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

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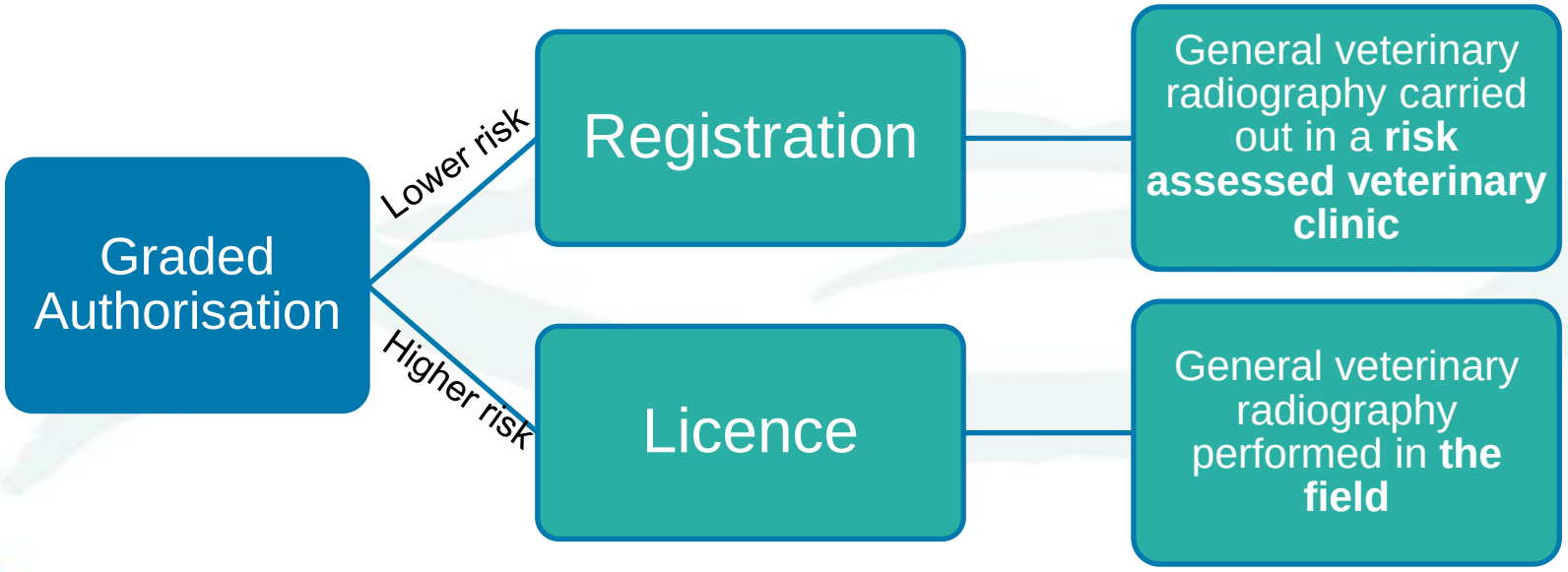
1. Authorisation

- 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

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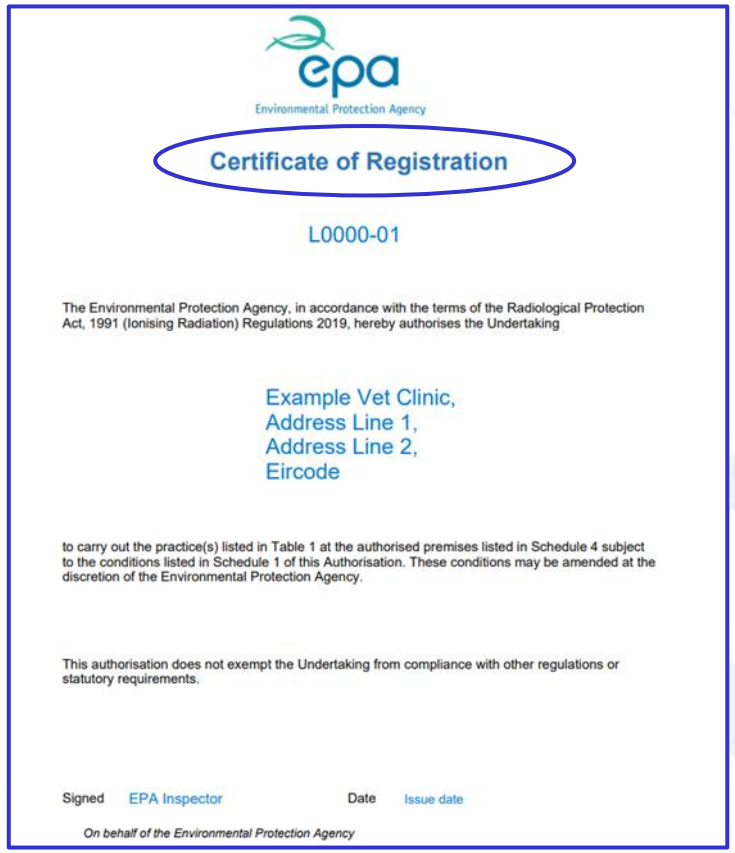
Last Week's Recap

	Registration	Licensing
Radiological practices	X-ray examination of small animals in a defined X-ray area	► 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	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. The undertaking is the person with primary legal responsibility for compliance with the regulations.
Radiation Protection Officer (RPO)	An individual or a unit designated by the undertaking to implement the radiation protection arrangements. This is usually, but not always, a veterinary practitioner or nurse.
Radiation Protection Adviser (RPA)	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.

Registration / License



Environmental Protection Agency

Certificate of Registration

L0000-01

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

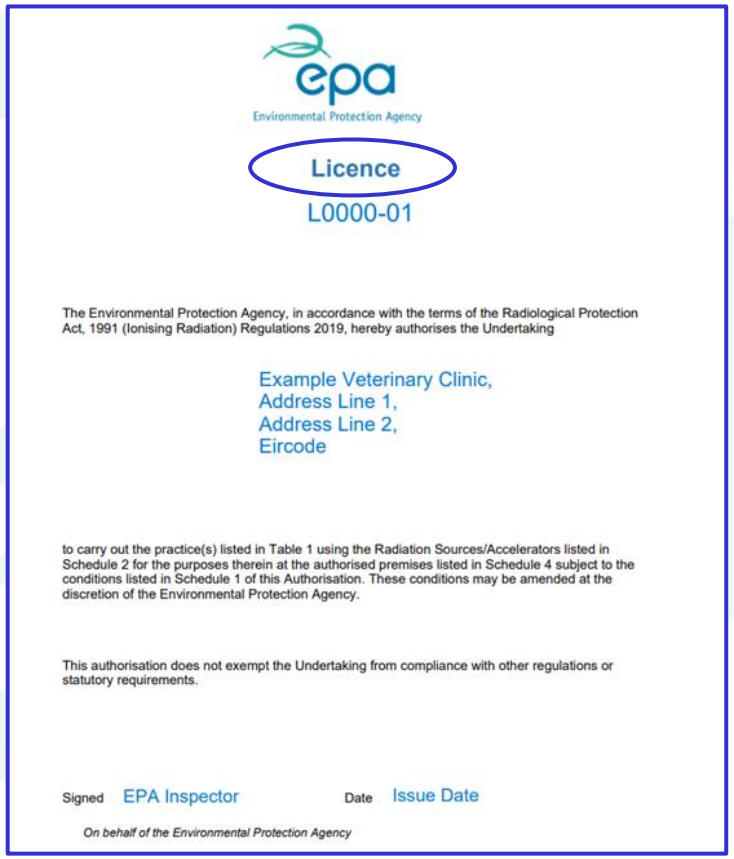
Example Vet Clinic,
Address Line 1,
Address Line 2,
Eircode

to carry out the practice(s) listed in Table 1 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 EPA Inspector Date Issue date

On behalf of the Environmental Protection Agency



Environmental Protection Agency

Licence

L0000-01

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

Example Veterinary Clinic,
Address Line 1,
Address Line 2,
Eircode

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 EPA Inspector Date Issue Date

On behalf of the Environmental Protection Agency

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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).	☐
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.

Signature: _____ Print Name: _____

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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.

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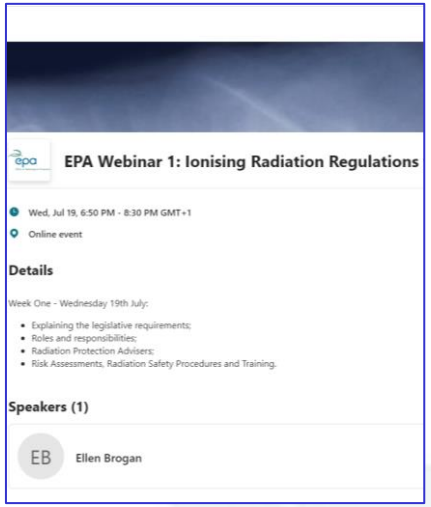
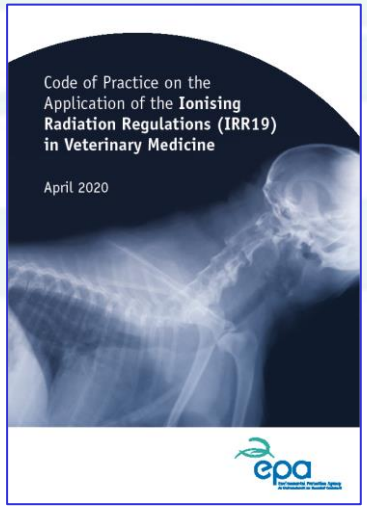
2. Guidance

Webinar One

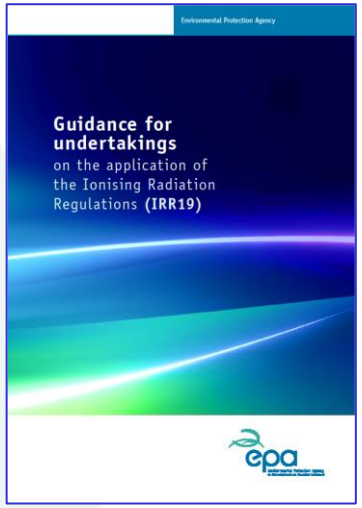
Recording to be made available on epa.ie



Vet Code of Practice



Guidance for Undertakings



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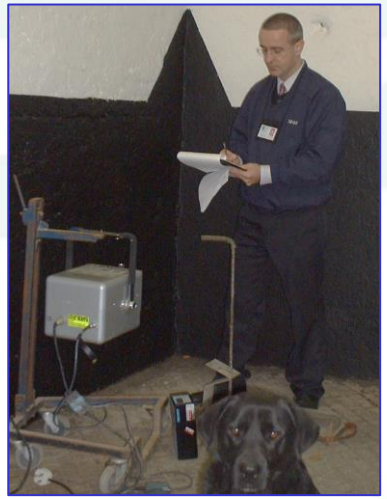
3. Compliance Assurance

