

EPA Webinar Series: The Application of the Ionising Radiation Regulations (IRR19) in Veterinary Medicine

Ellen Brogan

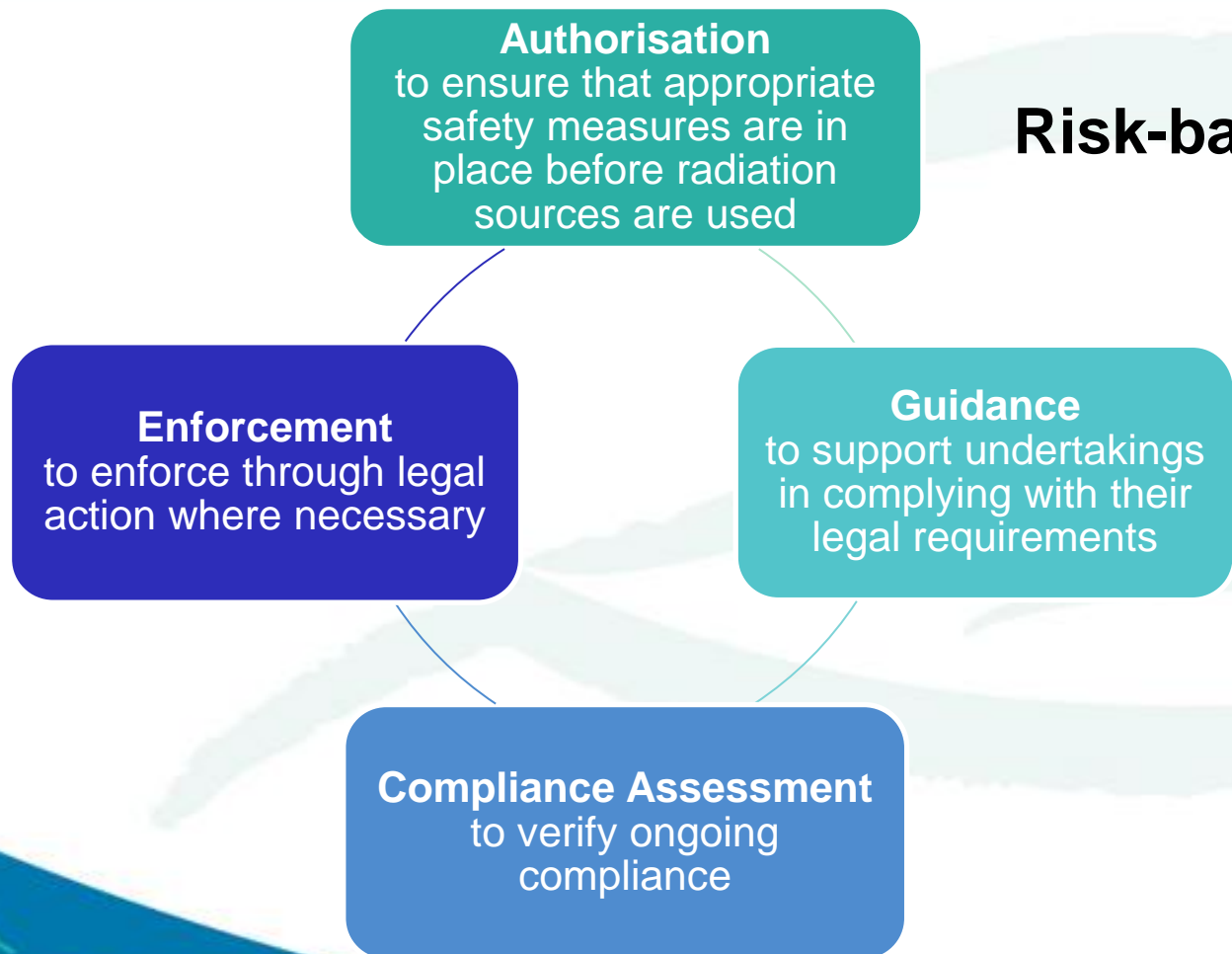
26/07/2023

Overview

- Enforcement policy
- The Authorisation Process
 - Cost of authorisation/ admin
- Guidance
- Compliance Assurance
 - Vet survey
 - Inspections
- Enforcement
- How to use EDEN
 - Accessing EDEN
 - Amending your Authorisation
 - Responding to Inspection Findings

Radiation Regulation: A Recap

Risk-based regulatory approach

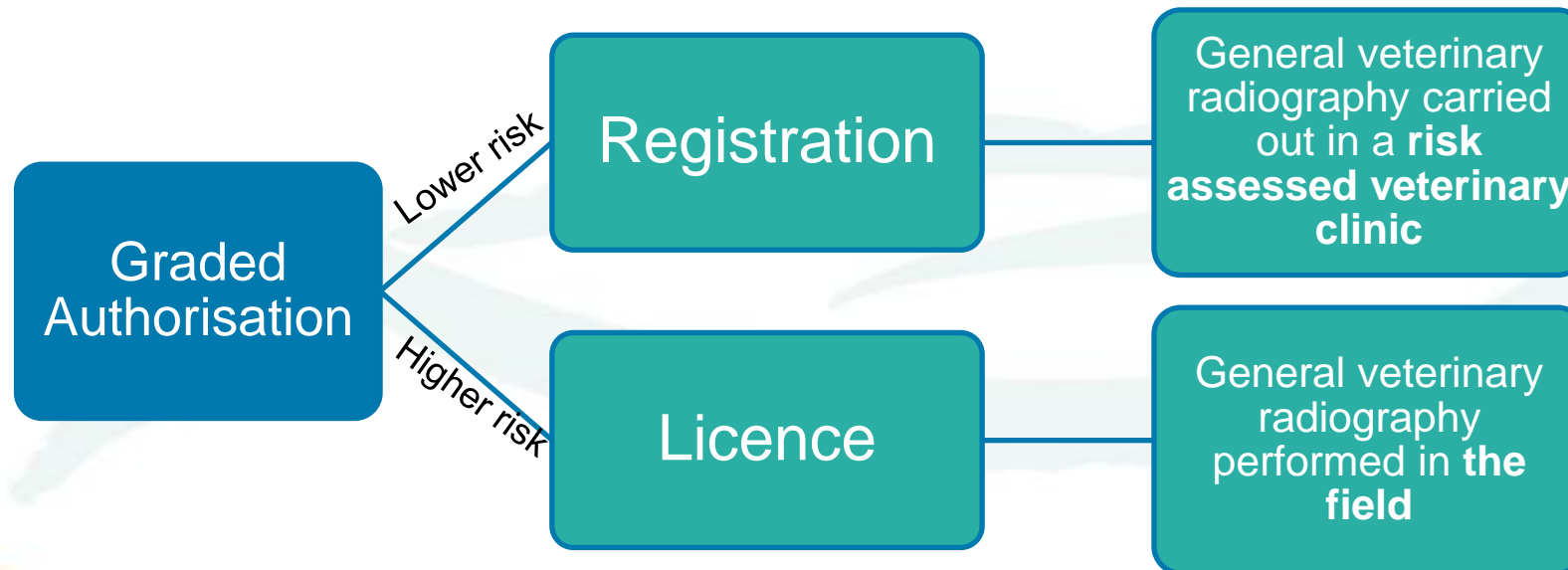


Vet Code of Practice



1. Authorisation

- Authorisation = consent to carry out a radiological practice.
- IRR19 provides for **Graded Authorisation** (two forms of authorisation commensurate with risk: registration and licensing).



List of practices



Last Week's Recap

	Registration	Licensing
Radiological practices	X-ray examination of small animals in a defined X-ray area	<ul style="list-style-type: none"> ▶ Off-site/large animal X-ray examinations ▶ Computerised tomography (CT) ▶ Fluoroscopy ▶ Nuclear medicine (diagnosis or treatment) ▶ Use of handheld intra-oral X-ray unit
Duration of authorisation	Indefinite (unless surrendered or revoked)	10 years (renewable)
Schedule of equipment	An up-to-date schedule of equipment must be retained on file by the undertaking	An up-to-date schedule of equipment must be retained on EDEN
RPO/RPA	Up-to-date evidence must be retained on file by the undertaking.	An up-to-date record must be retained on EDEN.
Risk Assessment	A risk assessment should be completed before bringing any new equipment into service. This must be retained on file by the undertaking.	A risk assessment must be completed before bringing any new equipment into service and must be reviewed and updated periodically. It must be submitted with the licence application through EDEN.
Local radiation safety procedures	Not required – compliance with this Code of Practice is sufficient.	Required and must be submitted with the licence application through EDEN.

Last Week's Recap – Statutory Roles

	Definition, as per IRR19
The Undertaking	<p>A natural or legal person with legal responsibility for carrying out the radiological practice. This is usually, but not always, the veterinary practitioner in charge.</p> <p>The undertaking is the person with primary legal responsibility for compliance with the regulations.</p>
Radiation Protection Officer (RPO)	<p>An individual or a unit designated by the undertaking to implement the radiation protection arrangements.</p> <p>This is usually, but not always, a veterinary practitioner or nurse.</p>
Radiation Protection Adviser (RPA)	<p>An individual or a body that meets the competence requirements set out by the EPA to provide radiation protection advice and whose name appears on the RPA register maintained by the EPA.</p>

Registration

- **€300 once-off** authorisation fee.
- No annual enforcement fee.
- **Indefinite** duration (unless surrendered or revoked).
- Do not need to submit equipment inventory or documentation but these must be retained locally.
- Only need to **amend** the Registration if you wish to:
 - Apply for authorisation of a new practice not covered by the existing registration.
 - Update legal entity or address.

Registration – the Self Declaration Form

Please complete all sections below

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).	<input type="checkbox"/>
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)	<input type="checkbox"/>
Will consult with a suitable Radiation Protection Adviser (RPA) as appropriate (regulation 33 and associated EPA guidance)	<input type="checkbox"/>
Have designated a Radiation Protection Officer (RPO) to supervise or perform radiation protection tasks (regulations 34 and 80 and associated EPA guidance)	<input type="checkbox"/>
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)	<input type="checkbox"/>
Have, where required, correctly classified and demarcated any controlled and/or supervised areas (regulations 36 and 37 and associated EPA guidance)	<input type="checkbox"/>
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)	<input type="checkbox"/>

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.

Signature: _____

Print Name: _____

Licence

- **€1000 once-off** authorisation fee.
- **€528 annual** enforcement fee.
- **10-year** duration with a **€250 renewal** fee.
 - Application reviewed by an Inspector.
 - **Must submit details** of the premises, personnel, equipment inventory, RA/RSPs, and documentation.
- Need to **amend** the Licence if you wish to :
 - Apply for authorisation of a new practice not covered by the existing Licence.
 - Update equipment inventory.
 - Update RPO/ RPA.
 - Update legal entity or address.




Note: if you have both registerable and licensable practices the higher form of authorisation, i.e., licensing, applies.

2. Guidance

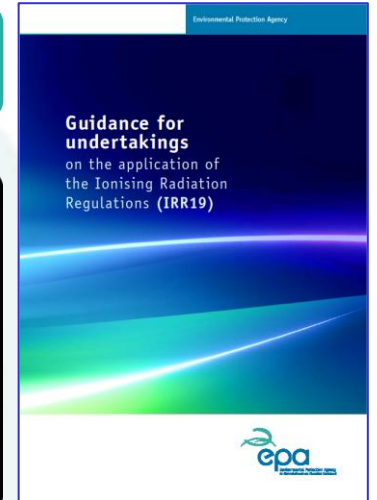
Webinar One

Recording
to be made
available on
epa.ie

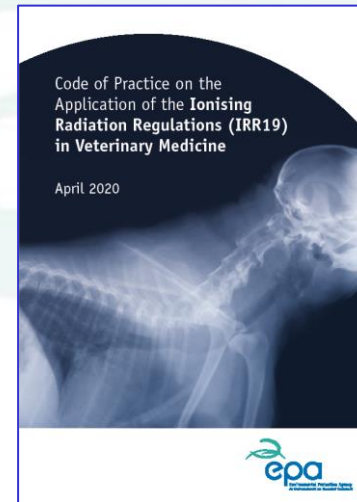


The screenshot shows the event page for 'EPA Webinar 1: Ionising Radiation Regulations'. It includes the EPA logo, the event title, the date and time (Wed, Jul 19, 6:50 PM - 8:30 PM GMT+1), and the event type (Online event). Under the 'Details' section, it lists the topic 'Week One - Wednesday 19th July' and a list of topics: 'Explaining the legislative requirements', 'Roles and responsibilities', 'Radiation Protection Advisers', and 'Risk Assessments, Radiation Safety Procedures and Training'. The 'Speakers (1)' section lists 'EB Ellen Brogan'.

