



Radiological Protection Institute of Ireland
An Institiúid Éireannach um Chosaint Raideolaíoch

Proposal for a model of graded authorisation

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***“Change is not made without inconvenience,
even from worse to better.”***

Samuel Johnson (1709 - 1784)



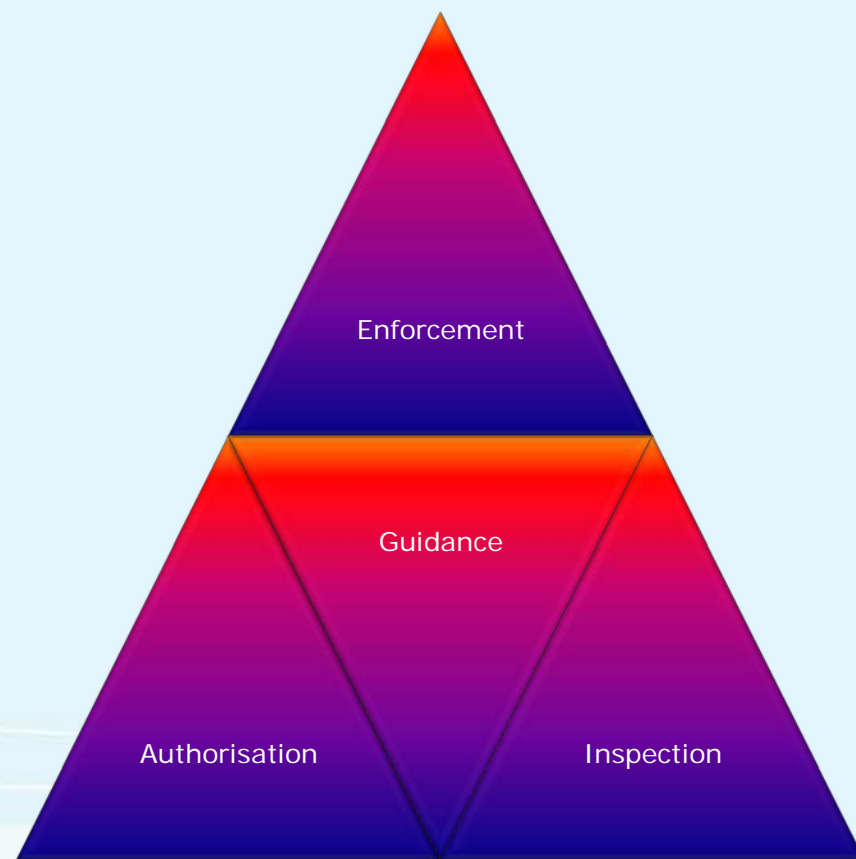
Regulatory Reform



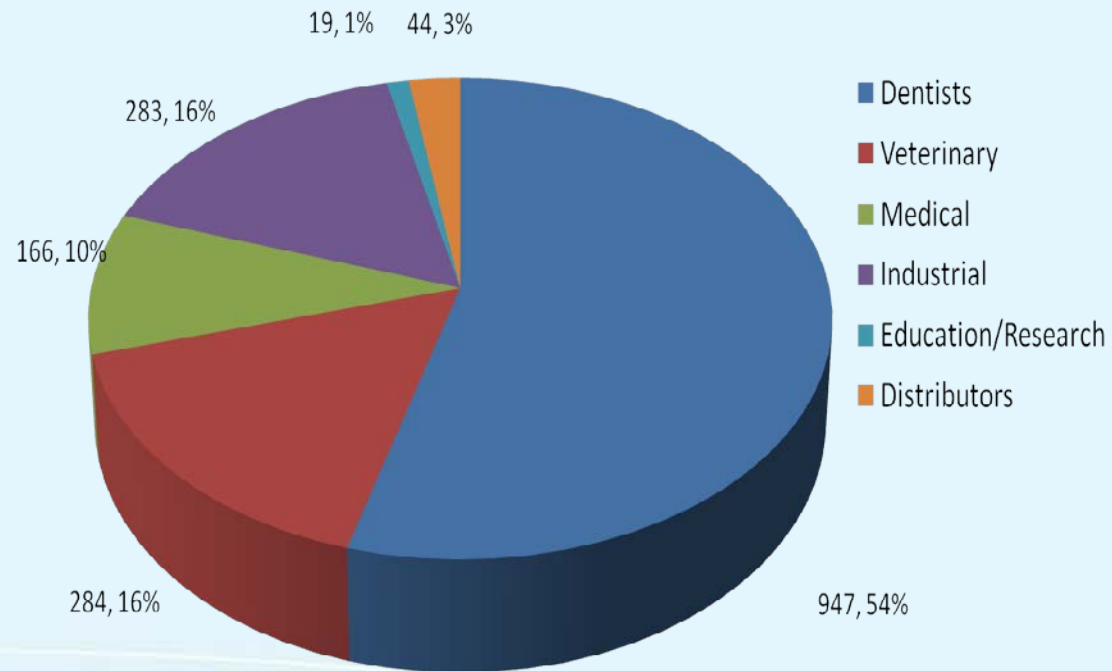
