Applying The Graded Approach To Authorisation Ireland

Noeleen Cunningham
Senior Inspector

Environmental Protection Agency

- The EPA is the national competent authority and regulatory body for regulating practices involving the use of ionising radiation.

- The EPA is primarily concerned with the radiological protection of Workers and Members of the Public against the hazards arising from exposure to sources of ionising radiation in the workplace.

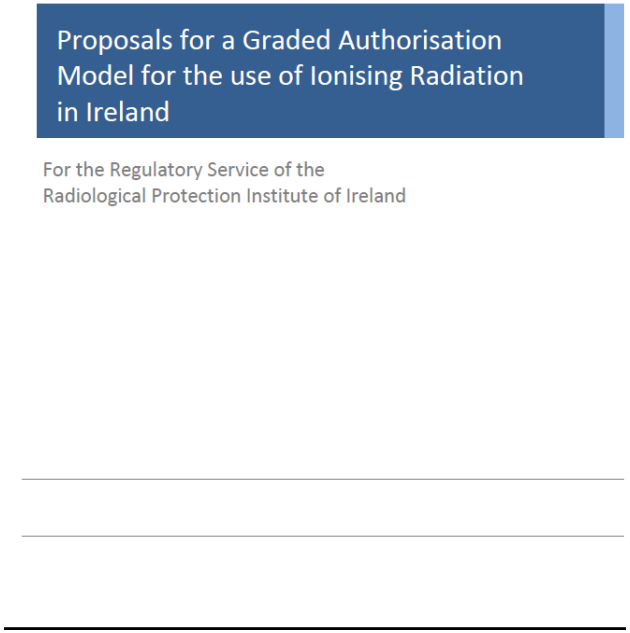
- Practices involving sources of ionising radiation are regulated through : Authorisation System
  Inspection Programme
  Enforcement Programme