Guidance for Undertakings



Vet Code of Practice



3. Compliance Assurance

1. Surveys/Self Assessment Questionnaires/Audits of documentation

- Sectoral surveys
- Registration – verification of self-declaration

2. Review of Safety Documentation

3. Inspections

- Announced or unannounced
- Annual Inspection Programme
- Risk-based i.e. designed to ensure that those licensees, where a greater radiological risk exists, are inspected most frequently
- Planned or reactive
- Accredited to ISO 17020:2012 standard for our inspection activities

4. Remote Compliance Assessments

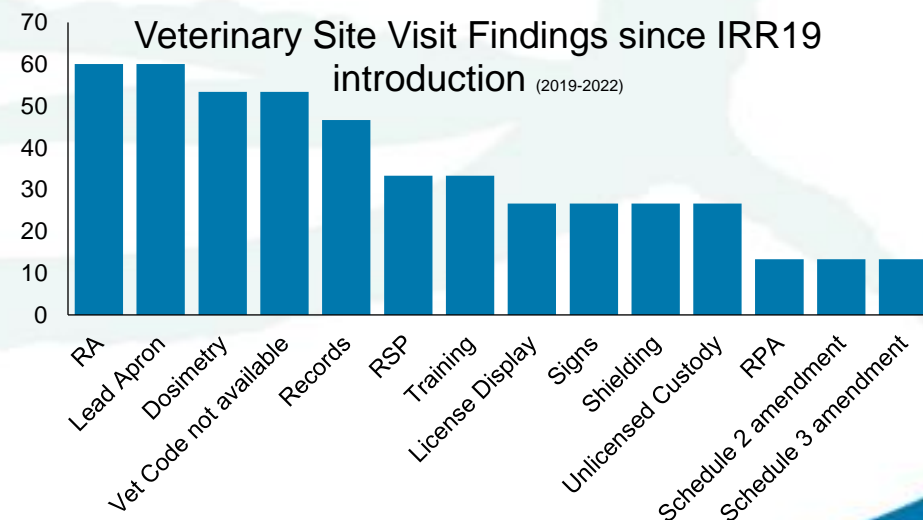


Online Compliance Assessment – the Vet Survey

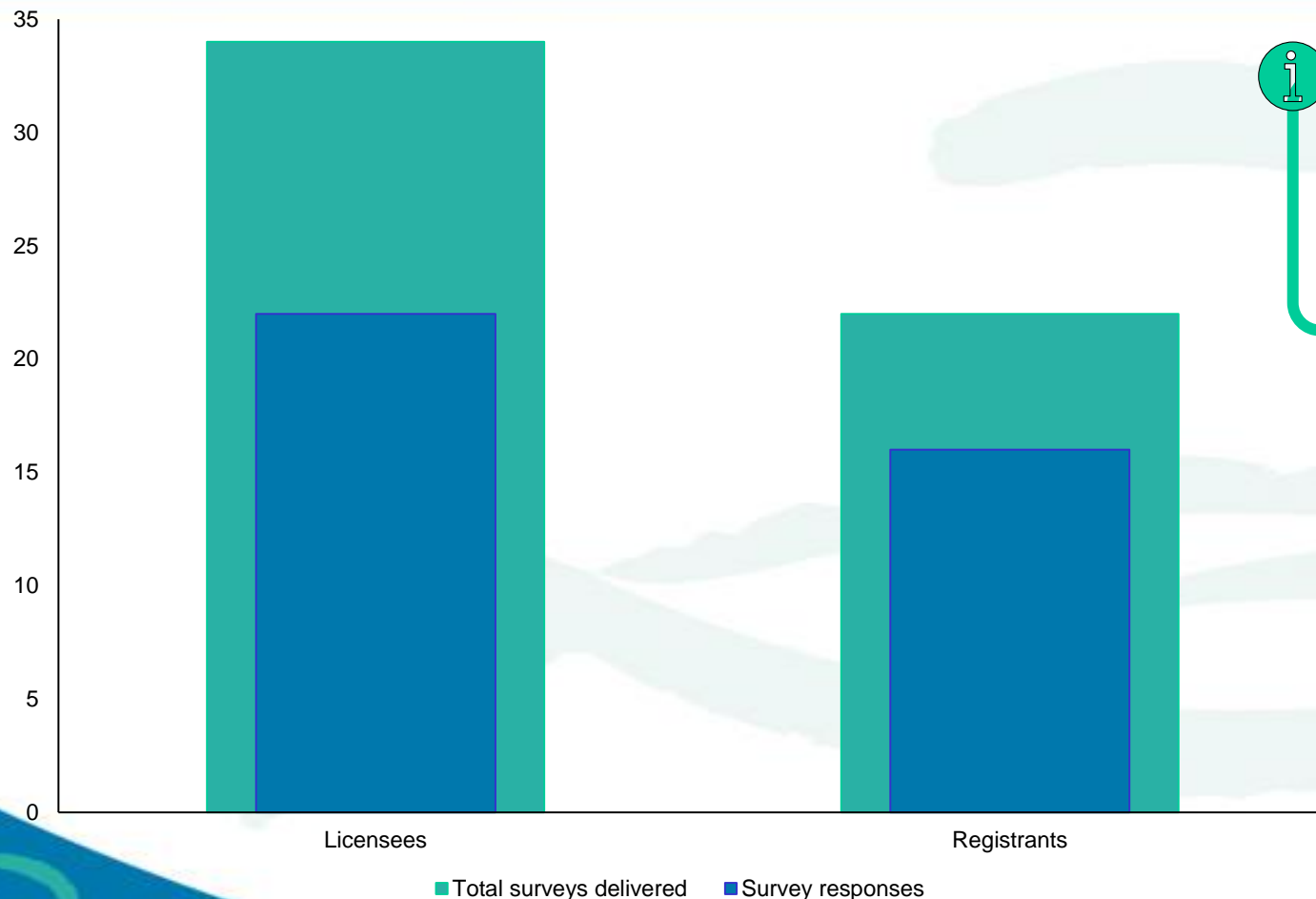
- 36 Questions for Licensees - 30 Questions for Registrants.
- Survey Questions were divided into sections:
 - Risk Assessment
 - Categorisation of Workers & Dosimetry
 - Radiation Safety Procedures
 - Governance and Responsibilities which included RPO/RPA arrangements
 - Radiation Protection Training
 - Personal Protective Equipment (PPE)
 - X- ray Equipment Inventory
 - Maintenance Of X- Ray Equipment
 - Quality Assurance



Survey sent on: 20/07/2022
Survey closed on: 10/10/2022
83 days in total (Or 2 months, 21 days)



The Vet Survey

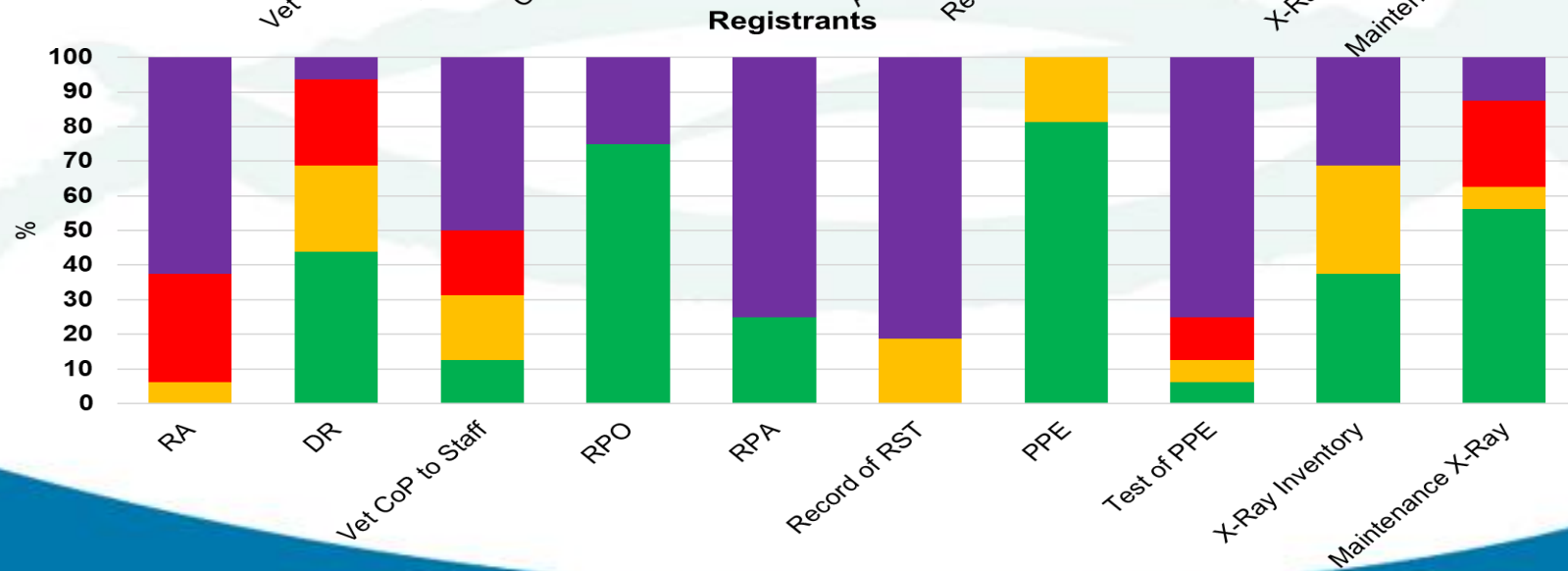
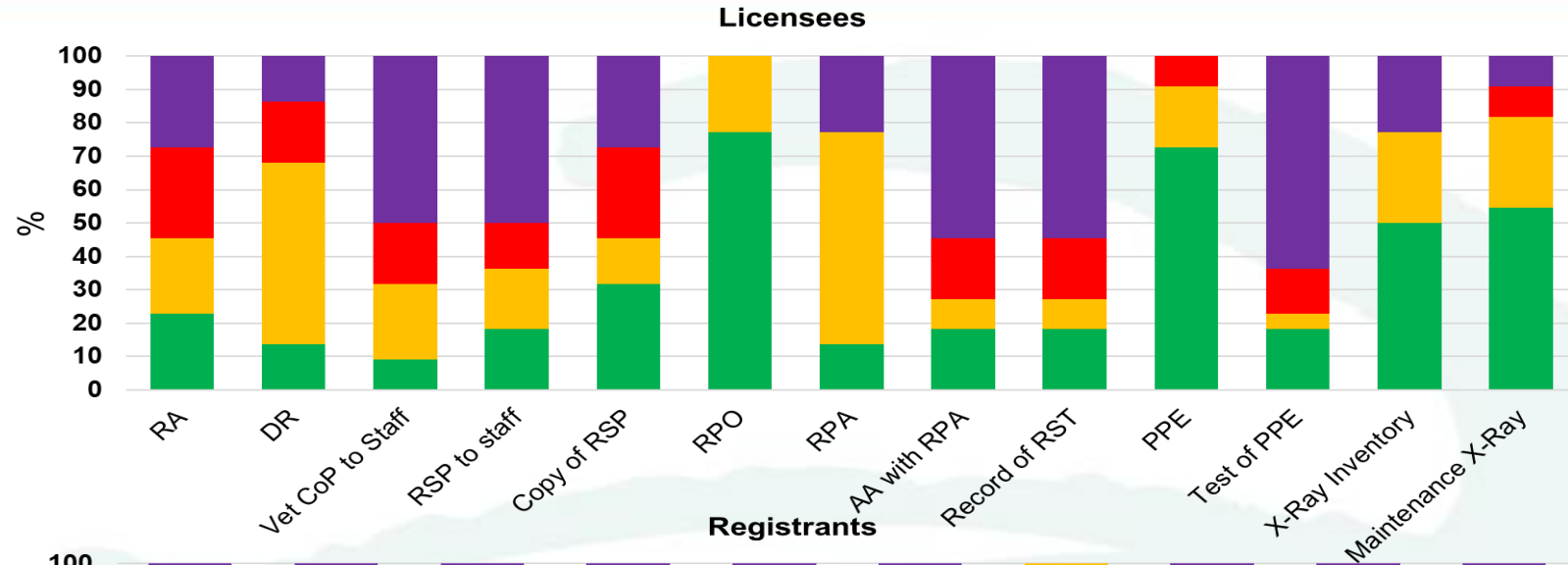


