections

On-line services, two perspectives



Licensees

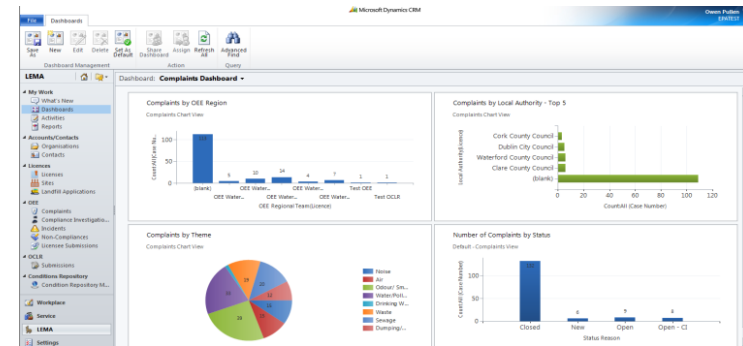
My Notifications for Wexford County Council

The list below summarises the notifications you have received.

License Name	Type	Subject	Due Date	Status
Ballycanew	Licensing Action	Reg 18(3)(b) Notice Sent		Closed
Ballymun	Licensing Action	Reg 18(3)(b) Notice Sent		Closed
Bridgetown	Licensing Action	Reg 18(3)(b) Notice Sent		Closed
Buncloody	CI Action	Action arising following meeting of 21-05-12	17/06/2012	Closed
Buncloody	CI Action	Breach of Ortho P/ total N and total NH3	18/06/2012	Closed
Buncloody	CI Instruction	Acknowledgement of final report and request to monitor plant performance	13/06/2012	
Buncloody	CI Action	Request for monitoring reports for August, September and October	31/10/2012	Open
Buncloody	CI Action	Discolouration of discharge at Buncloody	09/04/2012	Closed

EDEN
Portal

EPA Staff



LEMA /CRM
Platform

Online application – Registration

- Self declaration questions
- No inspector input/sign off
- Assumption of compliance
 - Onus on applicant to comply
- Compliance Assurance Methods
 - Sampling – QA of applications
 - Questionnaires
 - Inspections where necessary

Example of Registered Practices:

- Dental Radiography
- General Radiography
- Bone Densitometry

Declaration – Registration Only

Self Declaration

I confirm that, prior to the commencement of any registered practice, I have in accordance with the provisions of Ionising Radiation Regulations 2018 (IRR18) and associated EPA Codes of Practice (COP)

- Completed a prior radiation 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 COP of IRR18) ☐
- Have implemented the protective measures identified in my radiation risk assessment that will restrict my employees' and other persons' exposure to ionising radiation (regulation 32 and associated COP of IRR18) ☐
- Have consulted with a suitable Radiation Protection Adviser (RPA) (regulation 33 and associated COP of IRR18) ☐
- Have designated a Radiation Protection Officer (RPO) to supervise or perform radiation protection tasks within the practice (regulation 34 and associated COP of IRR18) ☐
- 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 COP of IRR18) ☐
- Have, where required, correctly classified and demarcated any controlled and/or supervised areas (regulations 36 and 37 and associated COP of IRR18) ☐
- Have drawn up emergency response plans for all reasonably foreseeable radiation accidents involving emergency exposure situations identified in the radiation risk assessment (regulation 57 and associated COP of IRR18) ☐

I declare that to the best of my knowledge the particulars given in this application for Registration are true, and that I am duly authorised to submit this application for Registration on behalf of the Undertaking XXXXXXXXXX.

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)

[Home](#)[My Account](#) ▾[Apply For](#) ▾[Notify/Manage It](#) ▾[EPA Services](#) ▾[Other Applications](#) ▾[Apply For](#) / [Amendment](#)

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](#)[Premises](#)[Personnel](#)[Inventory](#)[Documents](#)[Complete](#)

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 >](#)

What will a licence/ Registration look like


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




Environmental Protection Agency

Certificate of Authorisation

LXXXX-XX

The Environmental Protection Agency, in accordance with the terms of the Radiological Protection Act, 1991 (Ionising Radiation) Regulations 2018, hereby authorises the Undertaking

Name of undertaking
Address 1
Address 2

to carry out the practice(s) of

Practice	Grade	Authorised From	Authorised To
General radiography giving rise to a medical exposure in a medical radiological installation	Licensed	31/03/2018	31/03/2019
CT giving rise to a medical exposure in a medical radiological installation	Licensed	31/03/2018	31/03/2019
Nuclear Medicine giving rise to a medical exposure in a medical radiological installation	Licensed	31/03/2018	31/03/2019
Nuclear Medicine giving rise to a medical exposure in a medical radiological installation	Licensed	31/03/2018	31/03/2019
Interventional radiology giving rise to a medical exposure in a medical radiological installation	Licensed	31/03/2018	31/03/2019
Mammography for health screening in a medical radiological installation	Licensed	31/03/2018	31/03/2019
Fluoroscopy giving rise to a medical exposure in a medical radiological installation	Licensed	31/03/2018	31/03/2019
Mobile radiography giving rise to a medical exposure in a medical radiological installation	Licensed	31/03/2018	31/03/2019
PET/CT giving rise to a medical exposure in a medical radiological installation	Licensed	31/03/2018	31/03/2019
Specimen radiography for medical purposes	Licensed	31/03/2018	31/03/2019