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



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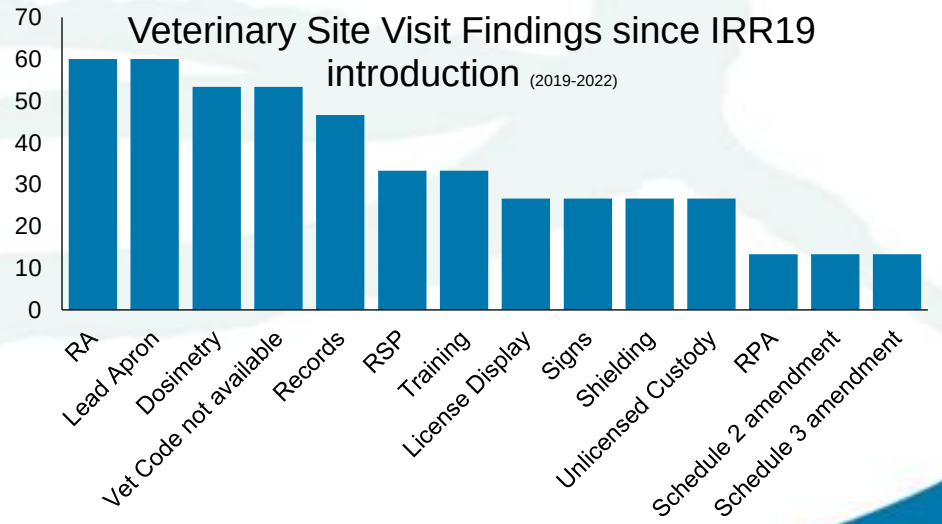
Online Compliance Assessment – the Vet Survey

- 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)



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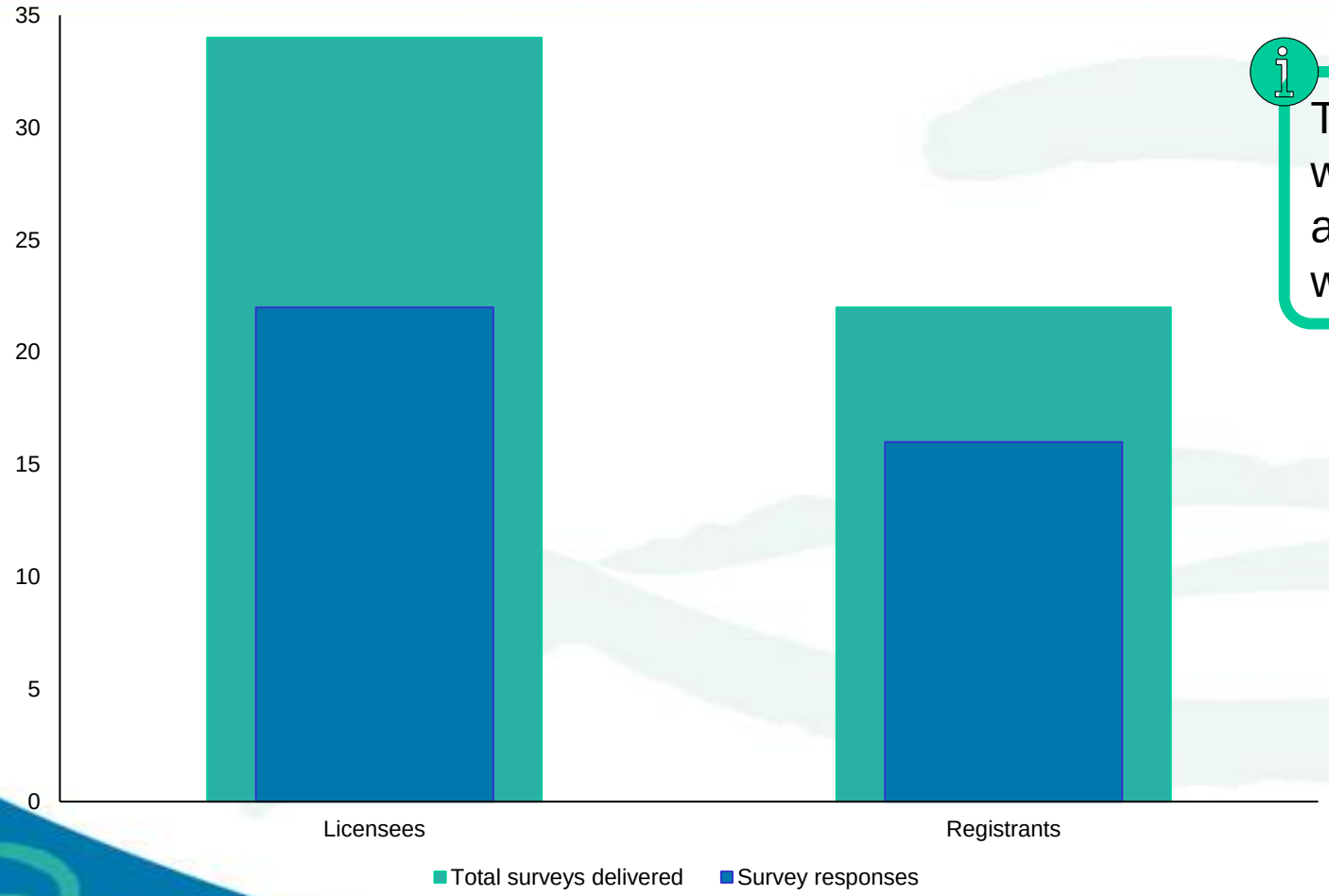
The Vet Survey



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

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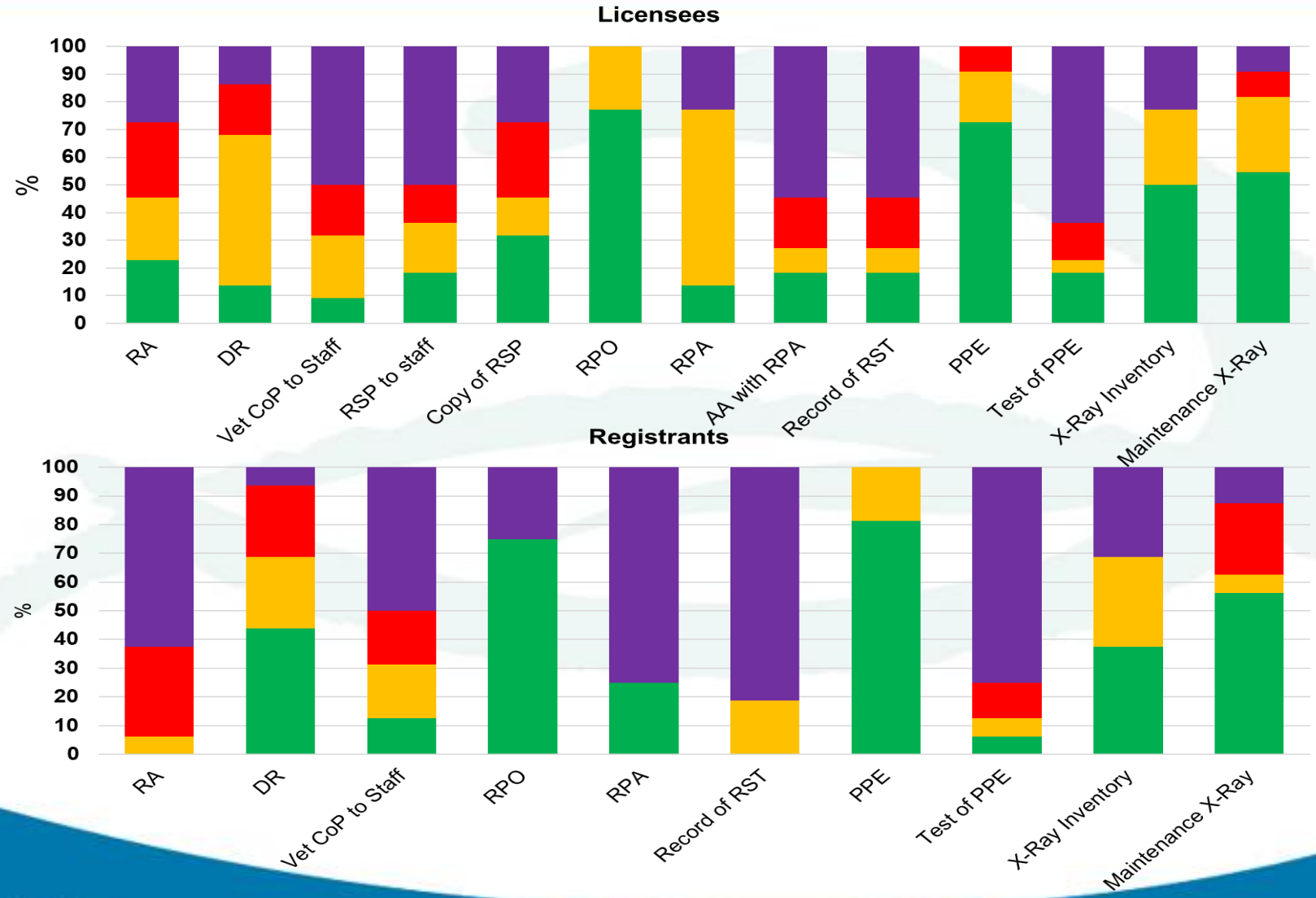
The Vet Survey – Compliance Results

	Good
	Satisfactory
	Unsatisfactory
	Not Submitted



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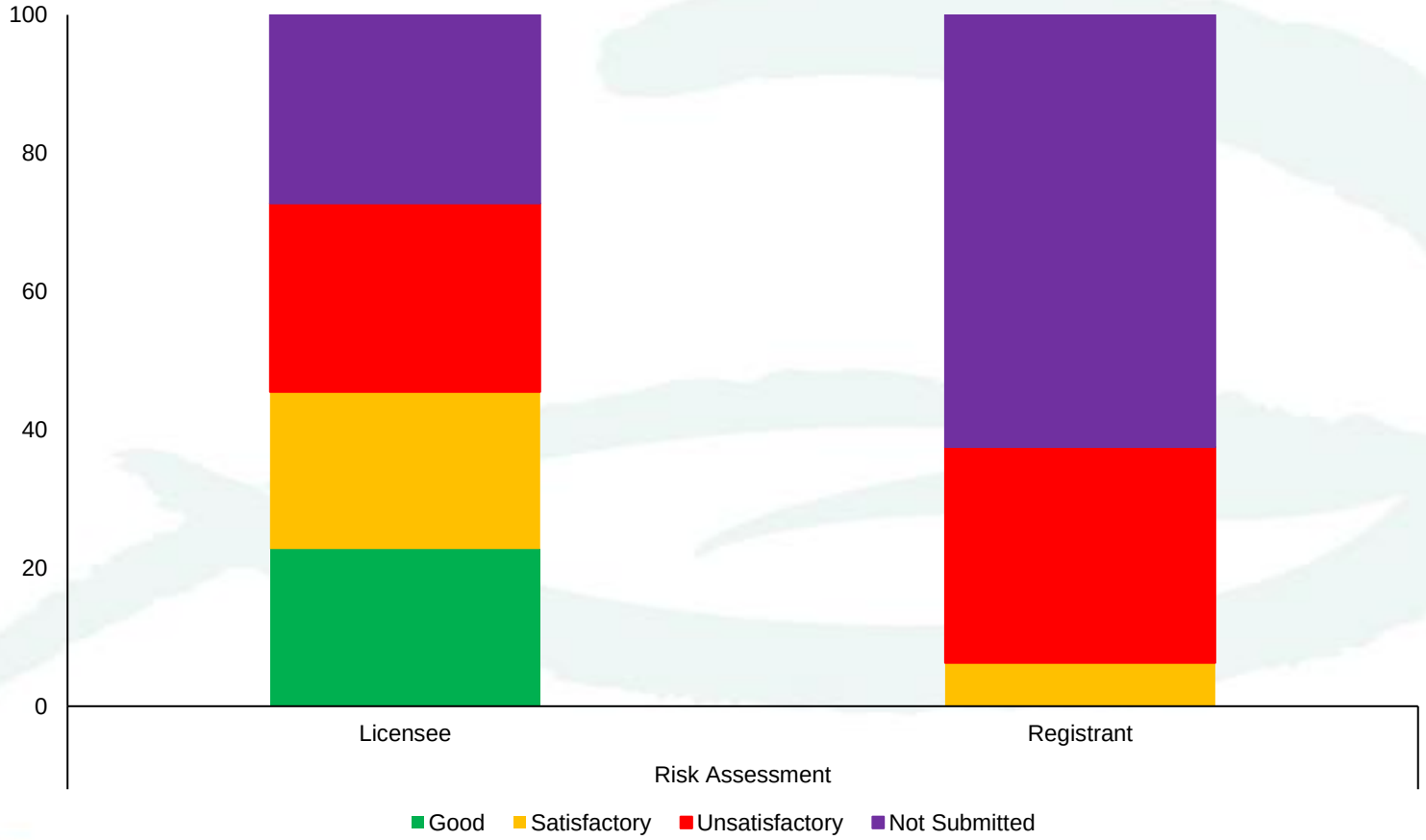
Compliance Results – the Risk Assessment