The participants (Licensees & Registrants) were randomly chosen (one per county) to answer the survey and their responses were mandatory

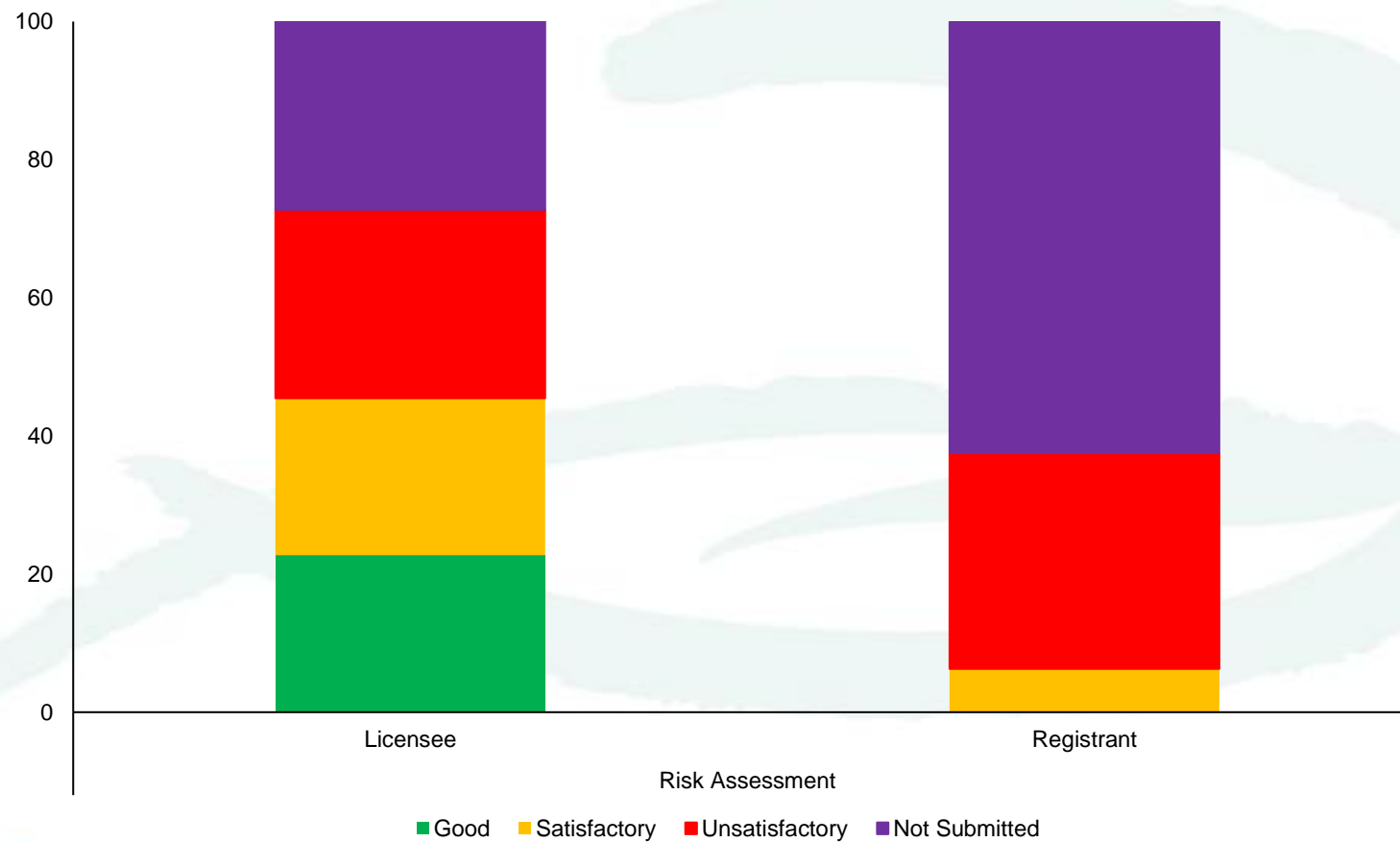
65% of Licensees responded

73% of Registrants responded

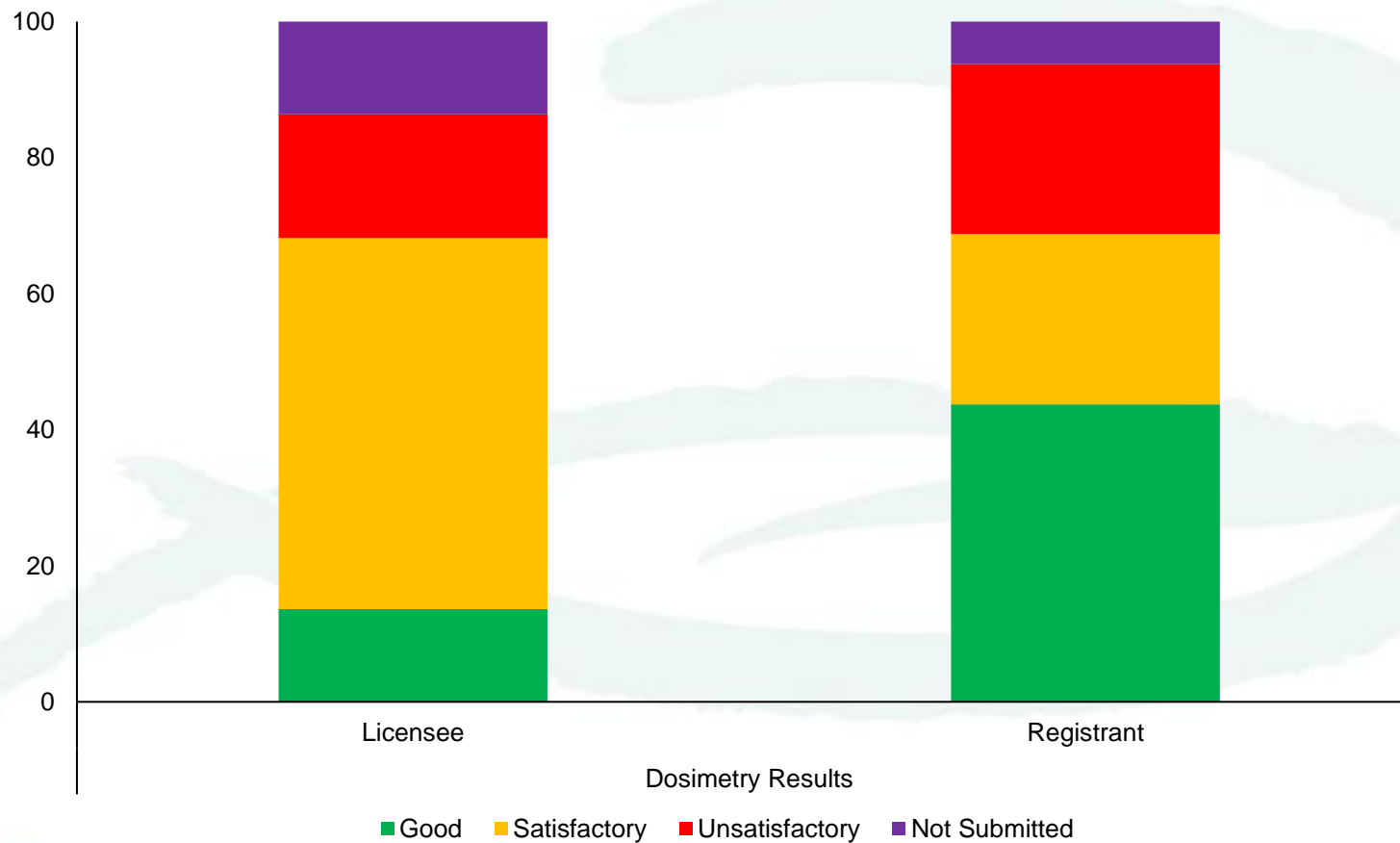
The Vet Survey – Compliance Results



Compliance Results – the Risk Assessment



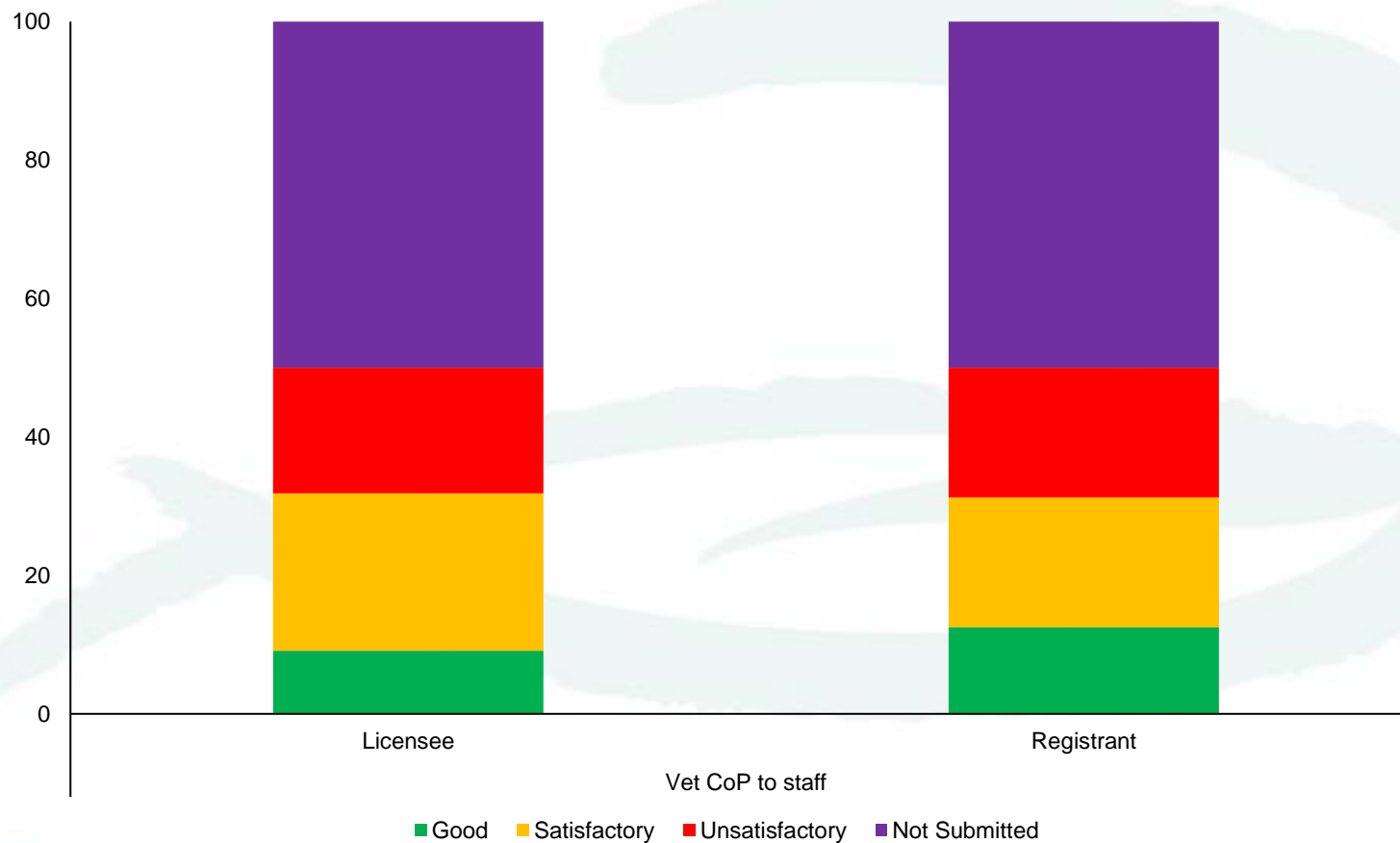
Compliance Results – Dosimetry Results Records