Regulatory Service – Principles

The Regulatory Pyramid

- Risk-Based
(Graded/Proportionate)
- Equity of Treatment
- Quality of Procedure
- Transparency of Process



Who do we regulate (licence)?

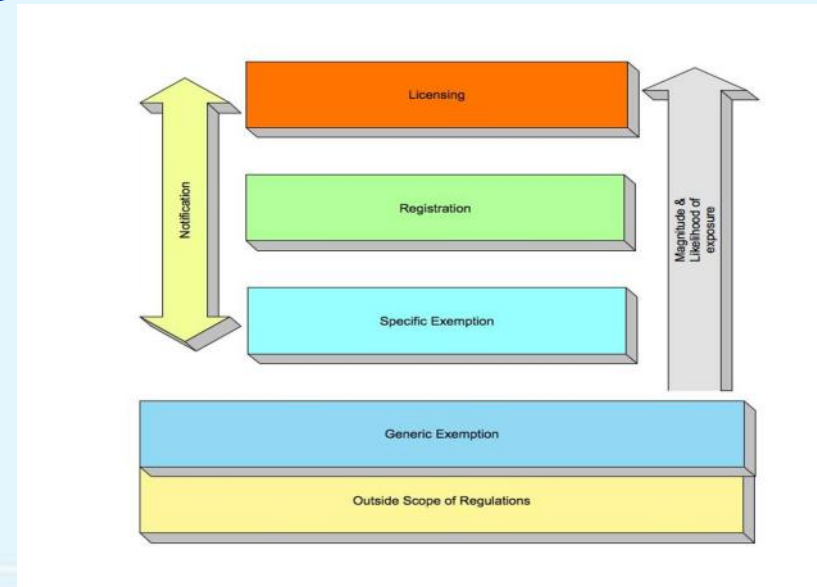


1743 Licensees



Drivers for Regulatory Change

- 70 years of collective regulatory experience
- New Basic Safety Standards Directive
- Sustainability
- Transparency
- Reduce the regulatory burden