Development of a Proposed Model for Graded Authorisation

October | 12

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



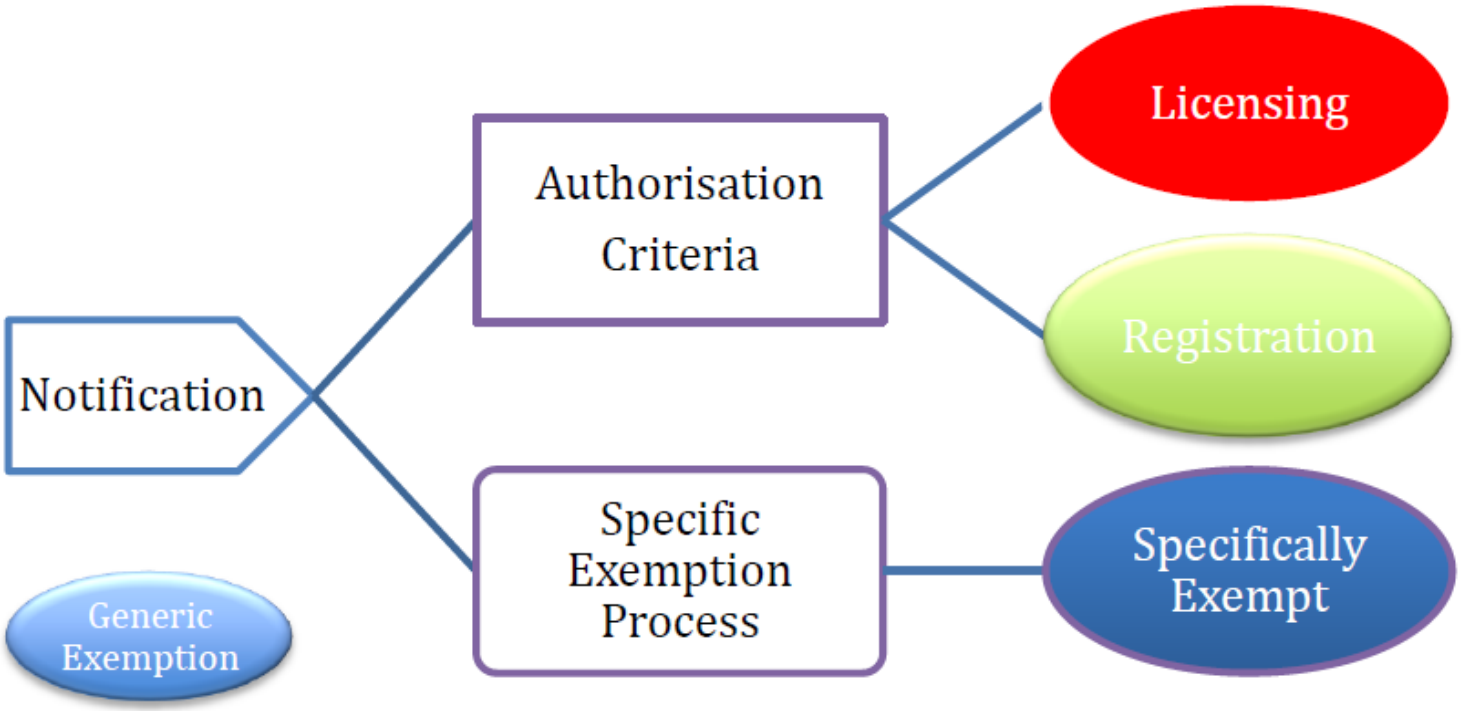
Some fundamentals

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

Authorisation

- Authorisation is the consent to carry out a practice
- New Irish Legislation now allows two forms of authorisation:
  - Registration and Licensing
- The BSS lists practices, which must be licensed (e.g. nuclear medicine, HASS)
- For other practices the decision on registration or licensing rests with the regulatory authority (EPA) and so can be changed based on experience, advances in technology etc

Graded Approach Model For Authorisation



Decision Criteria Determining The Appropriate Regulatory Approach

Licensing	• Specified as mandatory in the EURATOM BSS •Regulatory experience – decision criteria (IAEA Guidance)
Registration	•Analysis of Risk – Low •Safety largely ensured by design •Operating procedures easy to follow; safety training minimal •History of few problems
Specific Exemption	•Will require notification and a regulatory decision.
Generic Exemption	•Activity concentrations Annex VI BSS •Radiological risks of no regulatory concern •Inherently safe

Flow of Decision Criteria For Registration Practices

IAEA Categorisation of Sources

Based on Risk

Implement IAEA categorisation of sources

IAEA Regulatory Control

Suggested Criteria for Registration (IAEA BSS)

Further Development

- Analyse Risk associated with the practice
- Apply Regulatory Experience

- Identification of the practices that are suitable for registration

Decision Criteria For Registration

- 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).

Example: Evidence Based Analysis of Risks for DXA Scanners

1. Application

- Two types: Central scanners & peripheral scanners.

2. Description of source of ionising radiation

- Energy range
- Type of X-ray beam
- Scan times

3. Persons at Risk

- Staff Members
- Members of the Public

Example: Evidence Based Analysis of Risks for DXA Scanners

4. Identification of Risks

Hazard	Persons at risk	Method of reducing risk from hazard (Control Measures)	Residual Risk from Hazard*
Radiation Exposure from primary and scattered radiation	Staff Personnel in adjacent rooms	Adequate training in radiation protection. Training provided from the manufacturer/ supplier in the correct use of the DXA unit. Maximising distance between source of radiation and staff. The controlled area is clearly defined. Use of protective lead screens where required e.g. in small rooms where the operator cannot be outside the controlled area when taking an exposure. Appropriate design of facility. RPA consulted at planning stages of facility. Adherence to the design code of practice and Radiation Safety Procedures (if required) Appropriate design of facility	Low**
Radiation Exposure due to inadvertent entry into controlled area	Staff & Member of public	Signage/warning lights where appropriate Room access controlled during exposure Staff Training	Low
Radiation Exposure due to inadequate design of facility	Staff & Member of public	Consultation with RPA at design stage and before any major modifications of the room	Low