EPA approved
dosimetry services



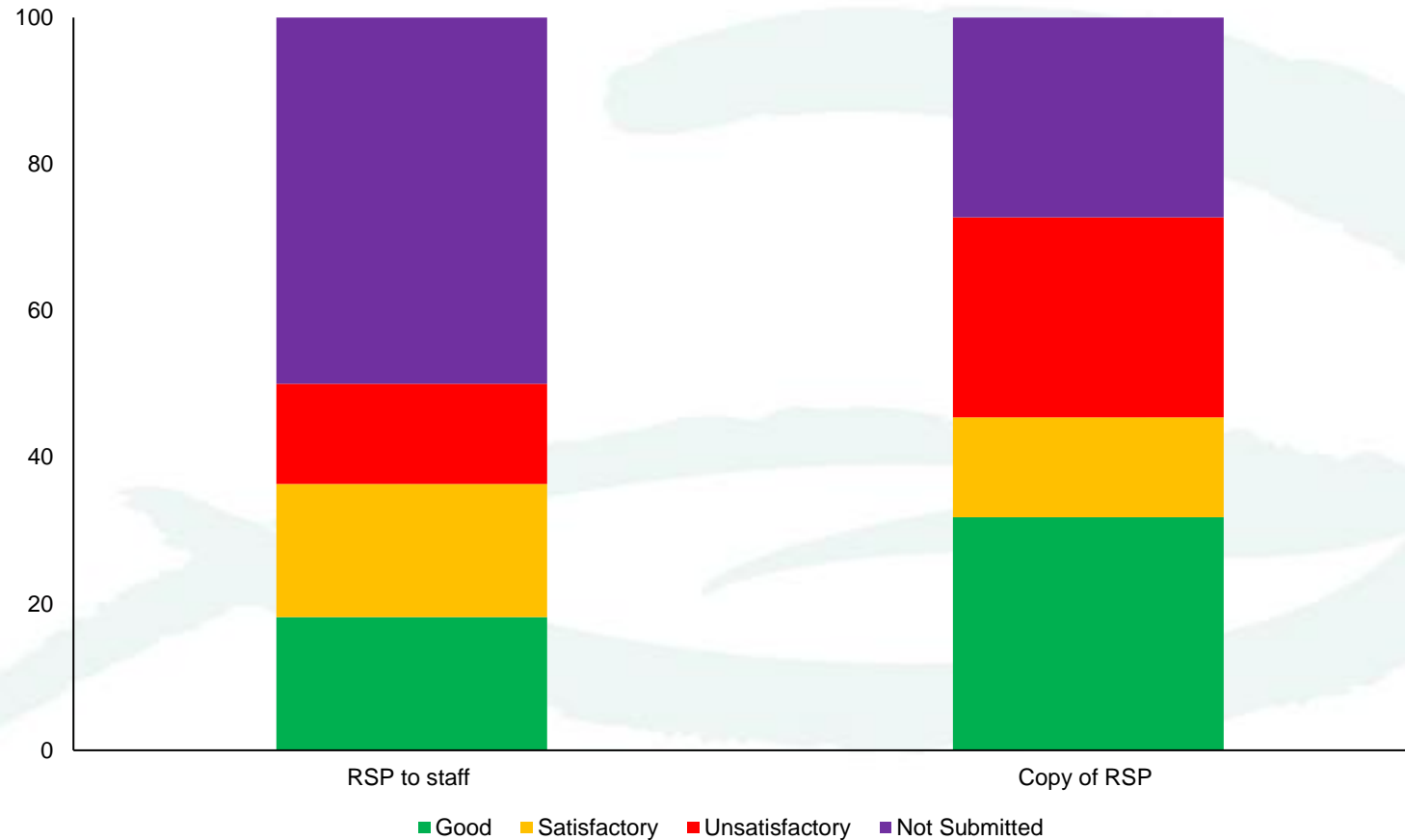
Compliance Results – Vet Code of Practice to staff



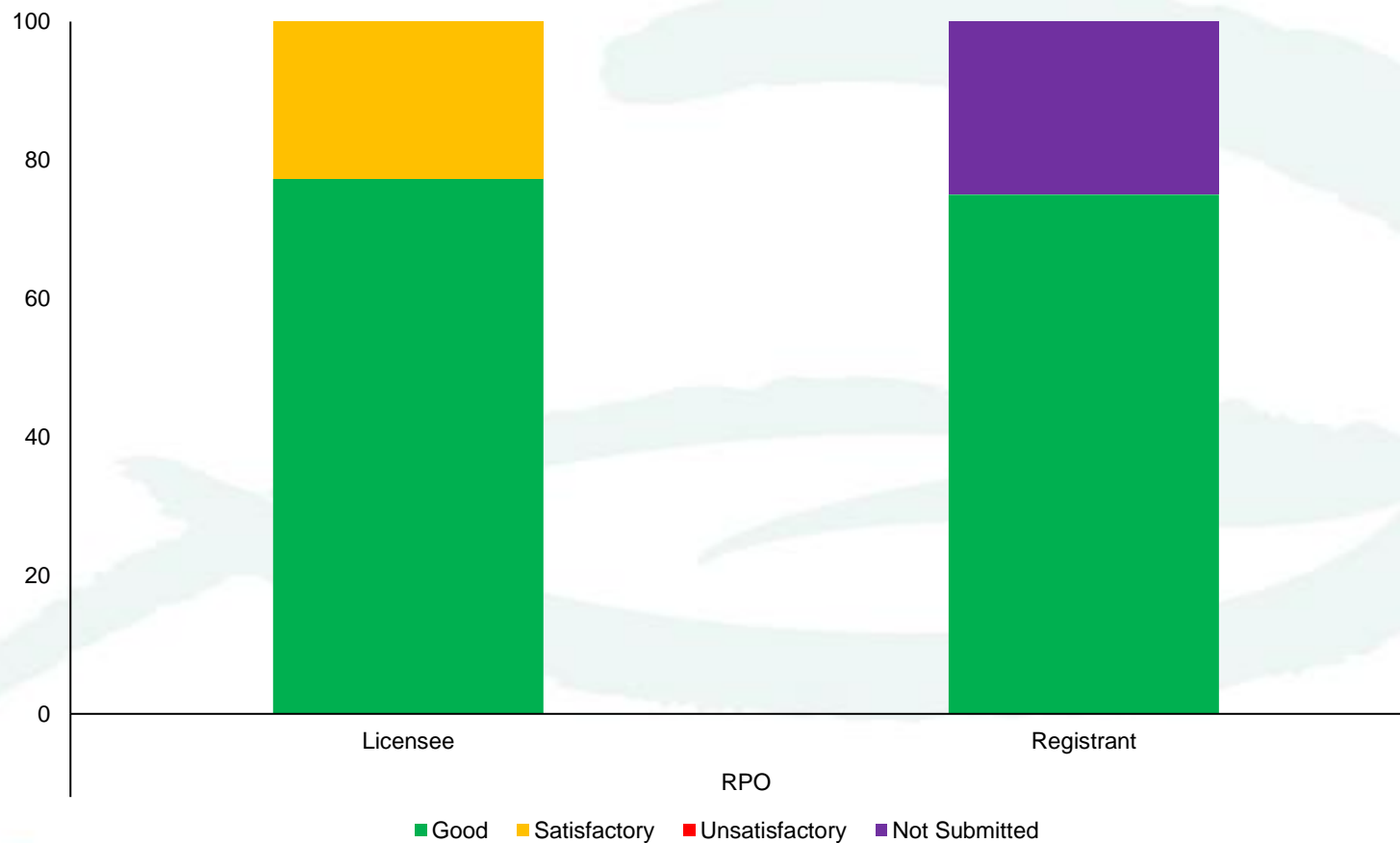
The Vet Code of Practice



Licensee Compliance Results – Radiation Safety Procedures

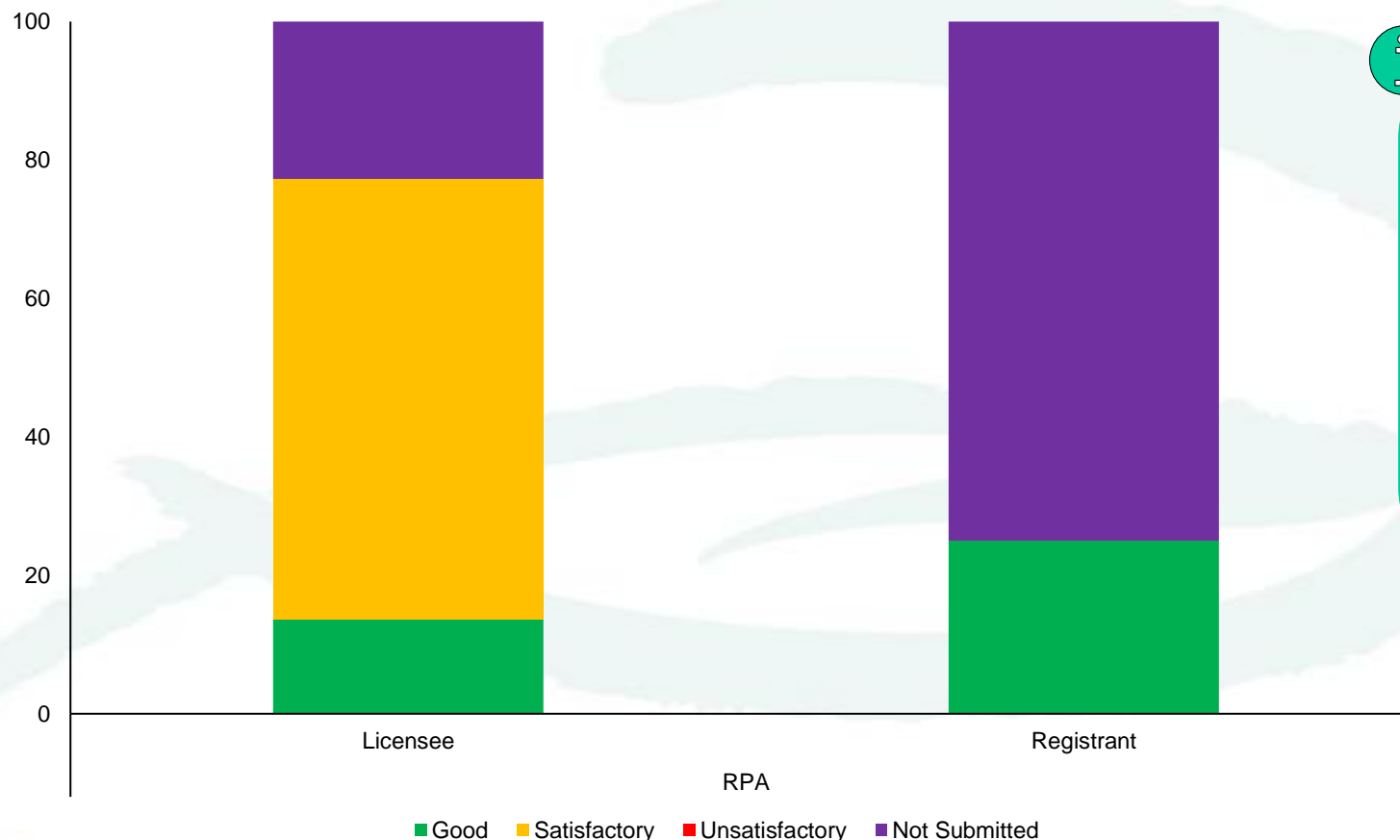


Compliance Results – Radiation Protection Officer (RPO)



i RPO is, for example, a veterinary practitioner/nurse, who is designated by the undertaking to supervise/ implement radiation protection arrangements.