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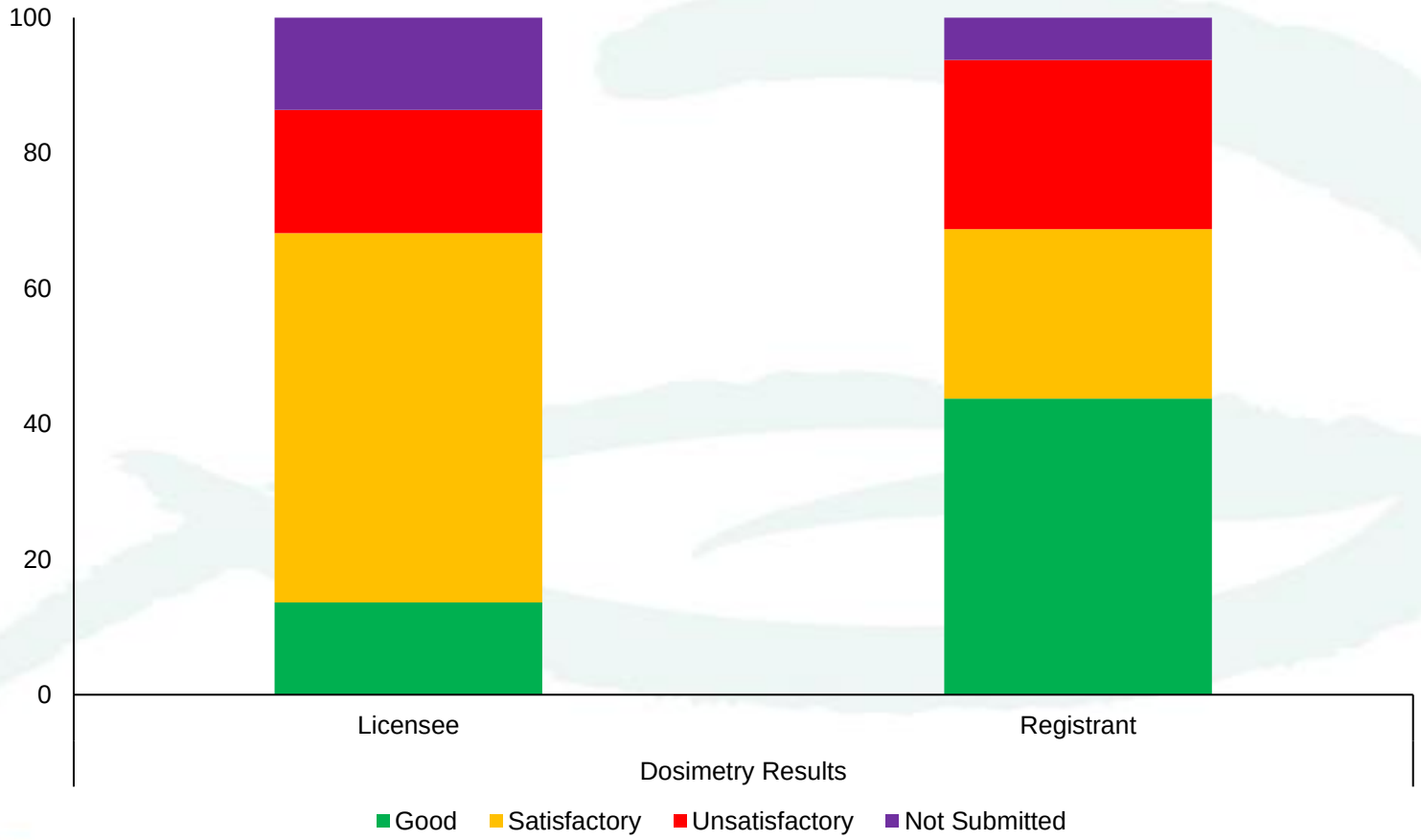
Compliance Results – Dosimetry Results Records



EPA approved dosimetry services

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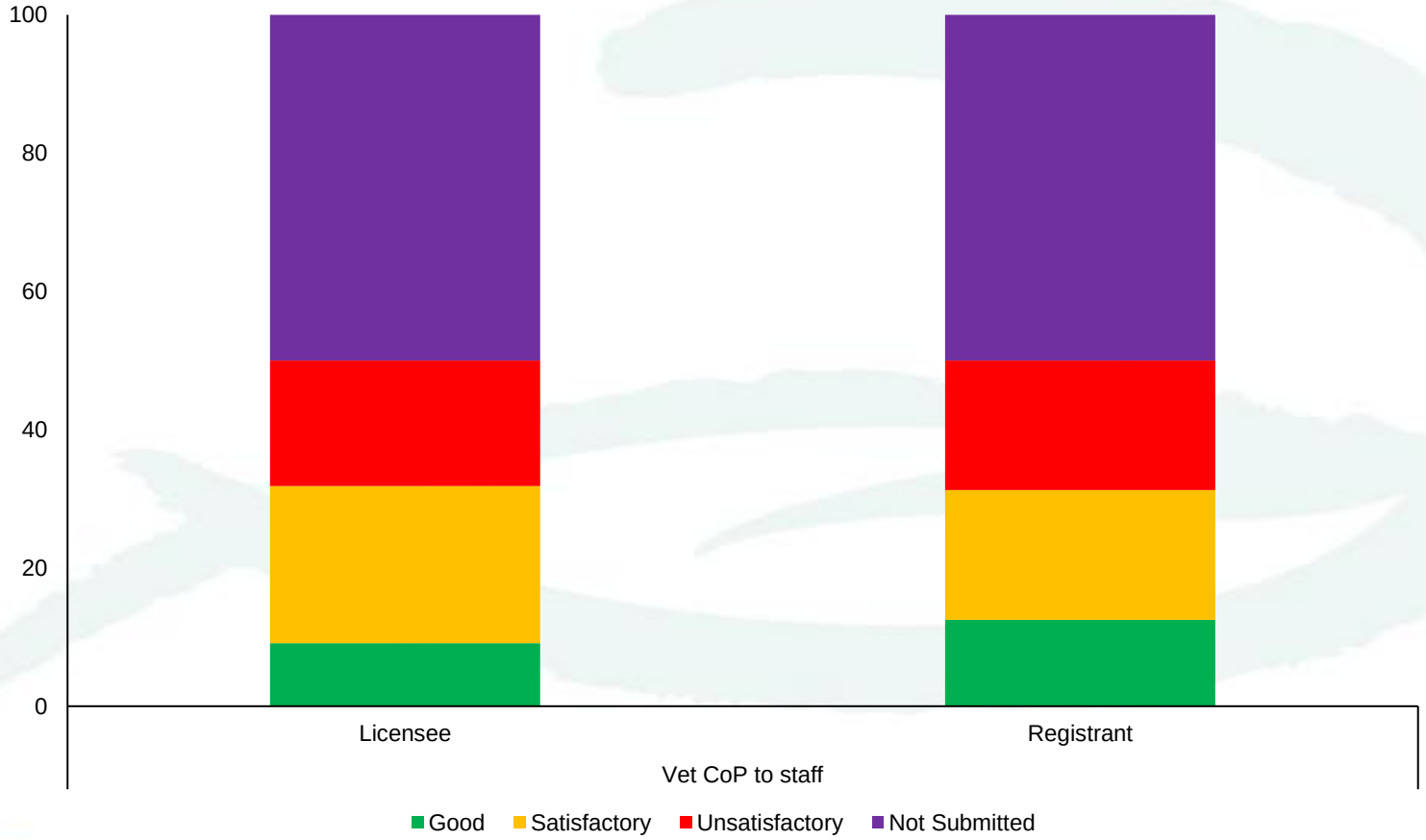
Compliance Results – Vet Code of Practice to staff



The Vet Code of Practice

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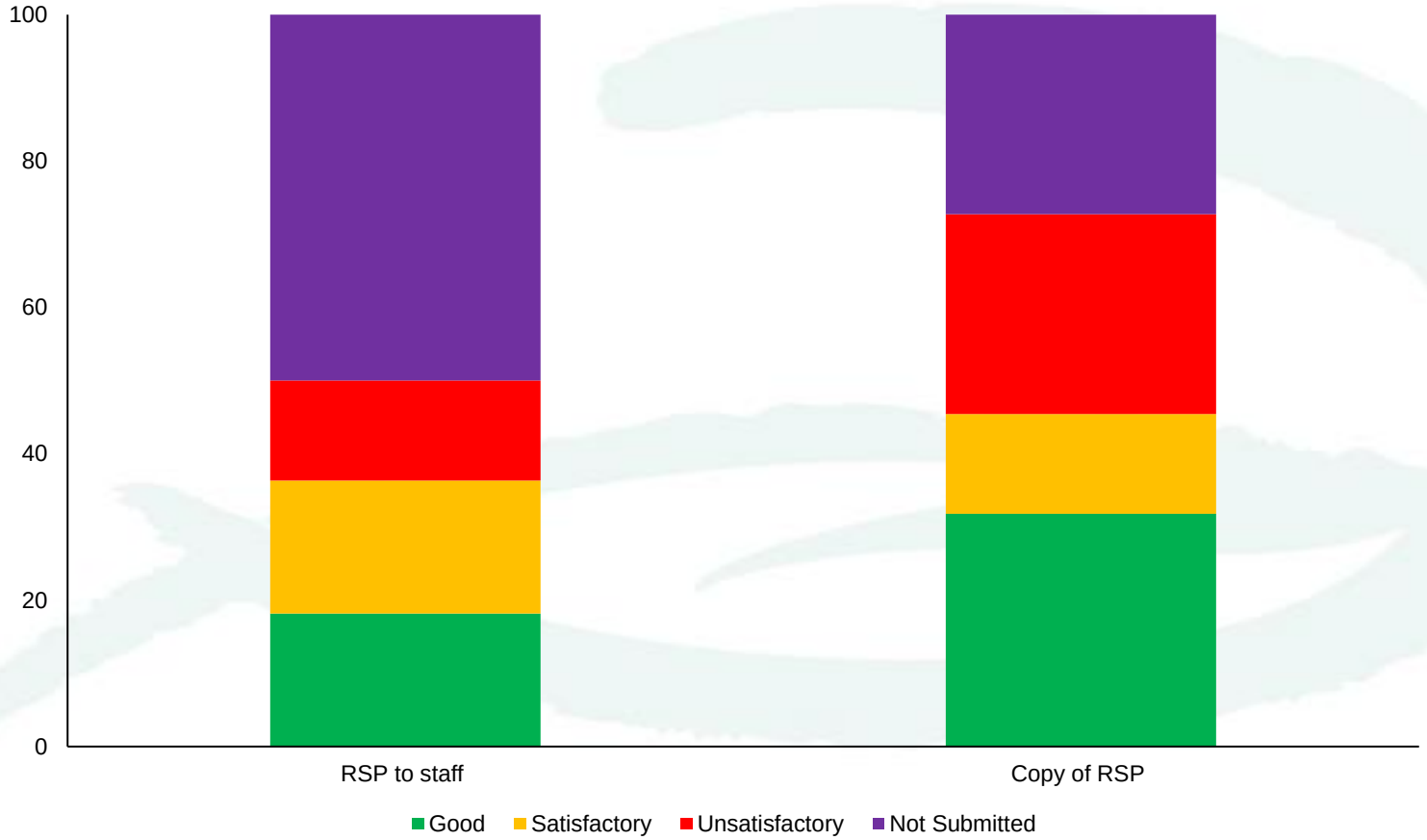
Licensee Compliance Results – Radiation Safety Procedures