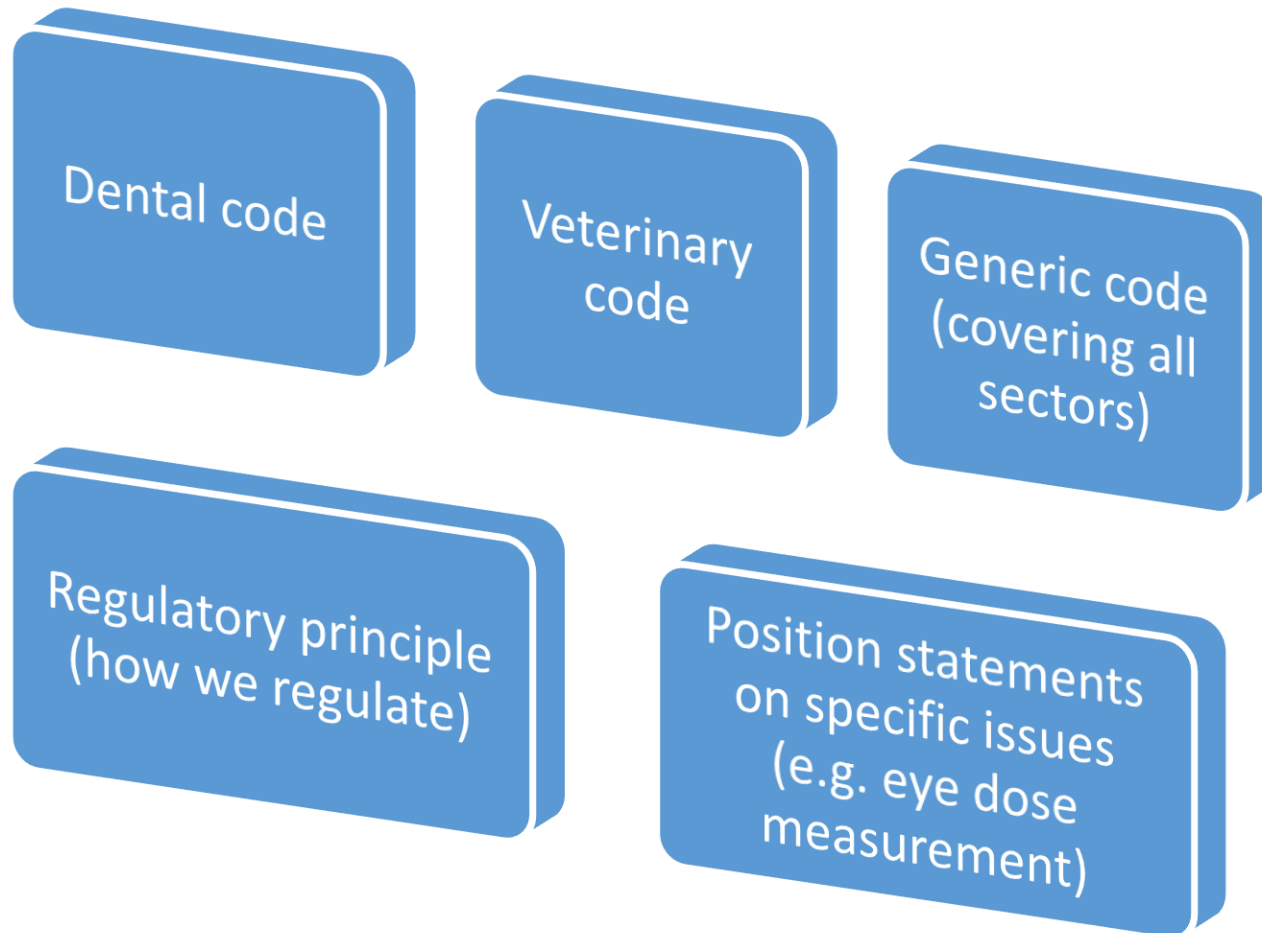
Schedules

1. Licence conditions
2. Sources
3. RPA/ RPO
4. Sites

Guidance/code of practice

- Move to simplify our current complex licence sets through the introduction of a code of practice.
- Aim to provide information necessary for compliance in the most simple/ efficient way possible.
- Code of practice sets out the regulator's view as to what constitutes compliance with the regulations. It is open to licensees to comply in some other way so long as they can demonstrate compliance.
- Plan to have 3 codes covering: dental, veterinary and a generic code covering all other sectors

Planned structure of code of practice



What Graded Authorisation means for Ireland

- Existing regulatory model 1740 licensees
- Move to approximately 400 licensees
- Better deployment of resources
- Regulatory Focus
 - Rebalancing of effort
 - Focus on higher risk practices
- For registered practices
 - Reduced administrative burden
 - Streamlined processes
 - Reduced fees
- Strengthened regulatory framework
- Improved Radiation Safety