Compliance Results – Radiation Protection Adviser (RPA)



RPA is a qualified expert (external consultant) approved by the EPA to give radiation protection advice pursuant to IRR19.

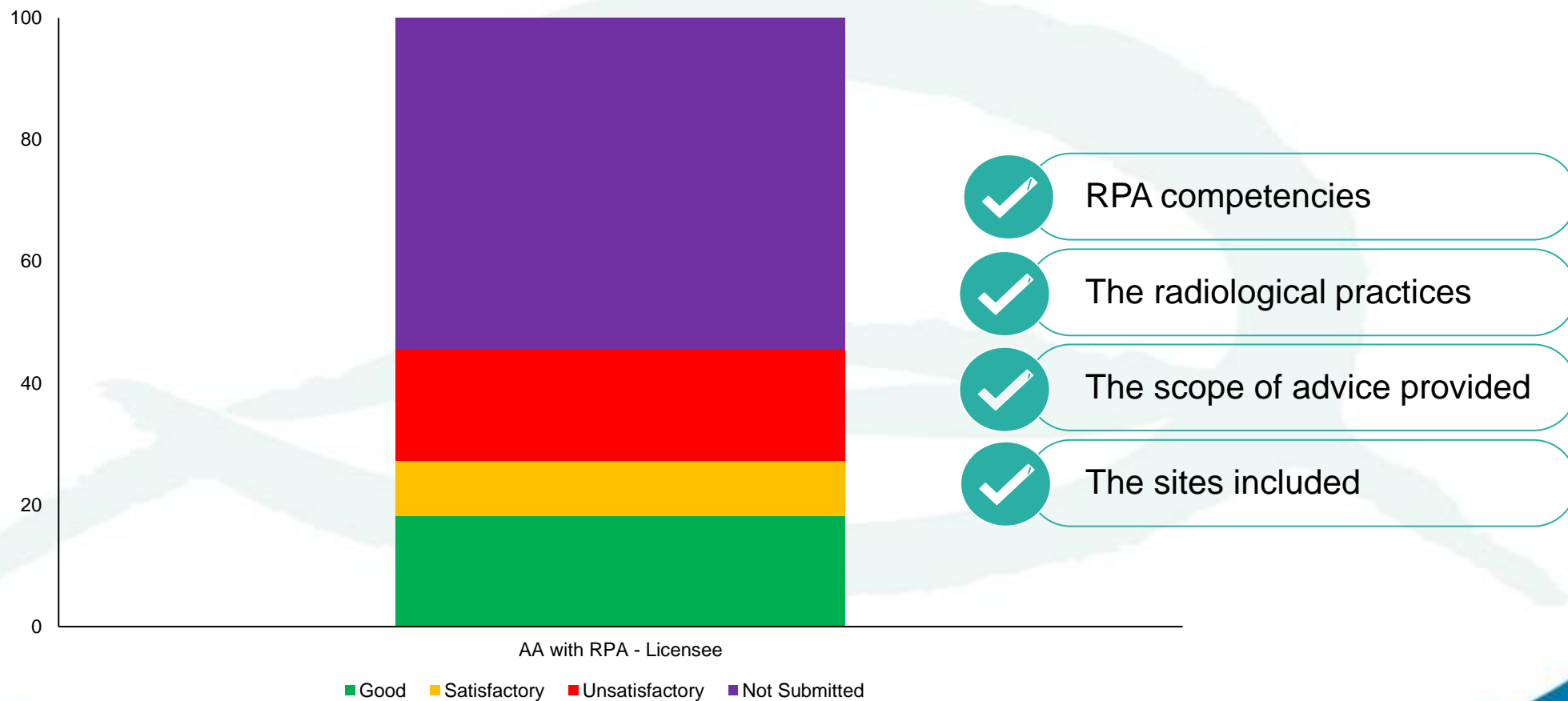
Philip Loan*
John Upton**
Daniel Cannon
Brendan Tuohy
Eoin O'Scannail
Ruairi O'Donnell



* has a narrow availability

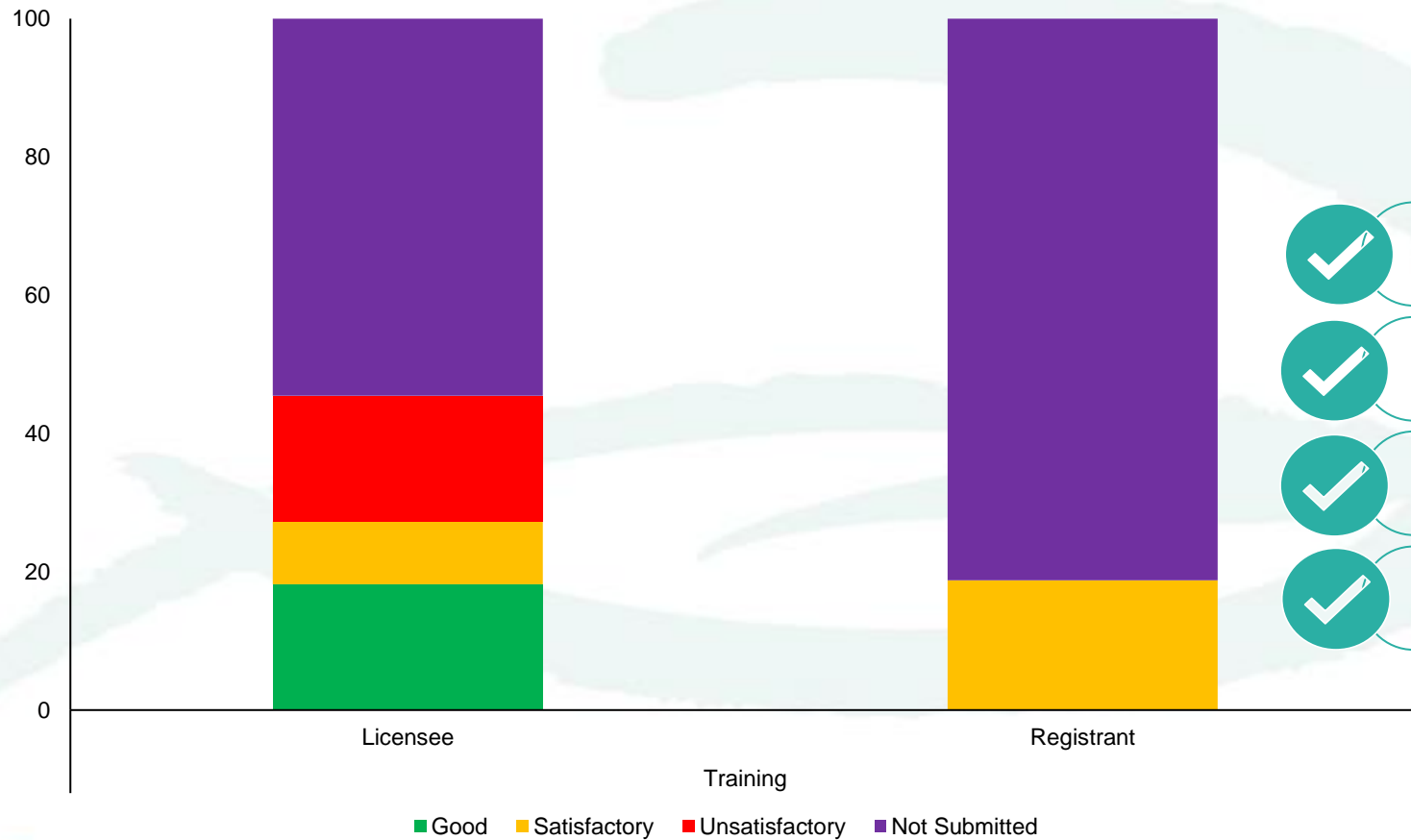
** service available for the southern part of the country

Licensee Compliance Results – Agreed Arrangements with RPA



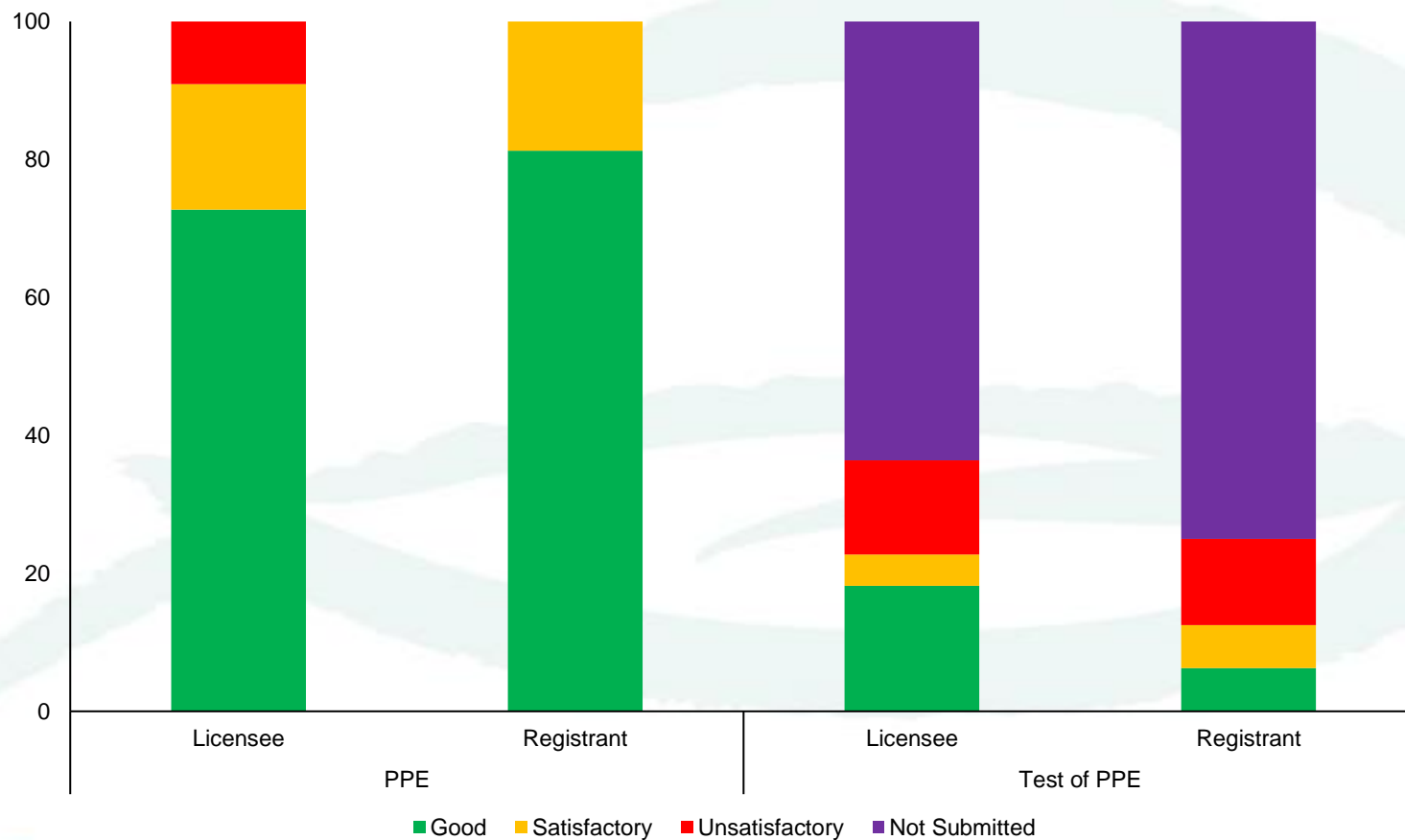
Compliance Results – Radiation Safety Training