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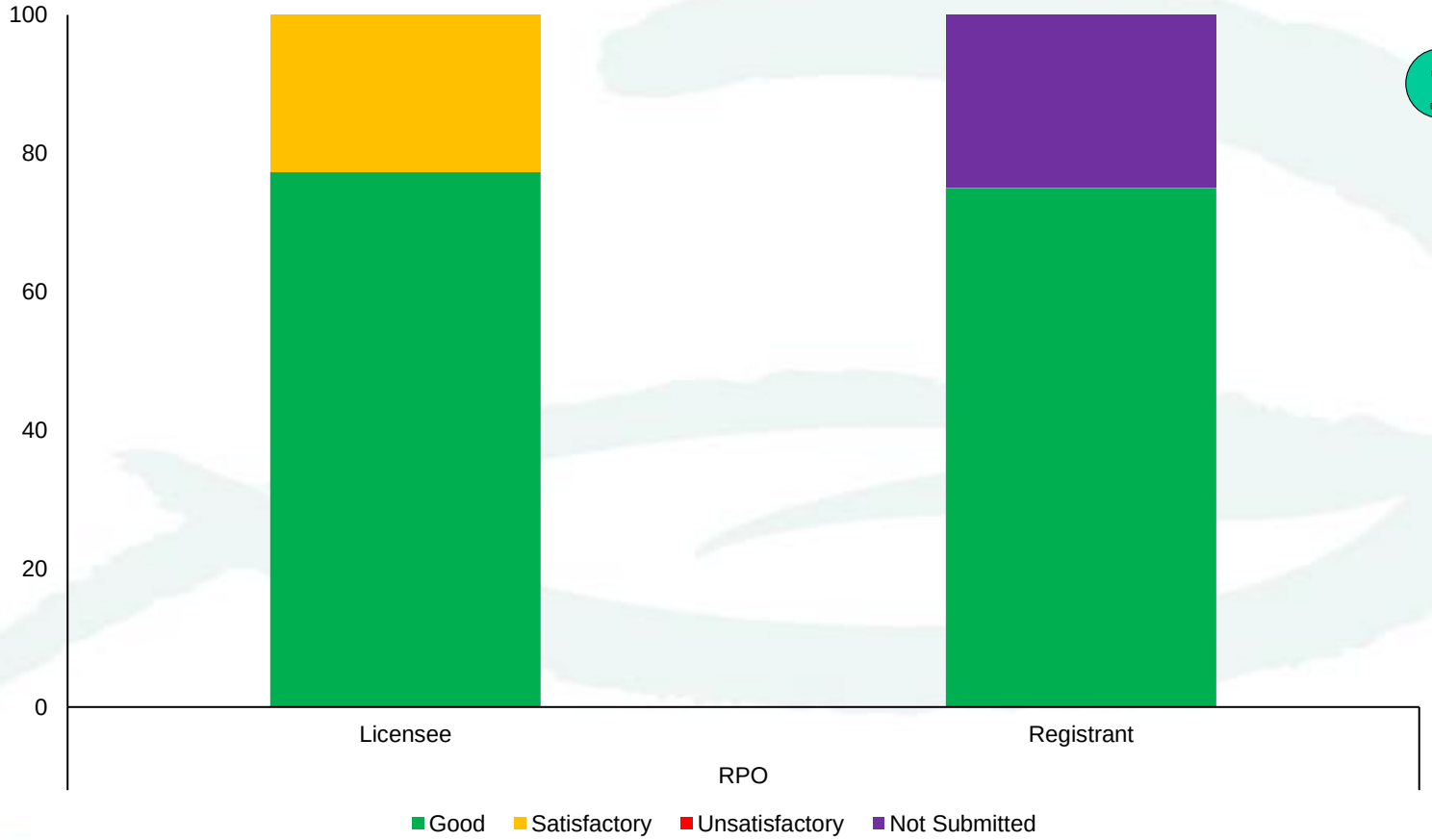
Compliance Results – Radiation Protection Officer (RPO)



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

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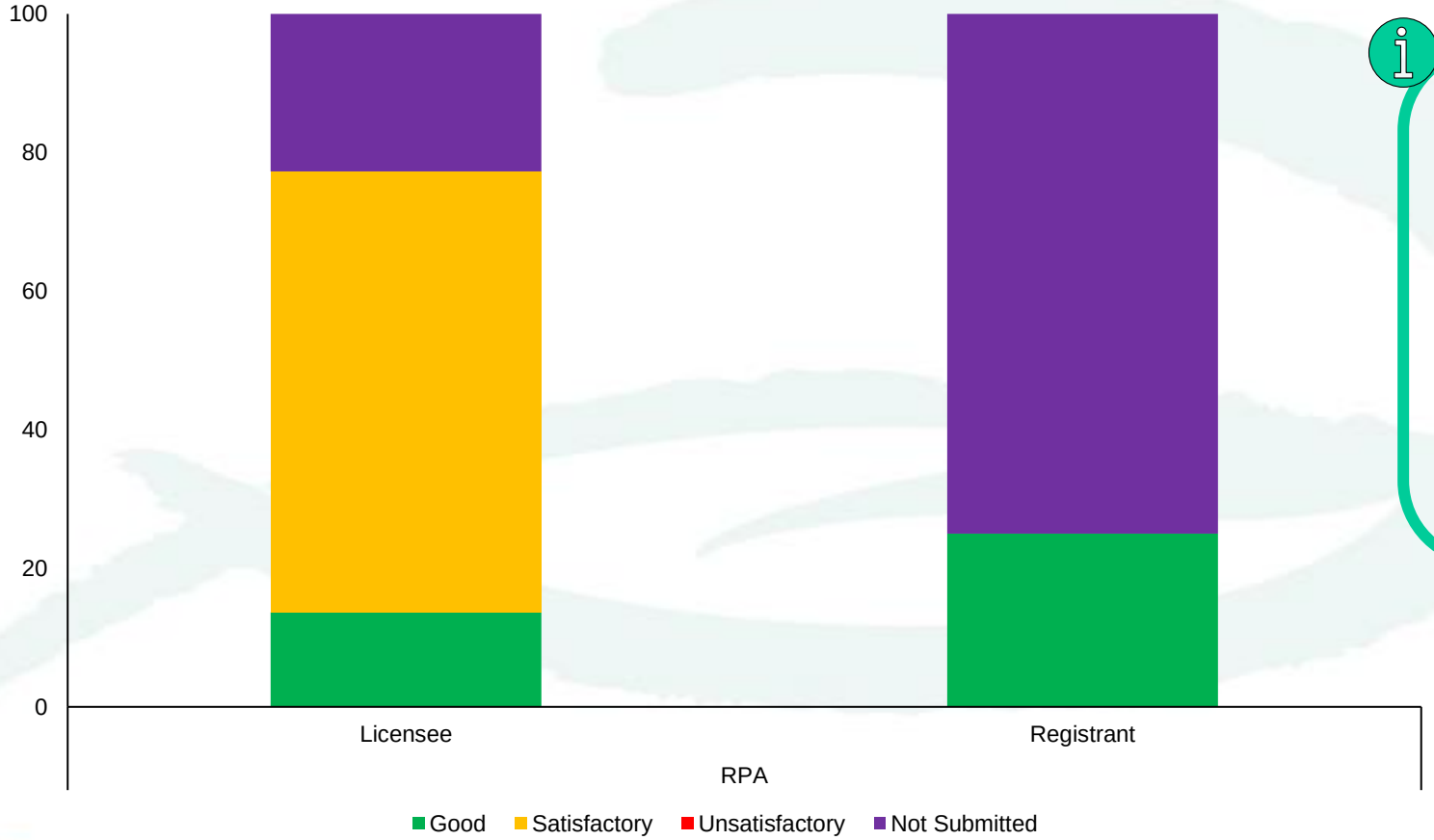
Compliance Results – Radiation Protection Adviser (RPA)



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

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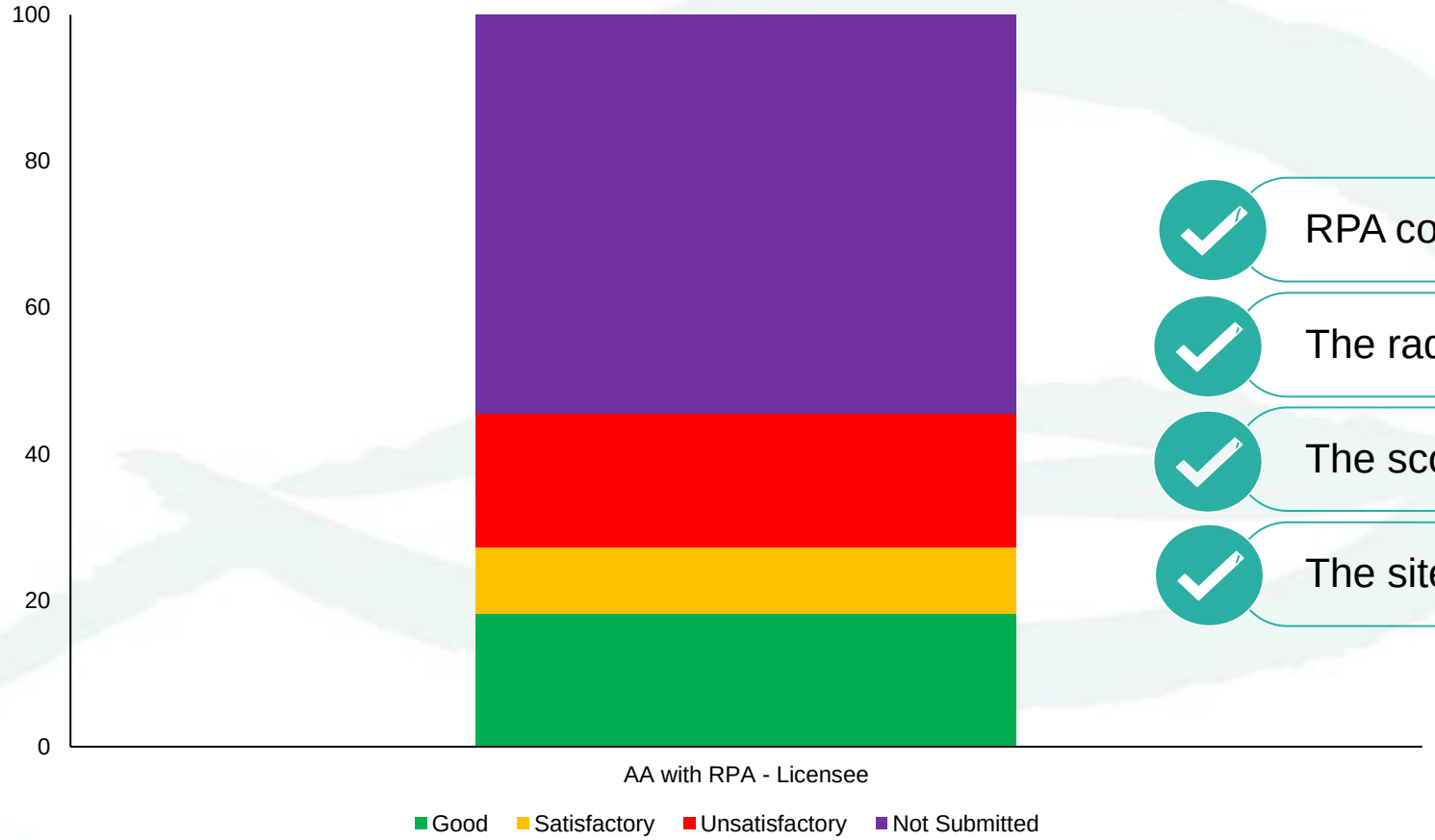
Licensee Compliance Results – Agreed Arrangements with RPA