Example: Evidence Based Analysis of Risks for DXA Scanners

Exposure due to equipment error	Staff & Member of public	This is not a foreseeable occurrence Regular in-house QC programme implemented to ensure quality of performance. In built software required a daily calibration check to be passed before the unit can be used.	Low
Prevention of loss or theft of equipment	Member of Public	Security of premises Peripheral scanners will only be used in designated locations where a Risk Assessment has been conducted.	Low

* Note the residual risk considered for reasonable foreseeable hazards under normal operation once the control measures have been implemented.

** Low risk definition: When the Detrimental *health effects* of *exposure* to *radiation* (including the likelihood of such effects occurring) is considered minimal. In general terms a low risk scenario is one where protection is optimised such that occupational risks may no longer be significant. In terms of dose it would be unlikely that any of the hazards identified with control measures in place would result in a dose in excess of 1 mSv.

Example: Evidence Based Analysis of Risks for DXA Scanners

- *5. Historical Data/Dosimetry*
  - Environmental dose monitoring
  - The occupational exposure to the operator
- *6. Availability of Codes of Practice (CoP) – Other Guidance*
  - Is there a specific code?
  - Is there a need for a code?
- *7. Minimum Requirements for CoP*
  - Need for CoP/ Simple Rules
- *8. Consideration of Registration Requirements*

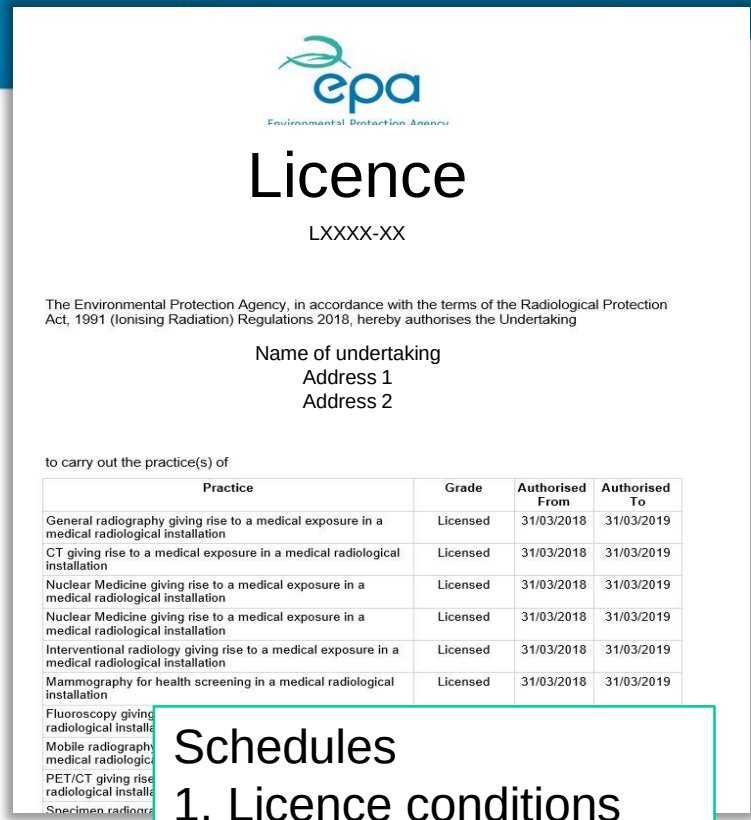
Example: Evidence Based Analysis of Risks for DXA Scanners

- *9. Recommendation – Specific Exemption, Registration, Licence?*

- *10. Effectiveness of Regulatory Control*
  - Would doses increase or the safety of installations be compromised by moving to registration from licensing?