i Refresher training every 3-5 years or if anything changes

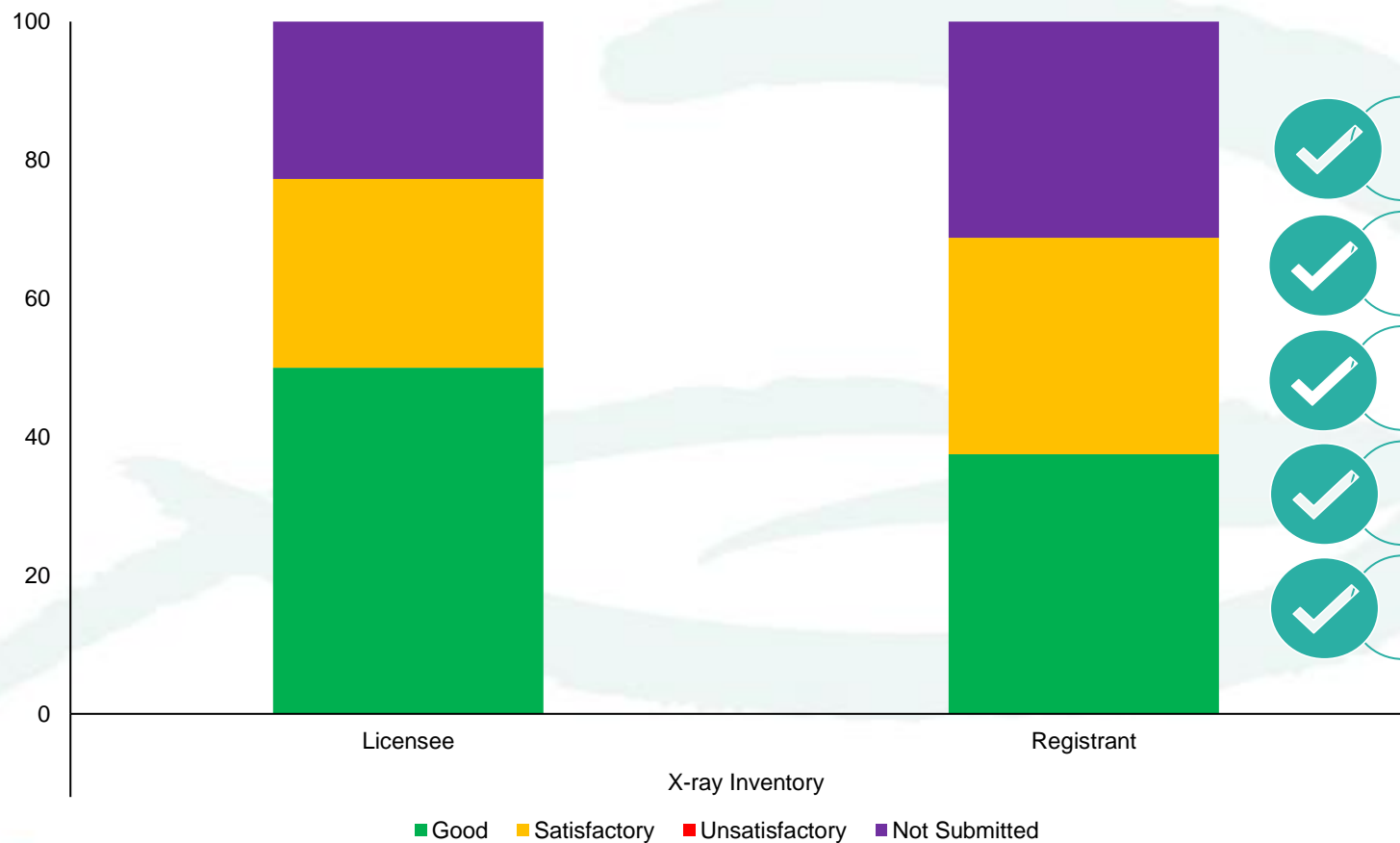


- ✓ Date of training
- ✓ Names of attendees
- ✓ Name of training provider
- ✓ Training topics covered

Compliance Results – Personal Protective Equipment

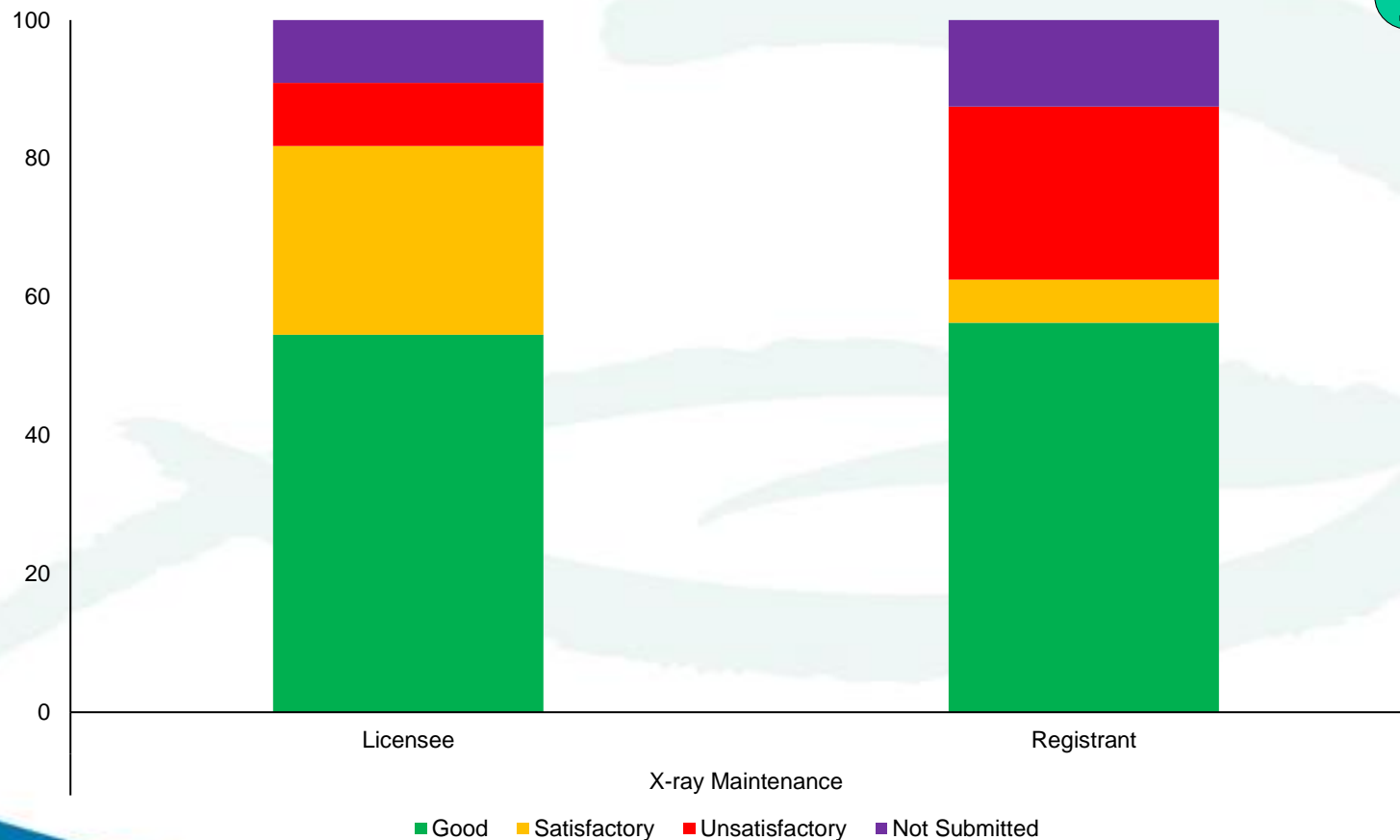


Compliance Results – X-ray Inventory



- ✓ Date of purchase
- ✓ Make and model of x-ray
- ✓ Serial number of x-ray
- ✓ Unique identifier of x-ray
- ✓ Keep record for 2 years

Compliance Results – X-ray Maintenance



Installation and servicing to be done by person who holds **EPA authorisation for installation/servicing of radiological equipment.**

Clear written arrangements for radiation safety responsibility are required before handover

The Inspection Programme

- ✓ Ensure the safety of workers and members of the public.
- ✓ Assess compliance with IRR19, Authorisation Conditions & the Vet Code of Practice.
- ✓ Assess how radiation protection arrangements are implemented in practice.
- ✓ Assess organisational culture and commitment to radiation protection.
- ✓ Promote good practice.
- ✓ Provide an opportunity for licensees to raise issues with the regulatory authority.



Powers of Inspectors

For the purpose of assessing compliance with IRR19 inspectors have the power to:

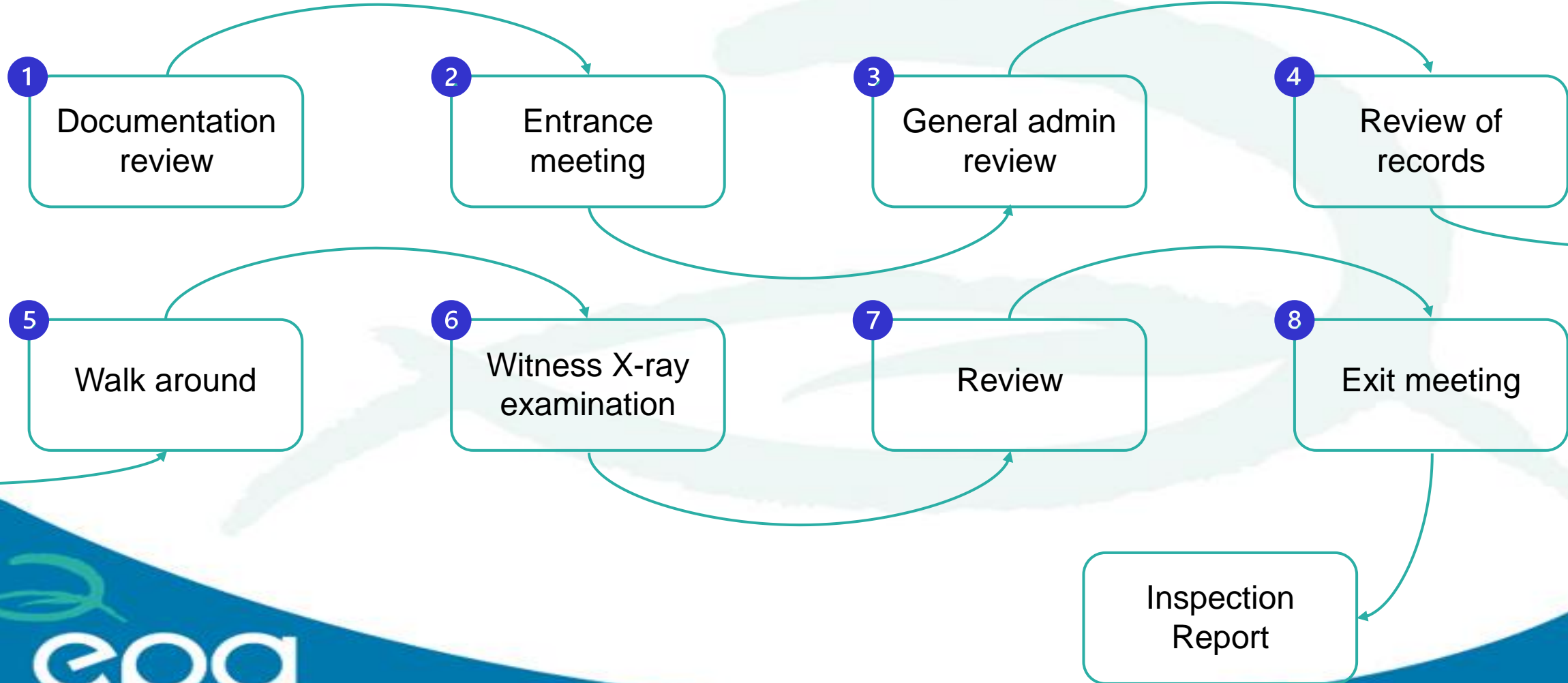
i Section 28 & 29
of the
Radiological
Protection Act
1991