- RPA competencies
- The radiological practices
- The scope of advice provided
- The sites included

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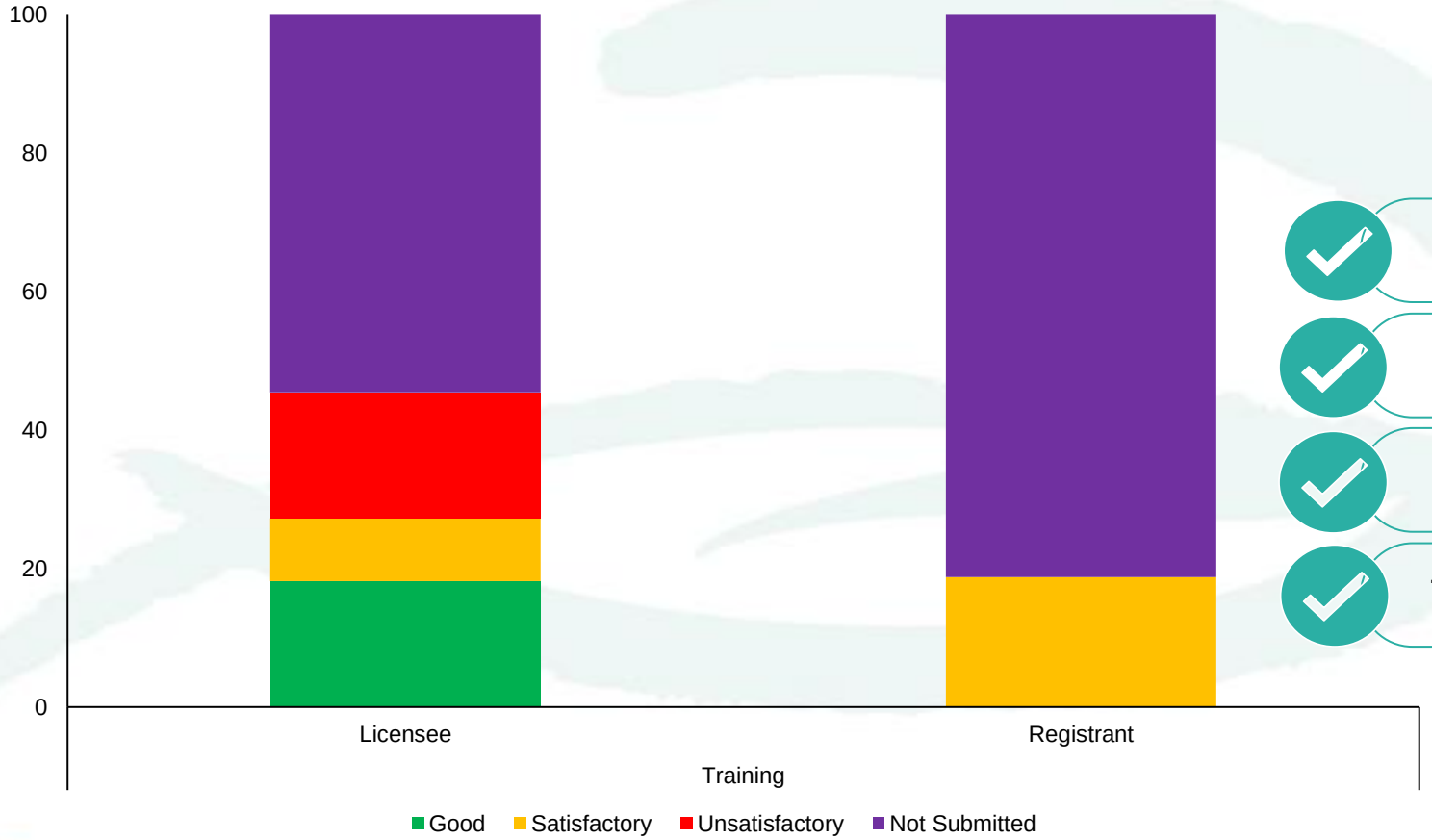
Compliance Results – Radiation Safety Training

Refresher training every 3-5 years or if anything changes



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

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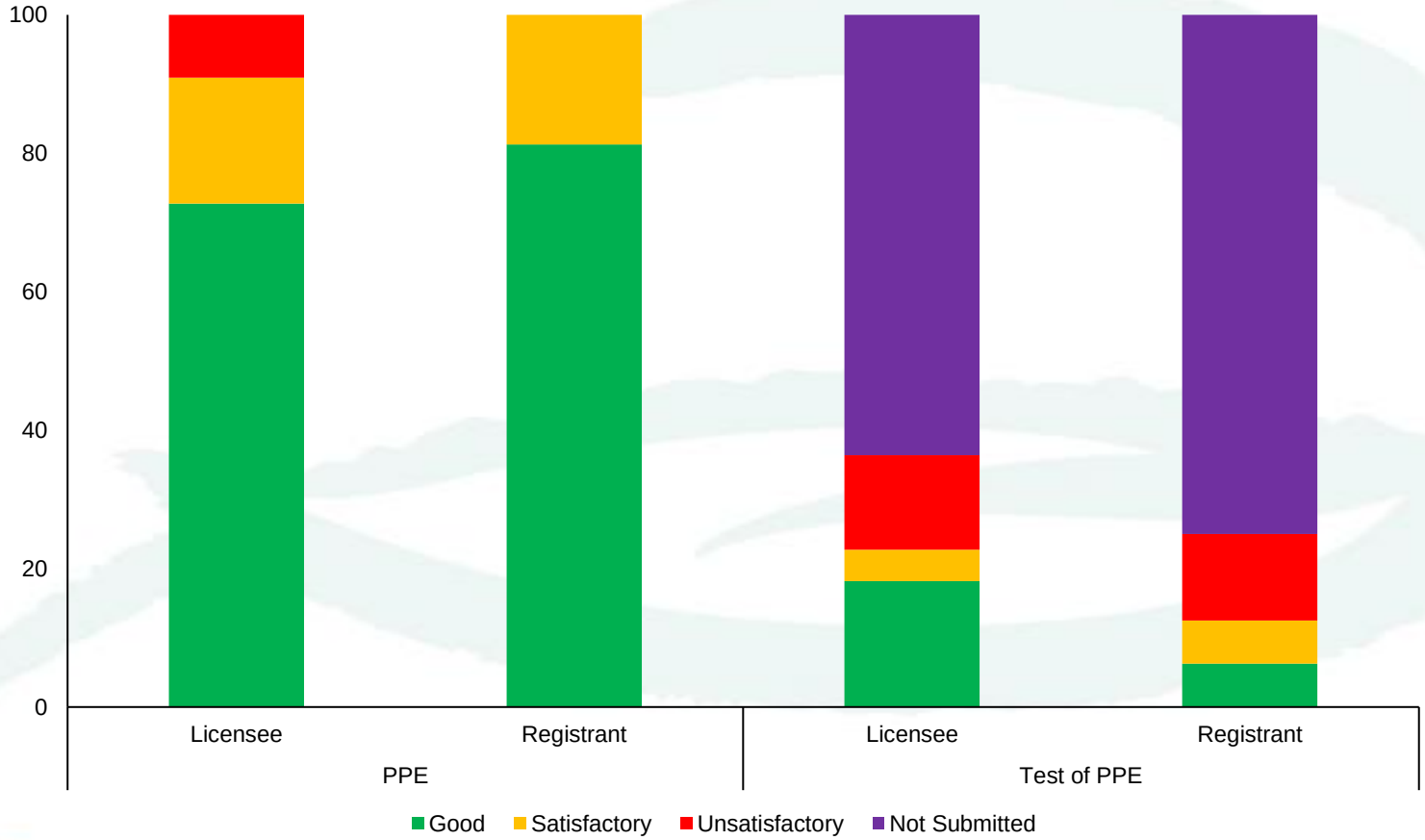
Compliance Results – Personal Protective Equipment



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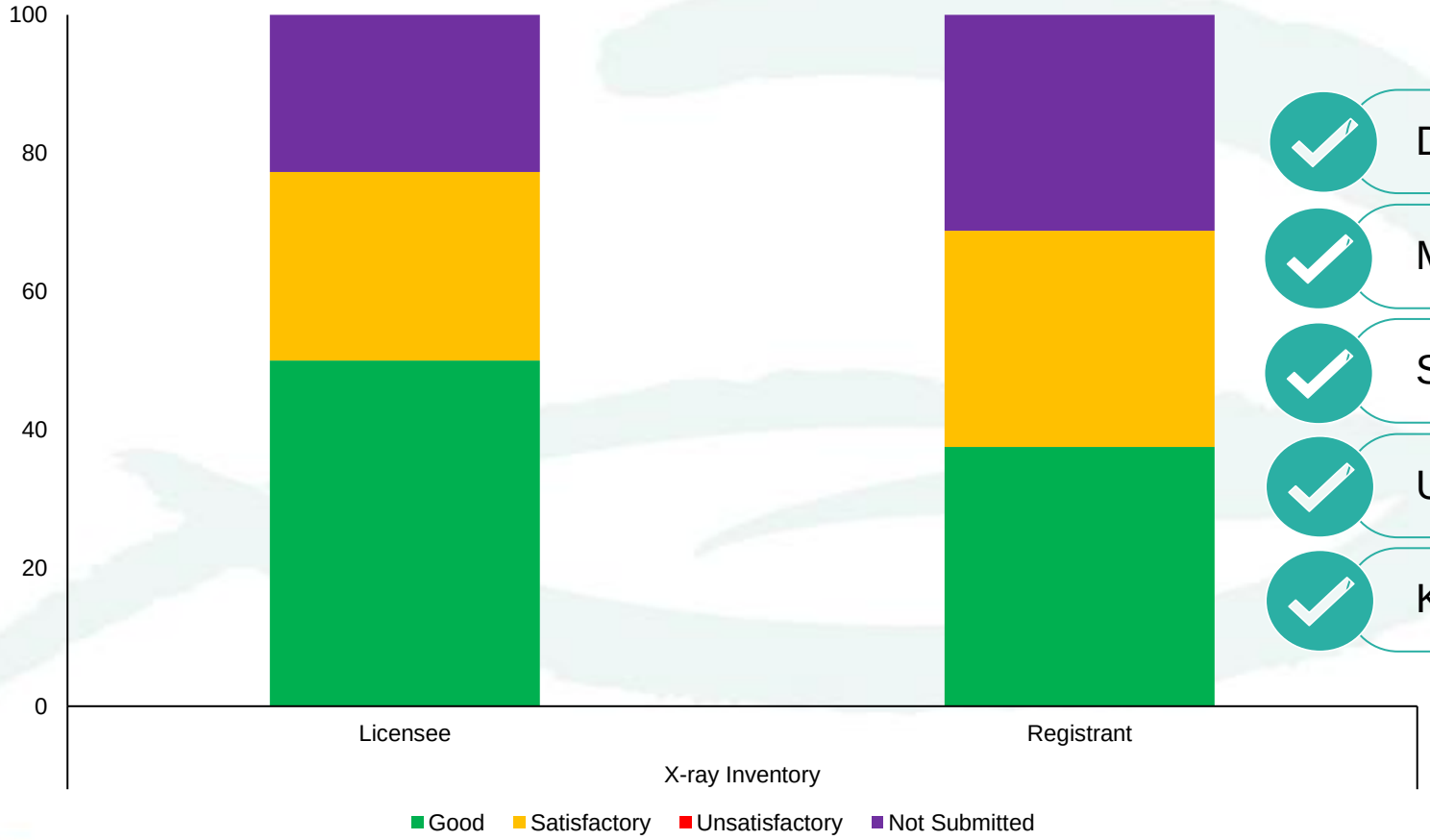
Compliance Results – X-ray Inventory