Licence

- Application through www.EDENIreland.ie
- Authorisation granted for the Practice
- Applications and subsequent licence amendments (including the addition of a new practice) require inspector input & approval
- Records to be maintained by legal entity licensed
- Specific Conditions can be attached
- Licence Duration – 10 years



Licence

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			
Mobile radiography			
PET/CT giving rise			
Specimen radiogra			

Schedules
1. Licence conditions
2. Sources – practices & activities
3. RPA/ RPO
4. Sites

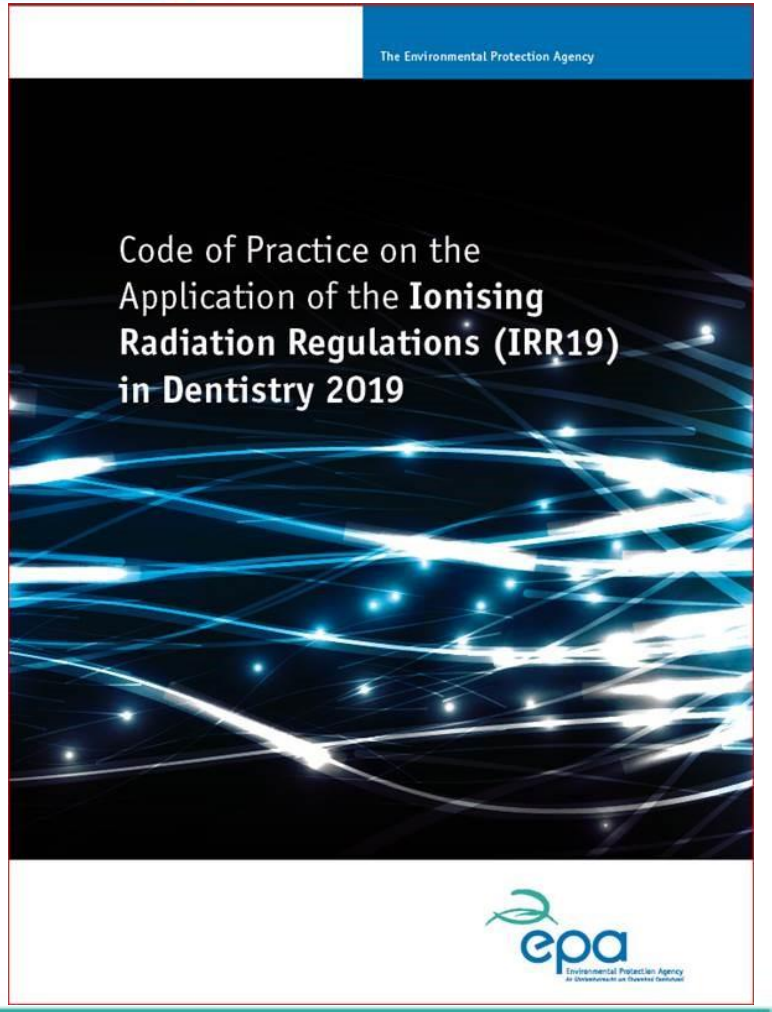
Licence Application Process – Information required

- 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)

Certificate of Registration

- Self Declaration on Application
  - Assumption of compliance
- Authorised for the Practice
  - Certificate of Registration includes Sites/Premises
- No inspector input/ sign off
- Records to be maintained by legal entity registered
- Specific Conditions can be attached
- Code of Practice Approach
  - Supporting undertakings in complying with their legal requirements.
- Indefinite (unless surrendered or revoked)



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 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)	☐

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.