- 1 enter a premises
- 2 inspect X-ray equipment and radioactive sources
- 3 require the production of documentation
- 4 take copies or extracts of documents
- 5 require a person to give reasonable information for the purpose of assessing compliance
- 6 take with them a member of An Garda Síochána (exceptional circumstances e.g. refusing inspector entry to premises)

The Inspection Programme Format

- Announced Inspection: Email notification will be sent of the planned date of inspection
- Unannounced Inspection: There will be no notification of the date of inspection
- Remote compliance assessment: An inspector will complete a desk-based assessment of compliance remotely
- In-person site inspection: An Inspector will assess compliance on-site
 - Duration: ~ 1.5/3hrs
 - Personnel required: Vet Practitioner/RPO (at least one staff member at all times)
 - Facilitate the inspection of radiography performed in the field
 - Records and documents

The Inspection Process



The Inspection Report – LEAP online

1. The inspection report
2. Inspection findings
3. Replying to findings
4. <https://leap.epa.ie/>





Site Visit Report

The site visit process is a sample on a particular day of an organisation's compliance with some of its authorisation conditions. This site visit report and its findings only relate to the scope of the site visit as identified below. Where no finding is raised against a particular condition this should not be construed to mean that there is full compliance with that condition of the authorisation. This site visit report shall not be reproduced, except in full.

The EPA must be notified of the actions to address each individual finding within 28 days unless otherwise specified through the EDEN Portal, www.edenireland.ie (via the Findings and Recommendations option, available through the Notify/Manage menu).

Authorised Body

Authorised Body	
Authorisation No.	
Contact Name	
Address	
Inspection Location - if different	
Site Visit Reference No.	

Report Details

Issue date	
Prepared By	Ellen Brogan
Version	1.0

Site Visit Details

Date of Inspection	
Time In	
Scope of Inspection	
EPA Inspector/s	Ellen Brogan
Accompanying Persons	
Authorised body Personnel and Role	
Equipment	

Summary and Key Findings

Site Areas Inspected

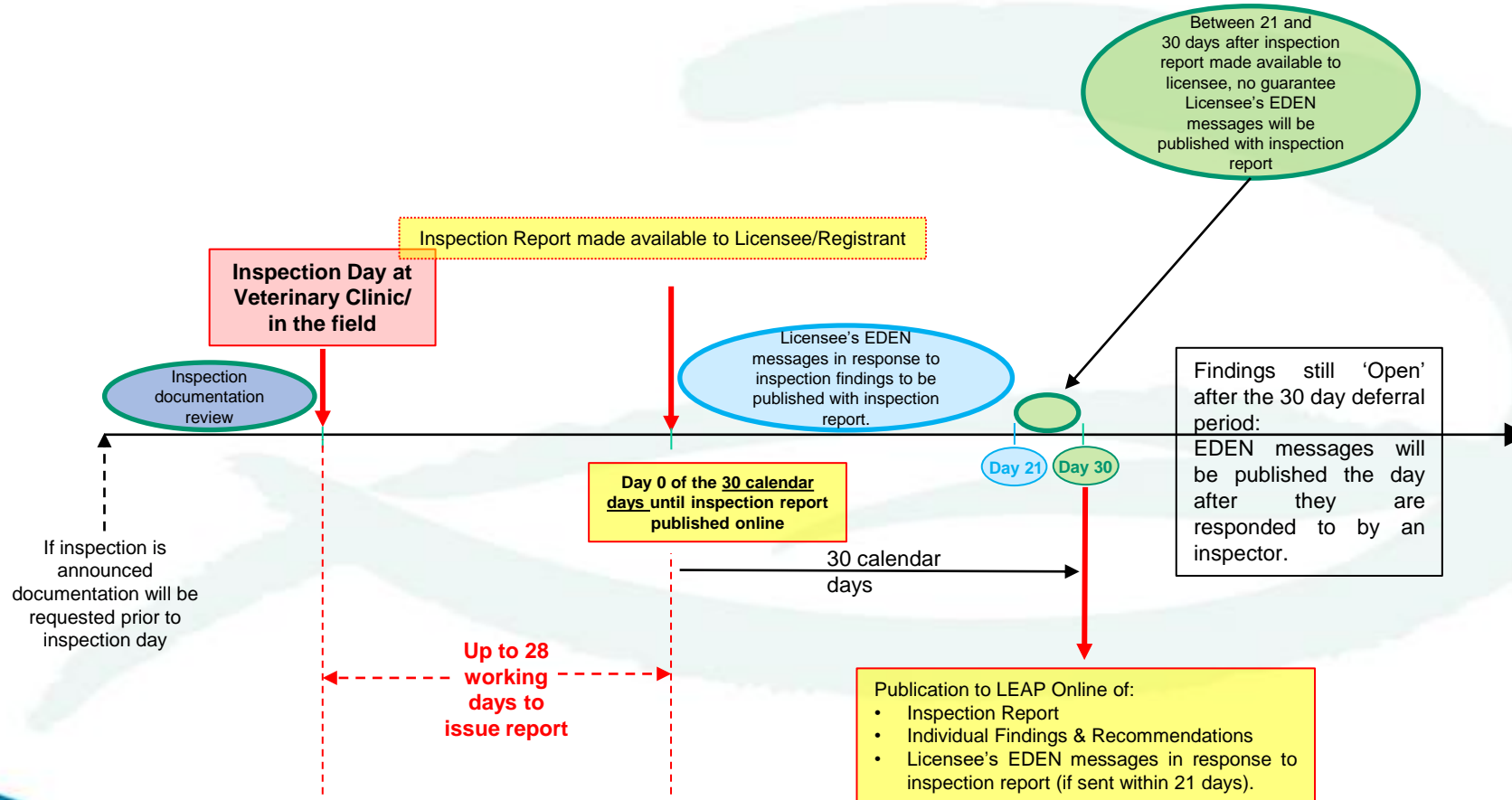
Documents Inspected

Findings

During the course of the site visit the following site visit findings were discussed with the licensee representative(s):

Reference	Observation	Action

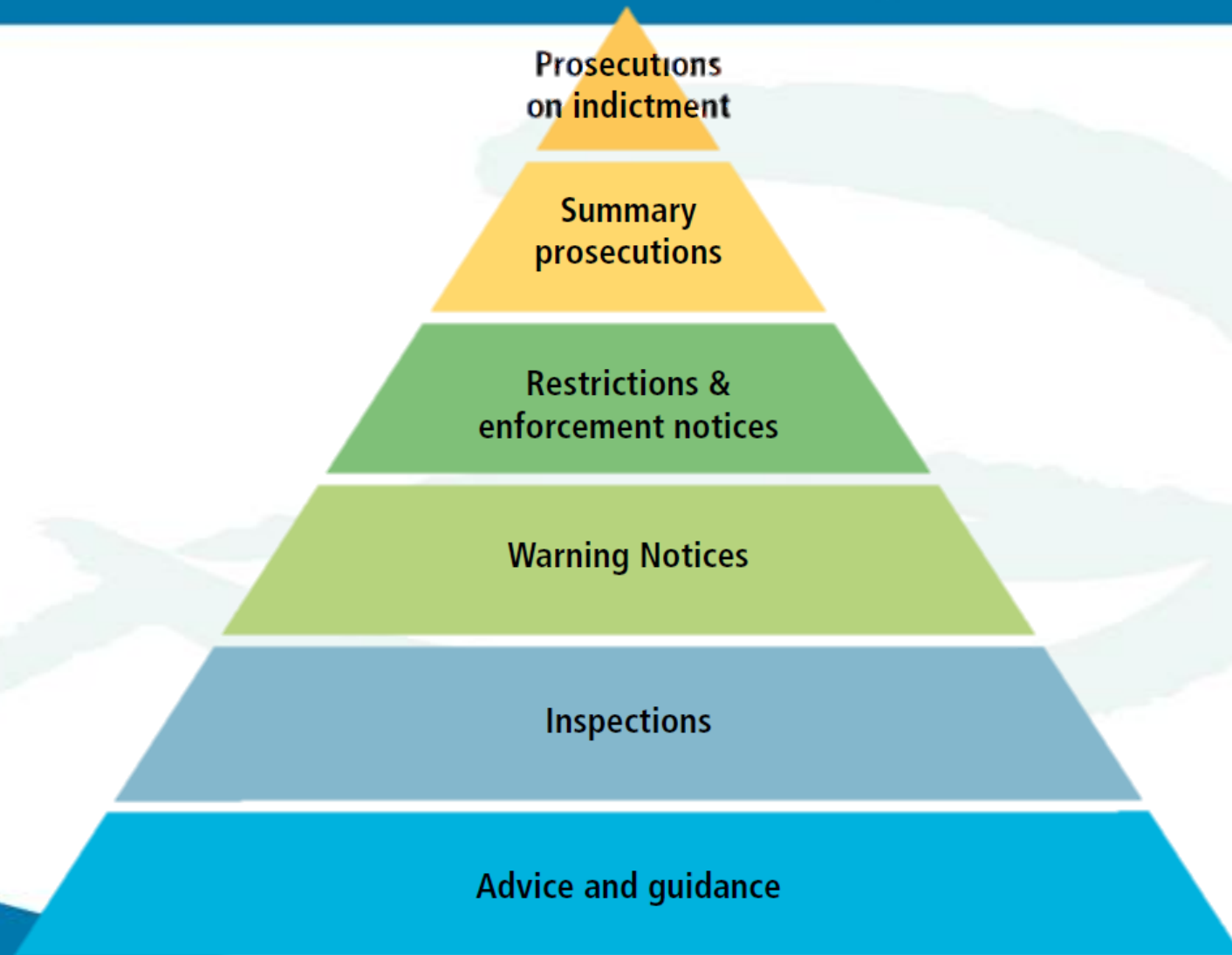
The Inspection Report and Publication Process



Some typical inspection findings

- Lack of clear governance arrangements/ responsibilities not defined.
- Inadequate Risk Assessments.
- Radiation Safety Procedures not reviewed/updated/provided to staff.
- Operational practice not matching procedures.
- QA programme not documented or implemented.
- No evidence of equipment service/ maintenance / calibration.
- Signage issues i.e., missing or inappropriate.
- Licence inaccuracies.
- Records not maintained.
- Staff not adequately trained.

4. Enforcement



How to create a profile / log in to EDEN



Sign in

EPA Services ▾

Welcome to EDEN

EDEN provides an online gateway to Environmental and Radiological Protection Licensing, Monitoring, GIS and Reporting applications for organisations with the EPA and share data with each other.

[Visit the EDEN Portal Help section](#)

Single Sign-On

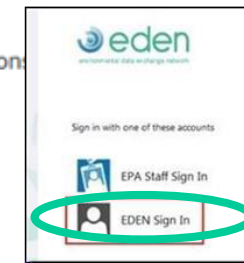
EDEN is based on single sign-on technology to allow users to logon to multiple applications using a single username / password combination.

Note: Requests for new organisations are approved by the EPA, requests for organisation membership and application access are approved by organisation and application administrators.

Please email eden@epa.ie for all technical issues and queries regarding the EDEN system.