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

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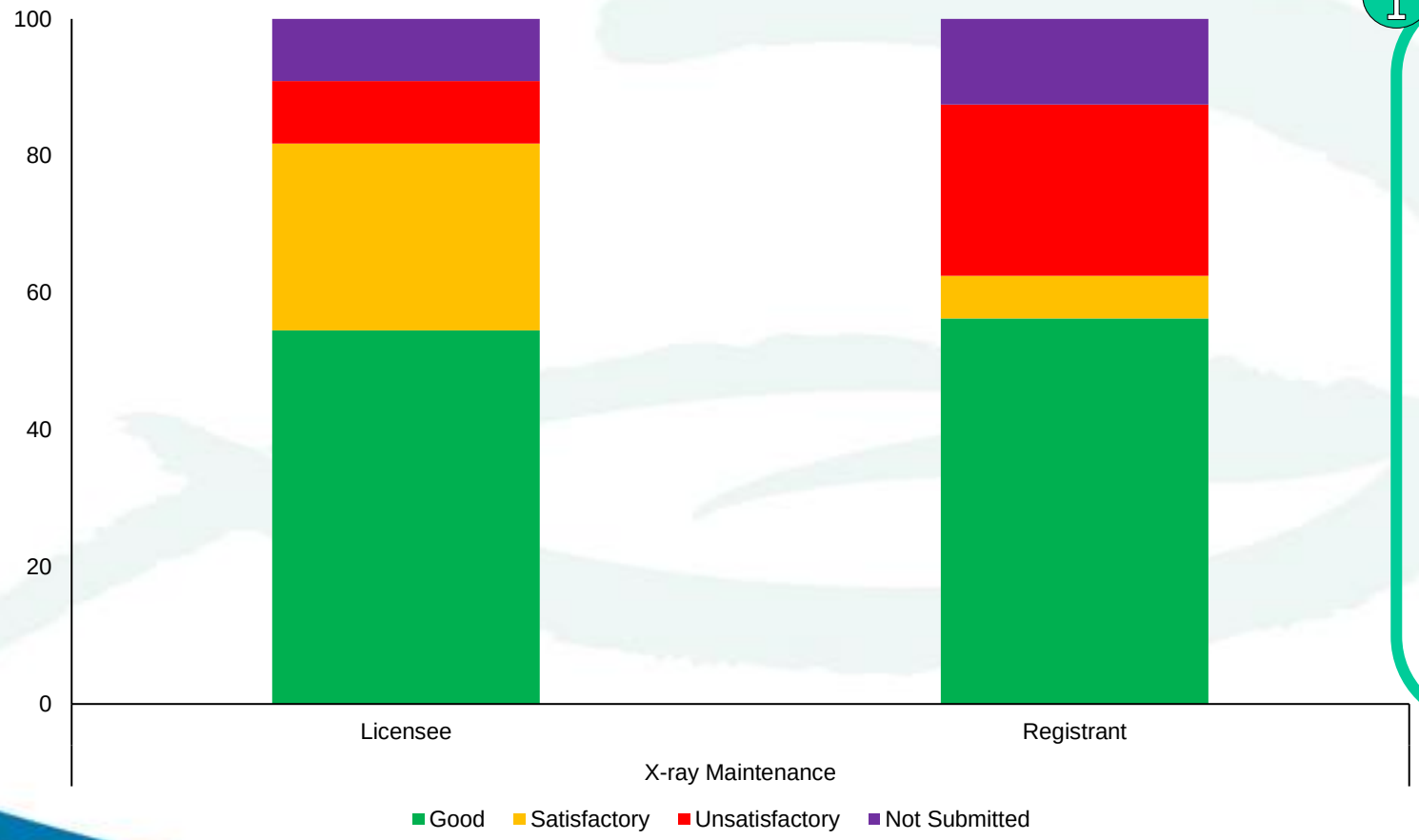
Compliance Results – X-ray Maintenance



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

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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.

ISO 17020
INAB
ACCREDITED
INSPECTION
DETAILED IN SCOPE REG NO.9009

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Powers of Inspectors

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

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)

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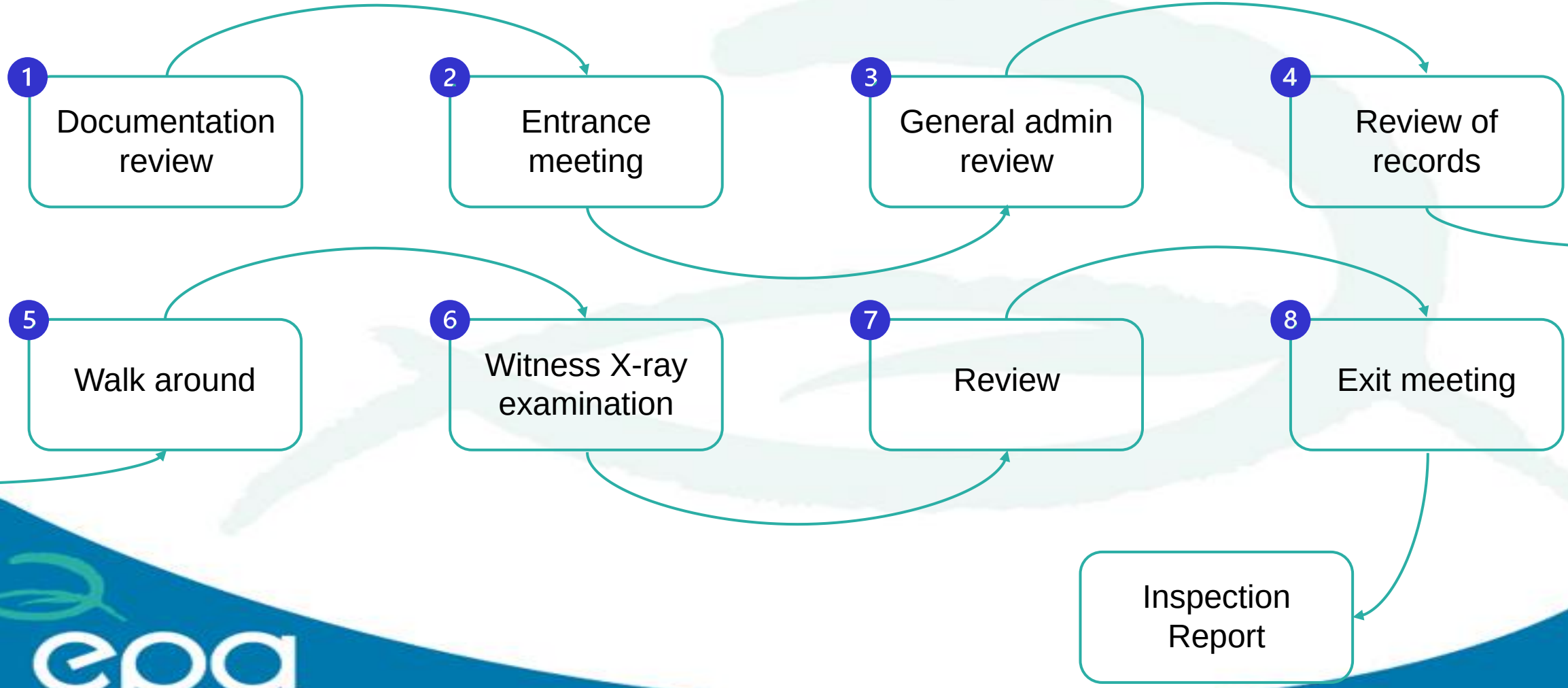
The Inspection Programme Format

- 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



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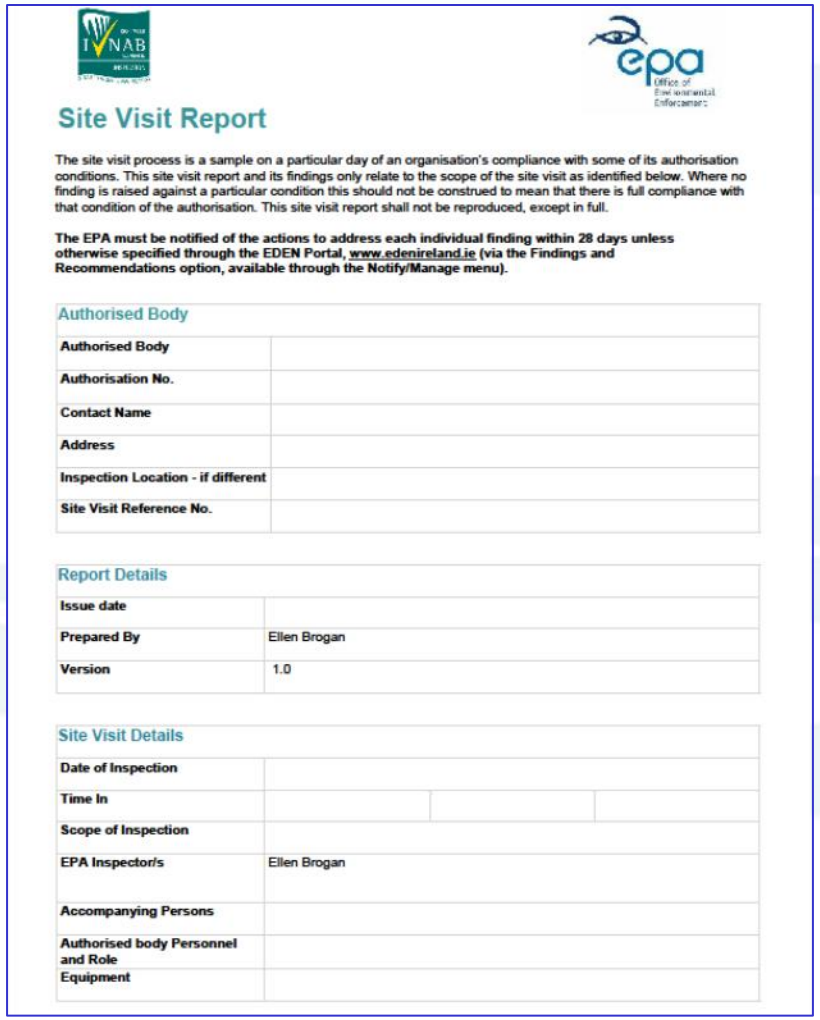
The Inspection Report – LEAP online

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

leap
Licence & Enforcement Access Portal



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

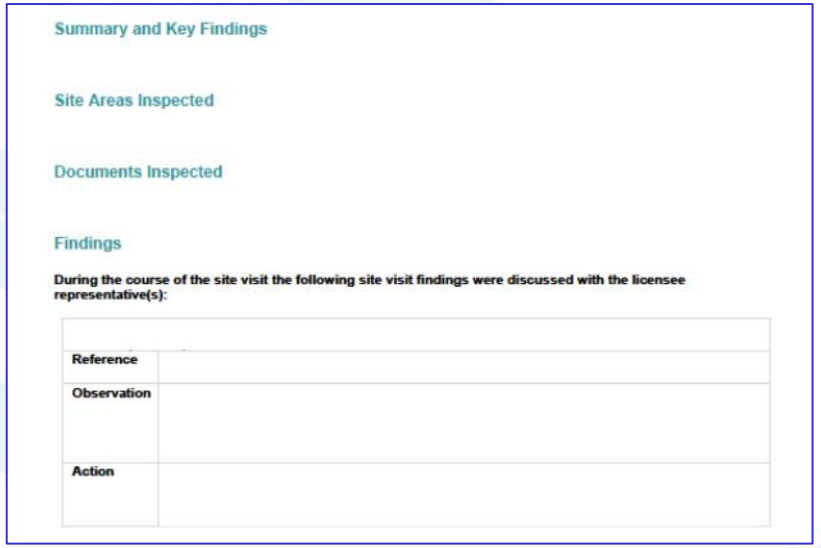
Authorised Body	
Authorisation No.	
Contact Name	
Address	
Inspection Location - if different	
Site Visit Reference No.	