Graded Authorisation Practices

Practices subject to Registration

Sector	Practice
Medical	General radiography giving rise to a medical exposure in a medical radiological installation.
	Bone densitometry giving rise to a medical exposure
	Mammography giving rise to a medical exposure
	Specimen radiography for medical purposes
	Dental radiography using an intra/extra oral unit (except handheld)
	Dental cone beam CT
Dental	Dental radiography using an intra/extra oral unit (except handheld)
	Dental cone beam CT
Veterinary	General veterinary radiography carried out in a risked assessed veterinary clinic
Industry	Product inspection/industrial radiography using cabinet X-ray systems
	Use of laboratory equipment incorporating sealed sources
	Use of XRF or XRD equipment
	Installation/servicing of radiological equipment
	Security screening of baggage, cargo or parcels using X-ray within shielded enclosure
	Security screening for explosive vapour detection using sealed sources
	Carriage of sources other than High Activity Sealed Sources
Security	Security screening of baggage, cargo or parcels using X-ray within shielded enclosure
	Security screening for explosive vapour detection using sealed sources

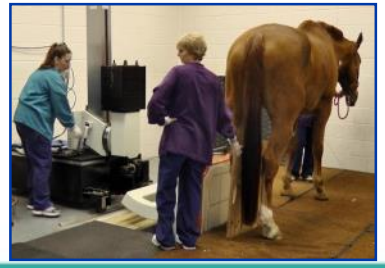
The EPA has published on its website a list of justified practices subject to registration or licensing

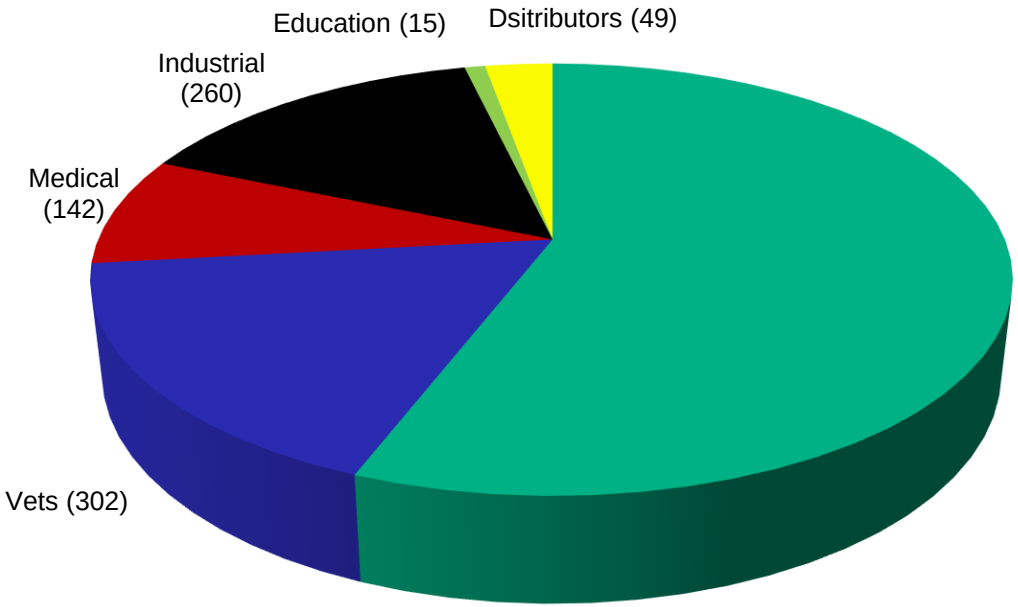
https://www.epa.ie/radiation/regulation/authorisation/