Sign In

Sign Up



Watch how to apply for an Authorisation

What if I forget my password?



eden
environmental data exchange network

Sign in with your EDEN account

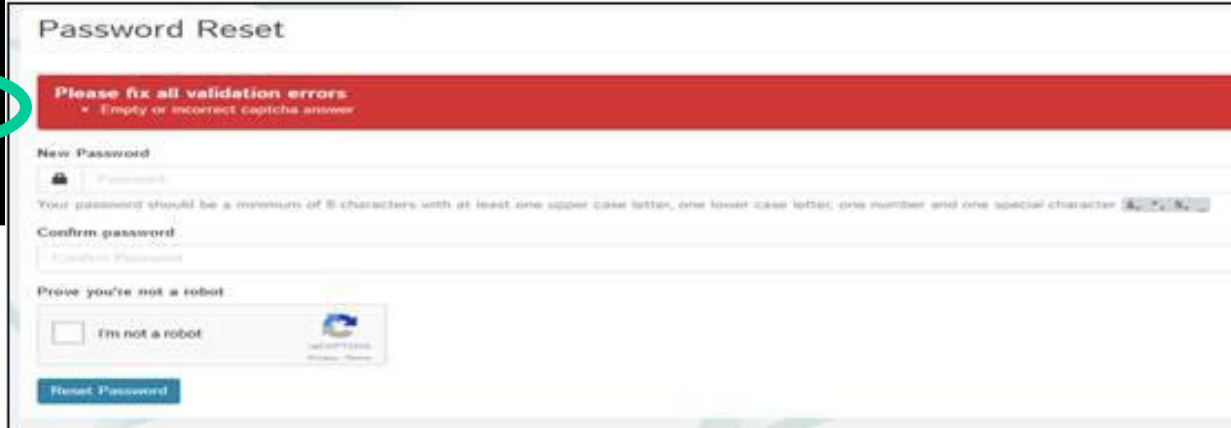
someone@example.com

Password

Sign In

Forgot Password

Use your EDEN username or email address to Sign In.



Password Reset

Please fix all validation errors

- Empty or incorrect captcha answer

New Password

Your password should be a minimum of 8 characters with at least one upper case letter, one lower case letter, one number and one special character

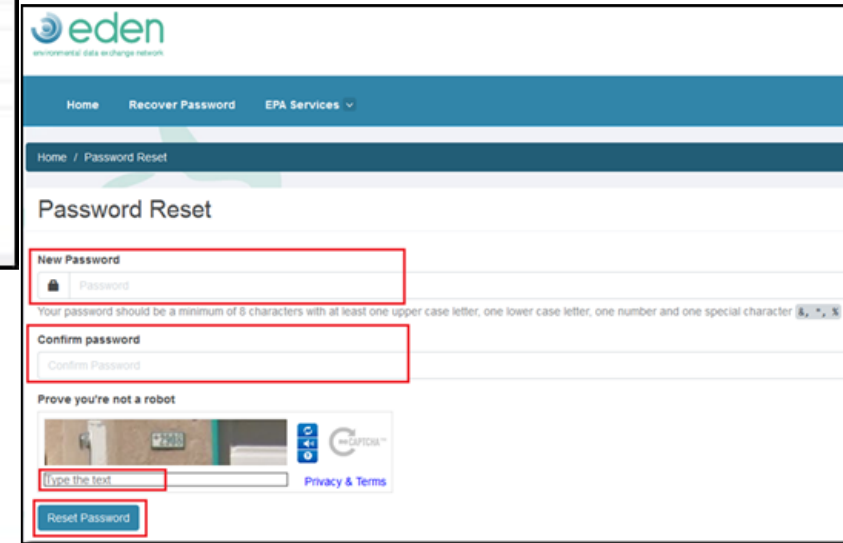
Confirm password

Prove you're not a robot

I'm not a robot

Reset Password

EDEN FAQs



eden
environmental data exchange network

Home Recover Password EPA Services

Home / Password Reset

Password Reset

New Password

Your password should be a minimum of 8 characters with at least one upper case letter, one lower case letter, one number and one special character

Confirm password

Prove you're not a robot

Type the text

Reset Password

How to pay your fee

Apply

My Applications
Amend/Change Authorisation
New Authorisation
Review Authorisation
Amend Radiation Authorisation
Renew Radiation Authorisation
New Radiation Authorisation

Notify/Manage

My Authorisations
Returns
Incidents
Compliance
Site Visits
Radiation Authorisation Dashboard
Pay Fee
Findings and Recommendations
Radiation Site Visits
Download Certificate of Authorisation
Environmental Performance Report

EPA Services

Beaches
Catchments
EPA Water Maps
SEA GIS

EDEN FAQs



How to pay your fee

ORP Test [L4469]

[Dashboard](#)[Notifications](#)[Returns](#)[Incidents](#)[Compliance](#)[Site Visits](#)[Complaints](#)[Non Compliance](#)[More... ▾](#)

Fee Payment

Fees

The total amount payable is **€1000.00**.

You must choose a payment option before submitting your application.

Pay by Card

Enter Purchase Order Reference to Pay by Invoice

The total of **€1000.00** will be paid in one transaction at the end of the online process.

You are committing to electronically paying the total due of **€1000.00** following receipt of an invoice from the Environmental Protection Agency.

Submit

- EPA Reports
- Environmental Performance Reporting
- Meetings
- Contacts
- Fee Payment**

How to access your Authorisation

Apply

- My Applications
- Amend/Change Authorisation
- New Authorisation
- Review Authorisation
- Amend Radiation Authorisation
- Renew Radiation Authorisation
- New Radiation Authorisation

Notify/Manage

- My Authorisations
- Returns
- Incidents
- Compliance
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- Radiation Site Visits
- Download Certificate of Authorisation
- Environmental Performance Report

EPA Services

- Beaches
- Catchments
- EPA Water Maps
- SEA GIS

EDEN FAQs



orpedensupport@epa.ie

If you have amended any details of your Authorisation, e.g. equipment, then only Schedules 2 - 4 will be visible here. If you want a copy of your Authorisation which also includes the front cover and Authorisation Conditions contact us via email.

If you have not amended any details of your Authorisation, you will be able to access front cover, Authorisation Conditions, and Schedules 2 - 4 here.

How to amend your Authorisation

	Registration	Licensing
When is it necessary to make a change/ amendment?	<ul style="list-style-type: none"> ▶ Change to legal entity or address. ▶ Change to the senior management contact or the contact for correspondence. ▶ Before carrying out a new veterinary radiology procedure not covered by the existing registration. 	<ul style="list-style-type: none"> ▶ Change to legal entity or address. ▶ Change to the senior management contact, the contact for correspondence, the RPO or the RPA. ▶ Change to the schedule of equipment linked to any licensable radiological practice. ▶ Before carrying out a new veterinary radiology procedure not covered by the existing licence.

How to amend your Authorisation

Apply

[My Applications](#)

[Amend/Change Authorisation](#)

[New Authorisation](#)

[Review Authorisation](#)

[Amend Radiation Authorisation](#)

[Renew Radiation Authorisation](#)

[New Radiation Authorisation](#)

Notify/Manage

[My Authorisations](#)

[Returns](#)

[Incidents](#)

[Compliance](#)

[Site Visits](#)

[Radiation Authorisation Dashboard](#)

[Pay Fee](#)

[Findings and Recommendations](#)

[Radiation Site Visits](#)

[Download Certificate of Authorisation](#)

[Environmental Performance Report](#)

EPA Services

[Beaches](#)

[Catchments](#)

[EPA Water Maps](#)

[SEA GIS](#)

EDEN FAQs



How to amend your Authorisation

Radiation Protection Authorisation

Please note that changes made to any records on your Authorisation (Authorisation 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.

Details

Premises

Personnel

Inventory

Documents

Complete

Details for ORP Test

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

Sector:

Industry

Practices: (please select any additional practices being requested)

× Product inspection/sterilisation/industrial radiography

× Use of laboratory equipment incorporating sealed sources

× Use of sealed sources in industry

Your approved dosimetry service provider:

Choose...

Details of approved dosimetry service providers are available on <http://www.epa.ie/radiation/regulation/dosimetry/>.

Details of practices and associated fees are available on <http://www.epa.ie/radiation/regulation/>.

Save

Go to Complete

Premises >

How to amend your Authorisation

Radiation Protection Authorisation

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Details

Premises

Personnel

Inventory

Documents

Complete

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Choose...

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Details of practices and associated fees are available on <http://www.epa.ie/radiation/regulation/>.

Save

Go to Complete

Premises >

How to amend your Authorisation - Personnel

Radiation Protection Authorisation

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Details Premises **Personnel** Inventory Documents Complete

Personnel for ORP Test

List the individuals associated with the roles below. One individual may be assigned to multiple roles.

Personnel	Role	Actions
Ciara Maguire	Contact for Correspondence	Edit Remove
Joe Bloggs	Senior Management Contact	Edit Remove
Joe Bloggs	RPO	Edit Remove

Total Items: 3

+ Add Senior Management Contact ⓘ

+ Add Radiation Protection Officer

+ Add Contact for Correspondence

+ Add Radiation Protection Adviser

Details of approved Radiation Protection Advisers are available on <http://www.epa.ie/radiation/regulation/rpa/rparegister/>

< Premises Go to Complete Inventory >

How to amend your Authorisation - Inventory

Details Premises Personnel **Inventory** Documents Complete

Inventory for ORP Test


Please add to, remove from and/or update existing items in your inventory, as required.

X-rays and radiation sources for the following registerable activities should not be listed in the Inventory: Product inspection/sterilisation/industrial radiography using X-ray cabinets, Use of laboratory equipment incorporating sealed sources.

X-rays and radiation sources for the following licensable activities should be listed in the Inventory: Use of sealed sources in industry.

Search:

+ Add Item

Premises ...	Location	Type	Practice	Details	Action
ORP Test (The Street, Town Square)					
ORP Test (...	Test	Sealed Source	Product irra...	Cobalt-60 500.00 TBq xxx	View Amend Remove 

Total Items: 1

View Inspection Findings

Apply

- My Applications
- Amend/Change Authorisation
- New Authorisation
- Review Authorisation
- Amend Radiation Authorisation
- Renew Radiation Authorisation
- New Radiation Authorisation

Notify/Manage

- My Authorisations
- Returns
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EPA Services

- Beaches
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- EPA Water Maps
- SEA GIS

EDEN FAQs



View Inspection Findings

ORP Test [L4469]

Dashboard

Notifications

Returns

Incidents

Compliance

Site Visits

Complaints

Non Compliances

More... ▾

Notifications

Search...

Show 10 ▾ entries



Title ▾ ↓	Regarding ▾	Type ▾	Issue Date ▾ ↓	Due Date ▾	Status ▾
Update Radiation Safety Procedures	L4469-01	Site Visit Findings	09/01/2023	06/02/2023	Action Required
Schedule 3 and Schedule 4 to be amended	L4469-01	Site Visit Findings	09/01/2023	06/02/2023	Action Required

View Inspection Findings

Update Radiation Safety Procedures

Authorisation Name: ORP Test **Reg No:** L4469-01
Type: SV Finding **Status:** Open
Due Date: 06/02/2023

Details:
A mechanism for ensuring that the RSP's are distributed to and read by all relevant staff shall be developed and records maintained. A copy of the current records shall be uploaded to EDEN, providing evidence that the updated RSPs have been brought to the attention of, and made available to the relevant workers concerned.

Messages

Show 5 entries



From ▼	Subject ▼	Date Sent	Actions
No Messages were found			

Showing 0 to 0 of 0 entries.

Reply to EPA

New Message

Message

Subject:

Message:

Message Documents

There are no documents available

Upload file

Send

Cancel

Technical Issues?

Online Contact Form



ORPedensupport@epa.ie

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Visit the EDEN Portal Help section

Single Sign-On

EDEN is based on single sign-on technology to allow users to logon to multiple applications using a single username / password combination.

Note: Requests for new organisations are approved by the EPA, requests for organisation membership and application access are approved by organisation and application administrators.

Please email eden@epa.ie for all technical issues and queries regarding the EDEN system.

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