Some fundamentals

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

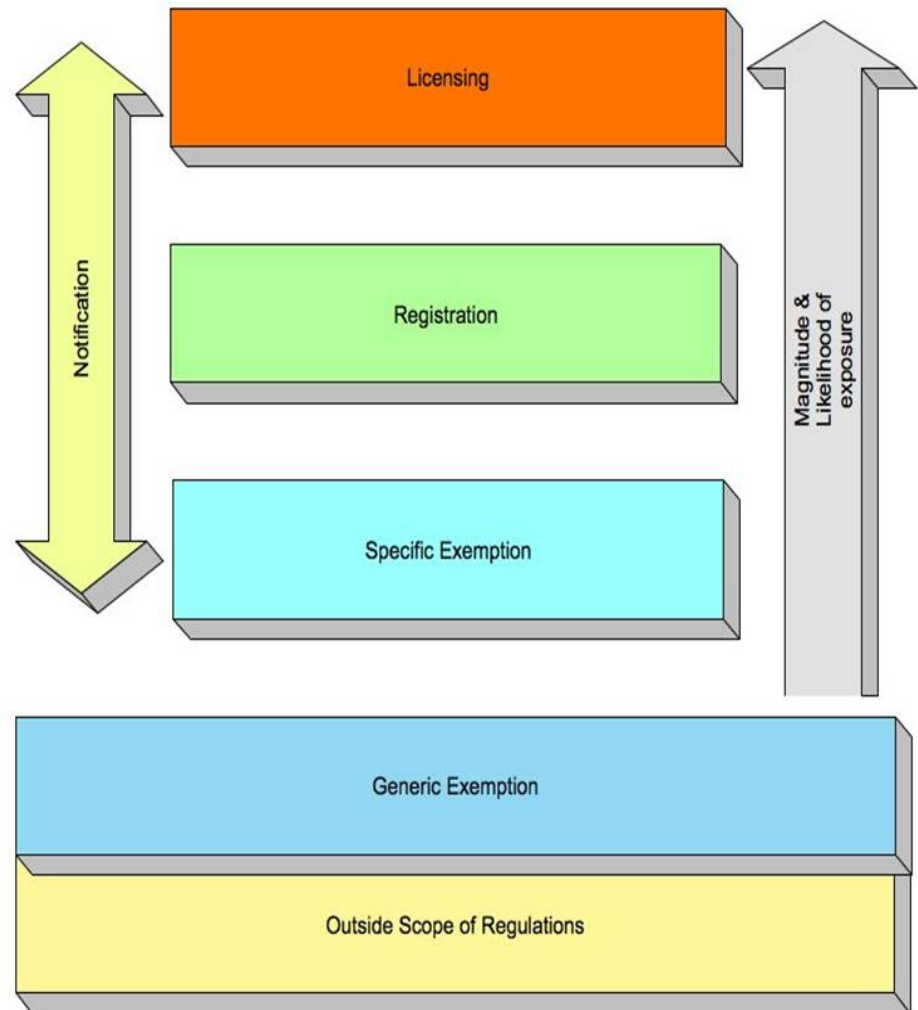


Model Development



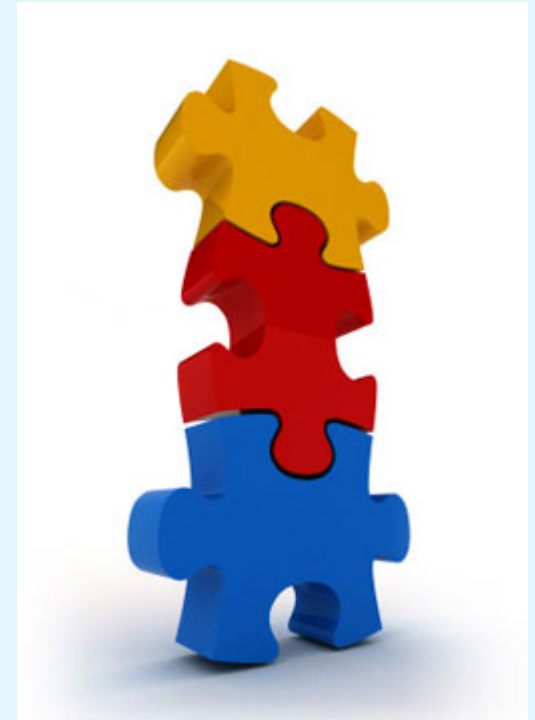
Project Aim

- Propose an Authorisation Model for Ireland
 - Risk based approach
- Considering
 - Exemption
 - Notification
 - Registration
 - Licensing



Project Methodology

- Facilitated Regulatory Workshops
- Brainstorming
- Focus Groups
- Analysis of Risks
- A vision of the future



Model Development

Identification of drivers and principles underlying change

Investigation of international guidance

Development of criteria for different levels of authorisation

Development of models for registration and licensing

Gathering evidence on practical implications and risks

Interpretation in Irish context (for existing licensee base)



Criteria for levels of Authorisation (licensing v registration)

- What Criteria could be applied to make decision on level of authorisation
 - Legislation
 - Mandatory Licensing – EU BSS
 - International Guidance (IAEA) & Expertise
 - Identify candidates for Registration



Evolution of Decision Criteria

EU BSS

- Mandatory Licensing
- Mandatory Authorisation

IAEA Categorisation of Sources

- Based on Risk
- Category 1-3 Licensing

IAEA Regulatory Control

- Suggested Criteria for Registration

Further Development

- Questionnaire compiled
- Expertise applied

Scoring Matrix

- Review to identify the candidates



High-level Decision Criteria

- Does the facility of 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?
- Could the application be addressed in generic risk assessment?
- What are the security considerations?