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	

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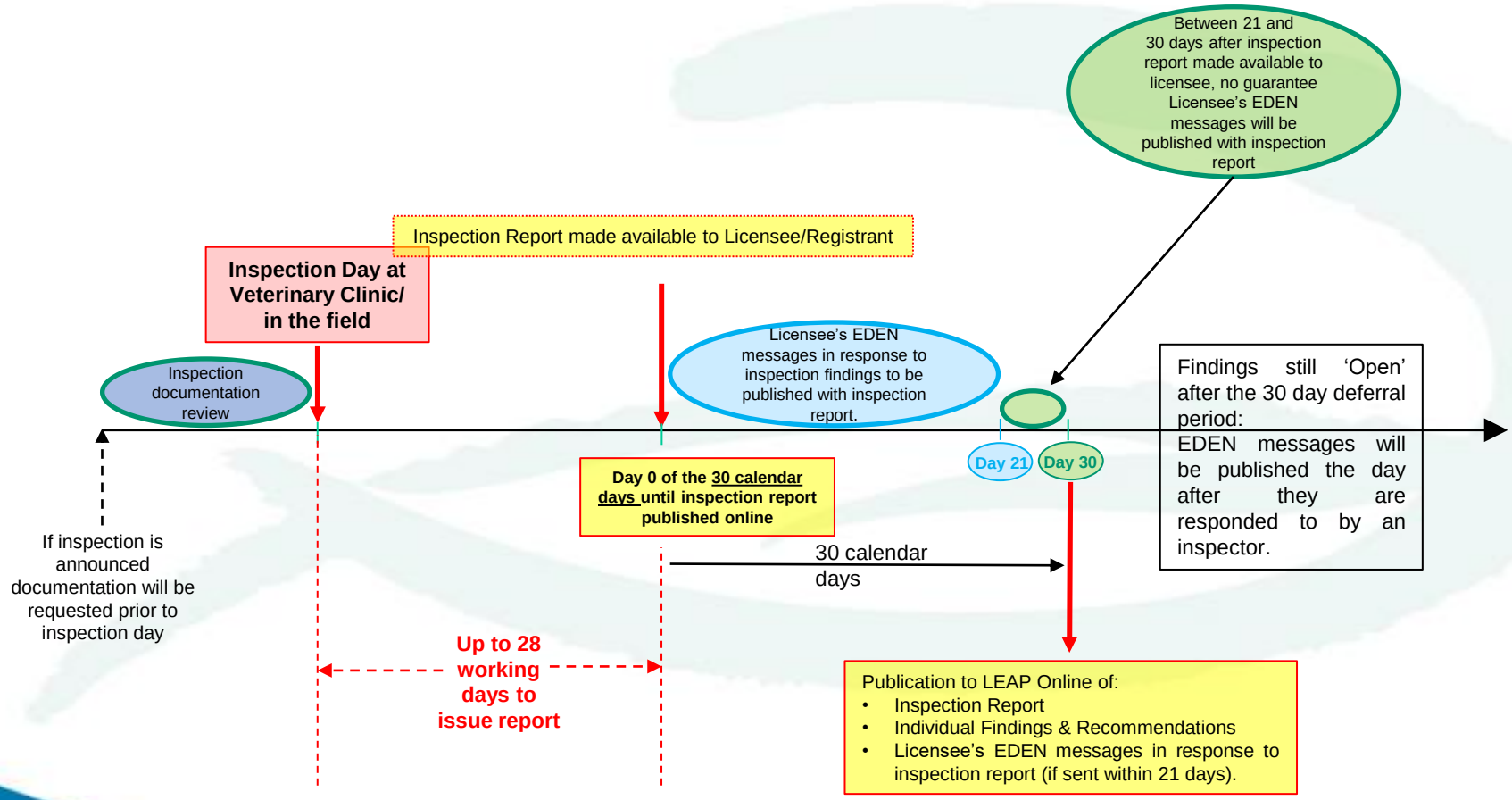
The Inspection Report and Publication Process



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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

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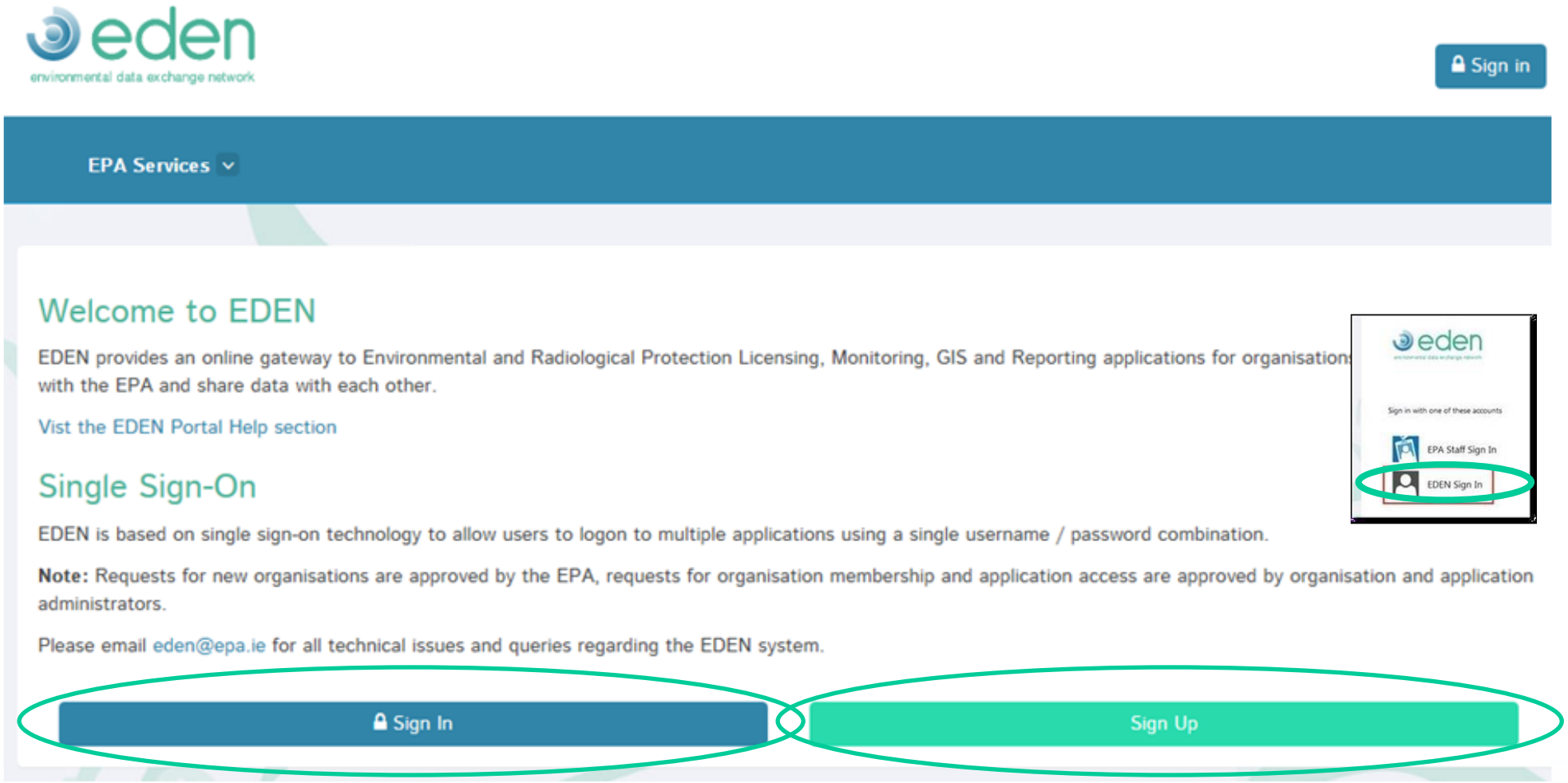
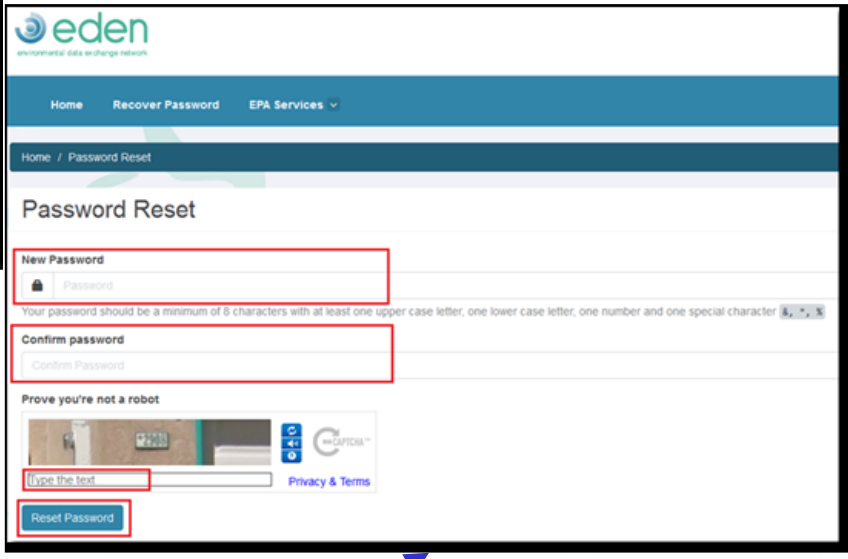
How to create a profile / log in to EDEN

Watch how to apply for an Authorisation



What if I forget my password?