Practices subject to Licensing

Sector	Practice
Medical	Radiotherapy using a LINAC in a medical radiological installation
	Radiotherapy using brachytherapy in a medical radiological installation
	Radiotherapy using X-Ray in a medical radiological installation
	Interventional radiology giving rise to a medical exposure in a medical radiological installation
	CT giving rise to a medical exposure in a medical radiological installation
	Mobile radiography/fluoro giving rise to a medical exposure in a medical radiological installation
	Fluoroscopy giving rise to a medical exposure in a medical radiological installation
	Nuclear Medicine giving rise to a medical exposure in a medical radiological installation
	PET/CT giving rise to a medical exposure in a medical radiological installation
	Dental radiography using handheld intra oral unit
	Product irradiation/sterilisation using HASS sources
Dental	Dental radiography using a handheld intra oral unit
Veterinary	Veterinary radiotherapy
	Veterinary nuclear medicine
	Veterinary fluoroscopy
	Veterinary radiography using CT
	General veterinary radiography performed in the field
Industry	Use of unsealed sources in industry/laboratories
	Use of sealed sources in industry
	Use of nuclear moisture density gauges
	Use of High Activity Sealed Sources in geophysical exploration[1]
	Radiopharmaceutical production in a cyclotron
	Product irradiation/sterilisation using High Activity Sealed Sources
	Product irradiation/sterilisation using E-beams
	Industrial radiography using X-ray systems[1]
	Industrial radiography using High Activity Sealed Sources
	Assembly or manufacture of devices incorporating sealed sources
	Industrial use of medical radiological equipment
	Carriage of High Activity Sealed Sources[2]
	Supply and distribution of radioactive sources[3]
Security	X-ray system for cargo/container screening of vehicles
Education	Use of ionising radiation in a third level college

Prior To Graded Authorisation

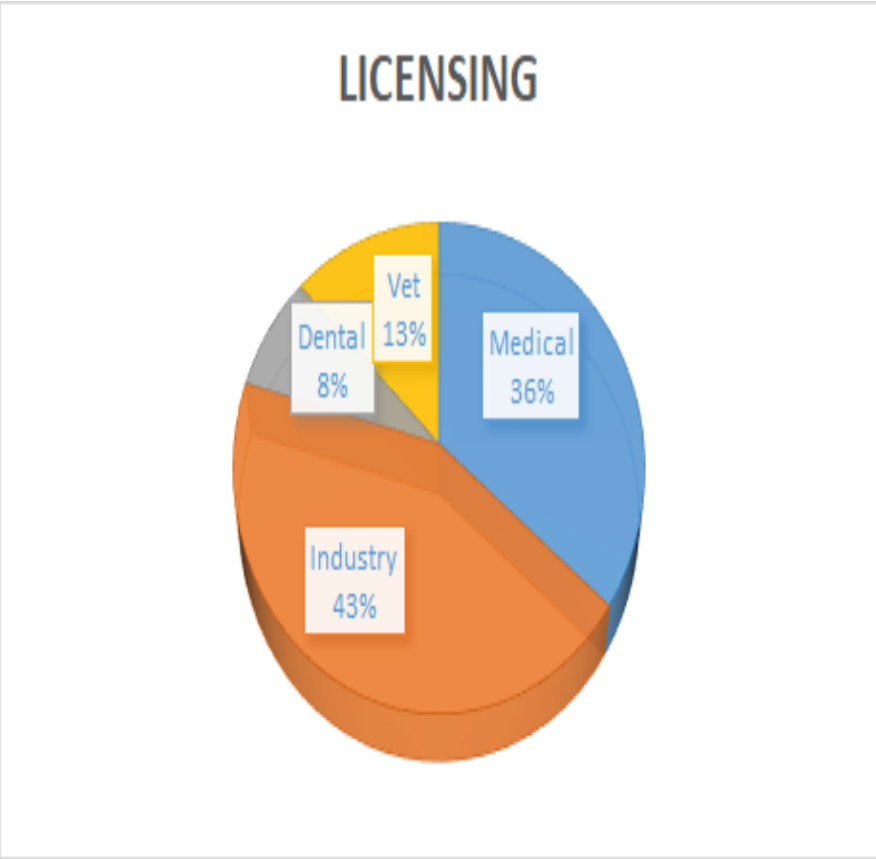




1740 Licensees

Dentists (972)

Current Graded Authorisation System



What Graded Authorisation Means For Ireland

- Previous regulatory model 1740 licensees
- Now 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