Analysis of Risks

- Focus Groups

- DXA
- Veterinary (fixed & mobile)
- Dental (Intra Oral & OPG)
- Cabinet X-Ray
- Standard X-ray (fixed & mobile)

- Evidence Based papers on analysis of risks

- Recommendation: licensing or registration



Evidence Based papers

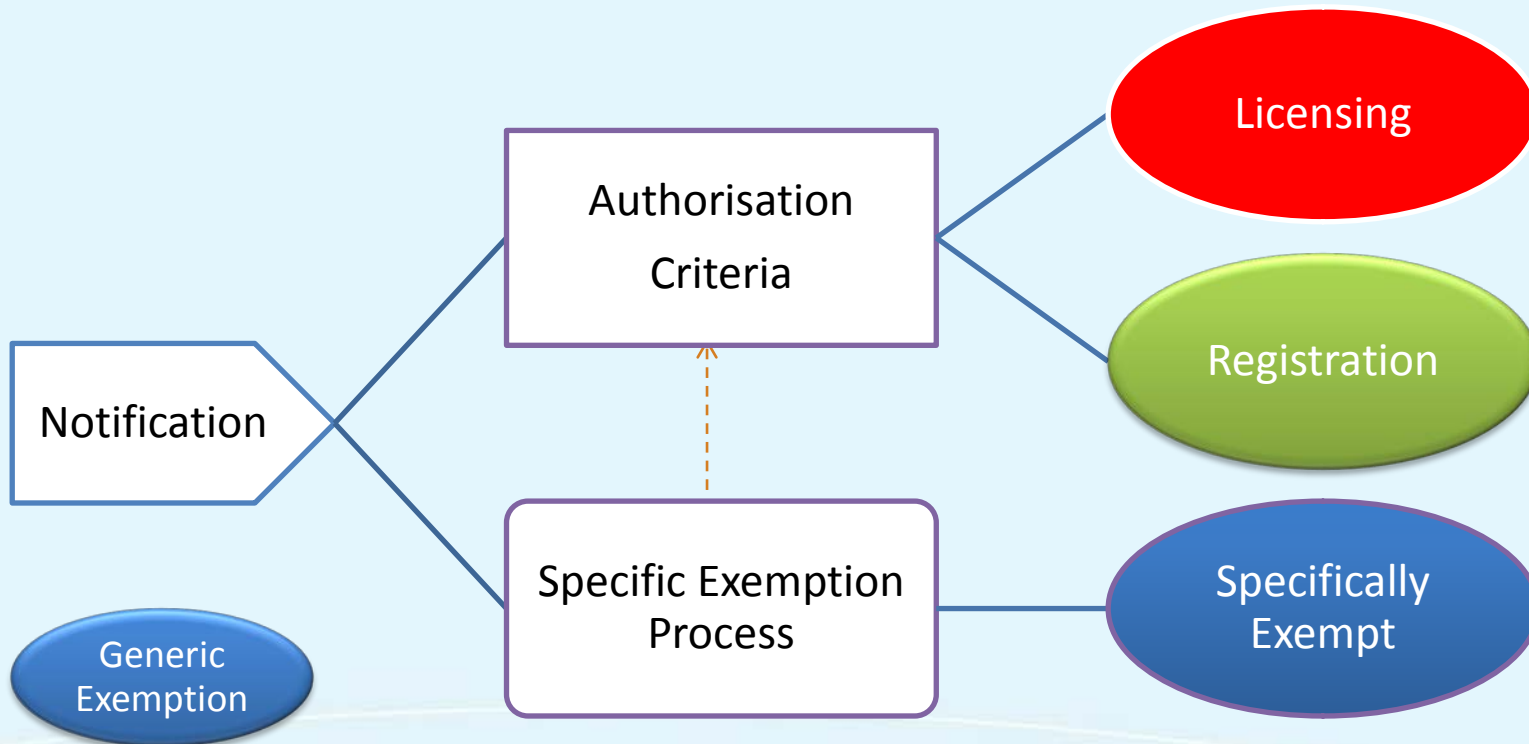
- Identification of the Hazards
- Persons at Risk
- Control measures in place to minimise risk
- Availability of Codes of Practice/other guidance
- Historical data and dosimetry
- Effectiveness of regulatory control



Proposed Model of Authorisation



Graded Authorisation Model



Summary of criteria

Licensing

- BSS List
- 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 below threshold (EU BSS)
- Radiological risks of no regulatory concern
- Inherently safe



International Peer Review



Peer Review

- Validation Process
- International Experts
- Assembled in Dublin
- Comprehensive Review
- High Level Questions
- Consolidated Opinion
- (Regulatory capture)



High Level Questions



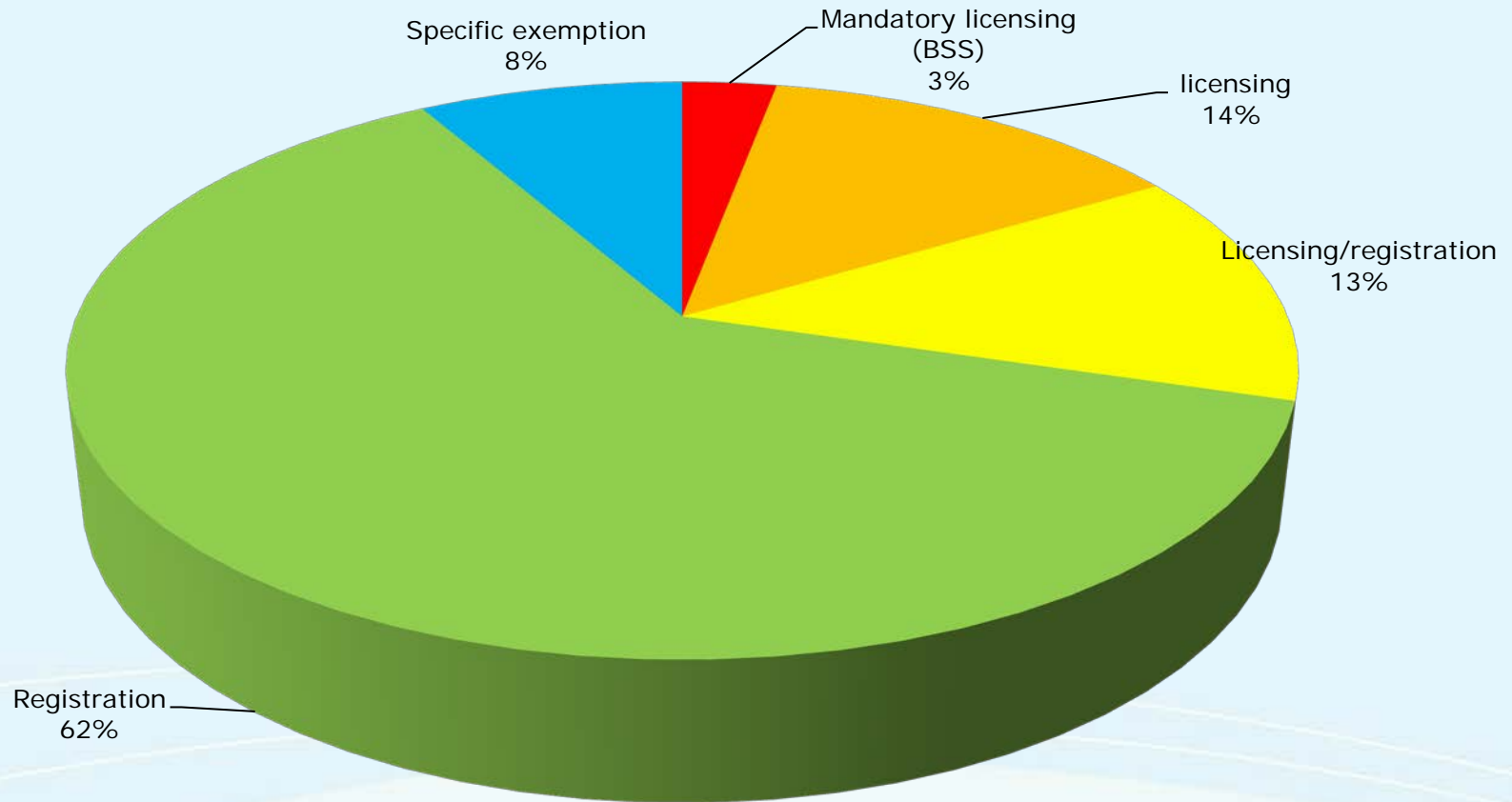
- Is the Model in line with International Best Practice?
- Is there any residual risk with the Model?
- Are the appropriate practices being licensed?
- Has a robust Methodology been applied?



What will it mean?



Preliminary application to current licensee base



Next steps

- Additional stakeholder consultation
 - RPAs, licensees, Dental & Vet Councils
- Development of new IT system
 - Process review
 - Invitation to tender
- Development of communication strategy
- Development of financial model
- Development of codes of practice