EDEN FAQs

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

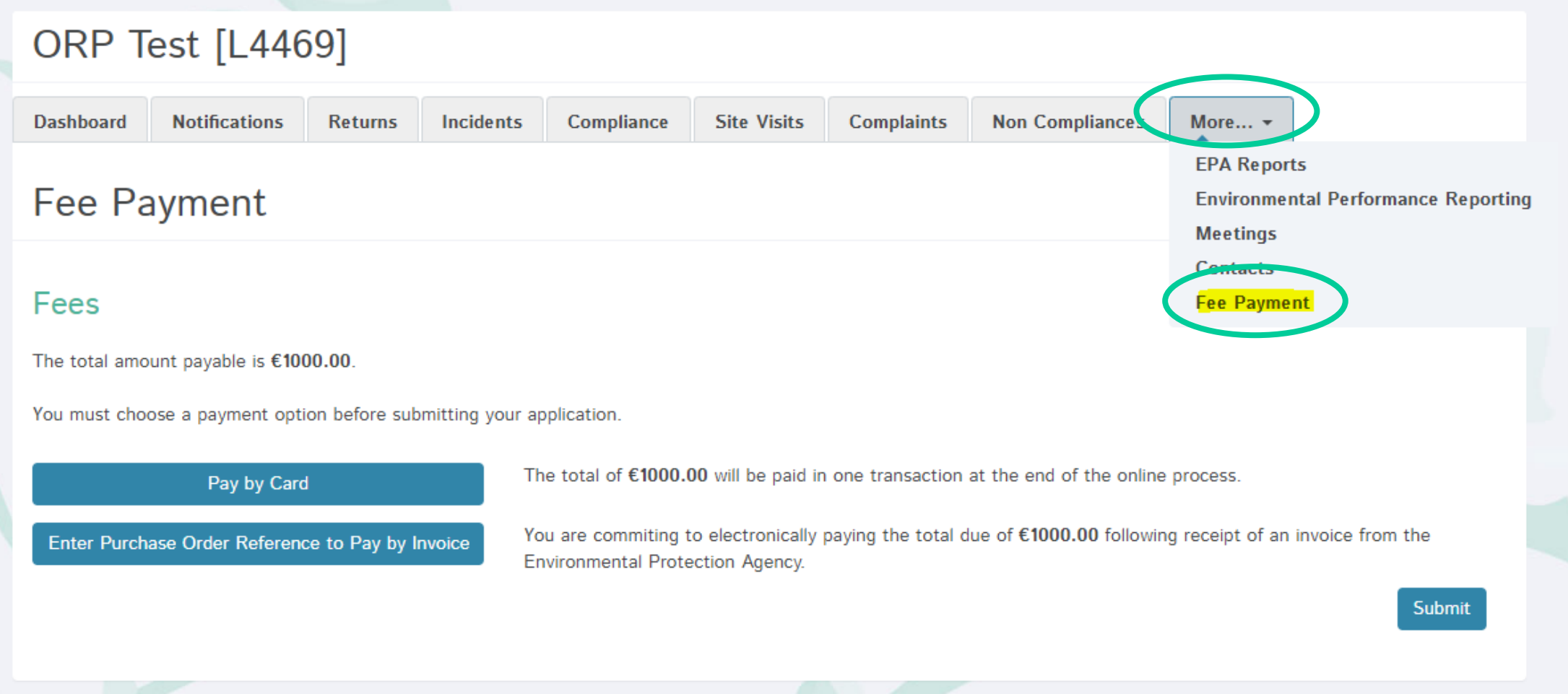
My Authorisations
Returns
Incidents
Compliance
Site Visits
Radiation Authorisation Dashboard
Pay Fee
Findings and Recommendations
Radiation Site Visits
Download Certificate of Authorisation
Environmental Performance Report

EPA Services

Beaches
Catchments
EPA Water Maps
SEA GIS

EDEN FAQs

How to pay your fee



How to access your Authorisation

Apply	Notify/Manage	EPA Services
My Applications	My Authorisations	Beaches
Amend/Change Authorisation	Returns	Catchments
New Authorisation	Incidents	EPA Water Maps
Review Authorisation	Compliance	SEA GIS
Amend Radiation Authorisation	Site Visits	
Renew Radiation Authorisation	Radiation Authorisation Dashboard	
New Radiation Authorisation	Pay Fee	
	Findings and Recommendations	
	Radiation Site Visits	
	Download Certificate of Authorisation	
	Environmental Performance Report	

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 tha 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?	► 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.	► 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

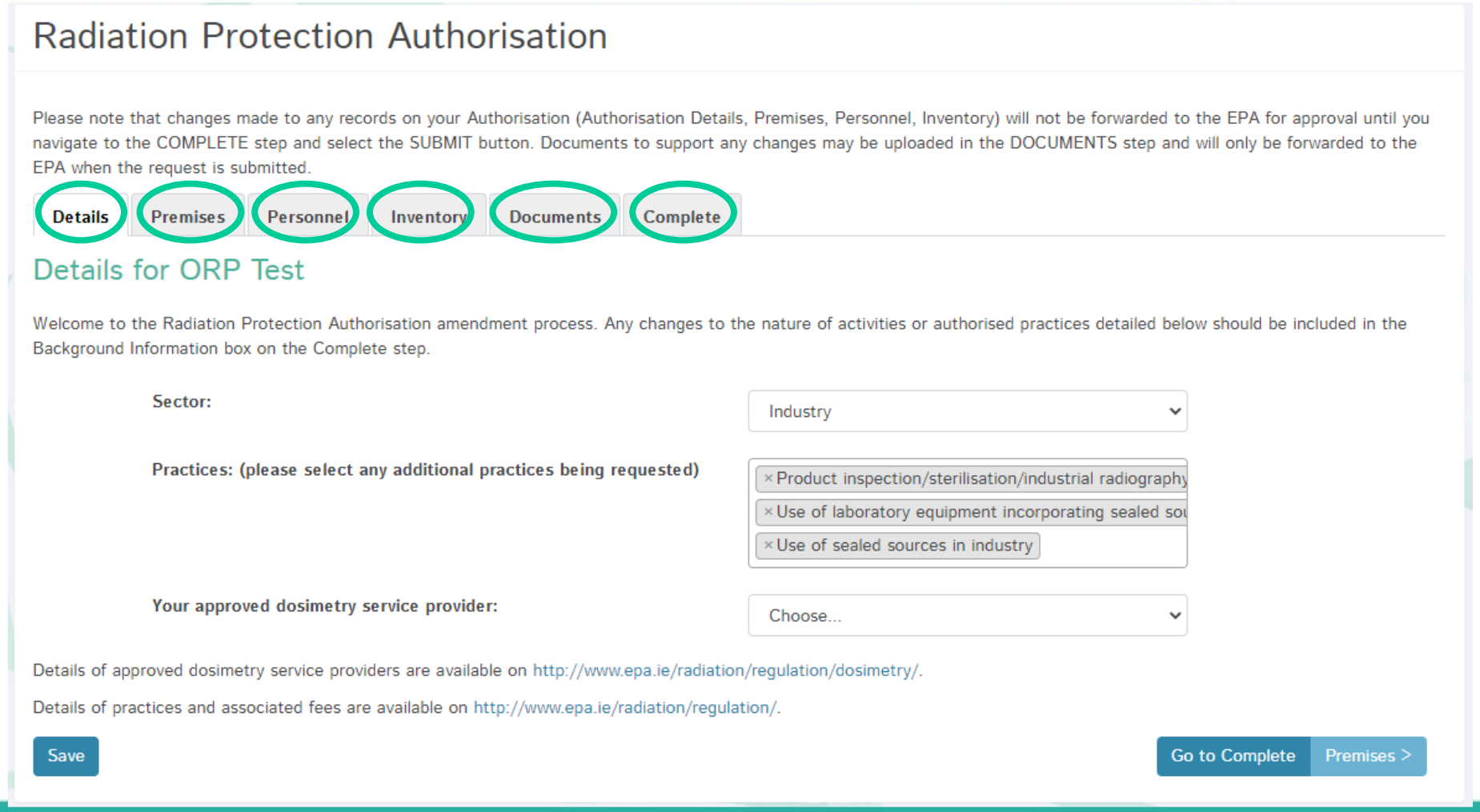
Catchments

EPA Water Maps

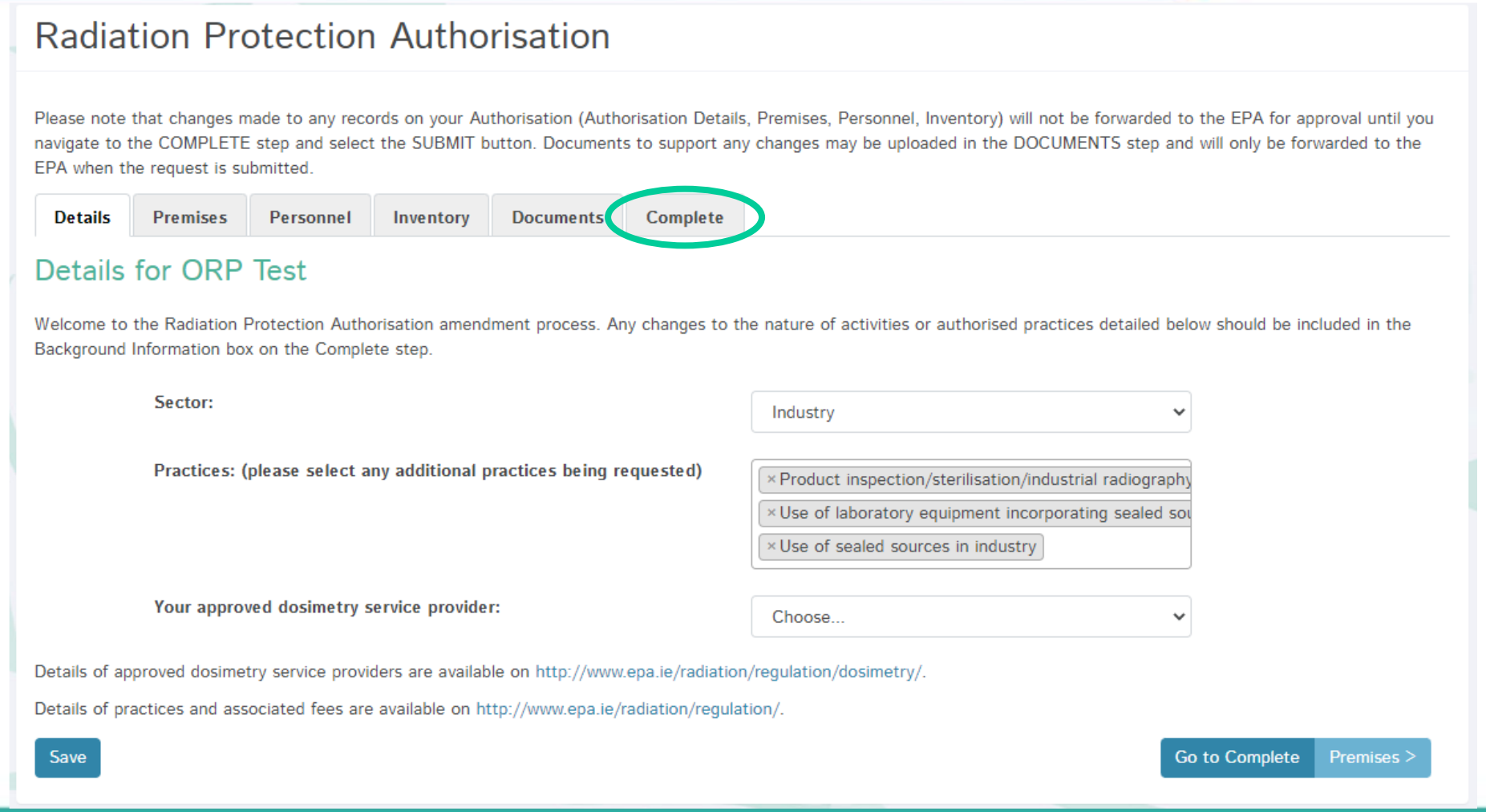
SEA GIS

EDEN FAQs

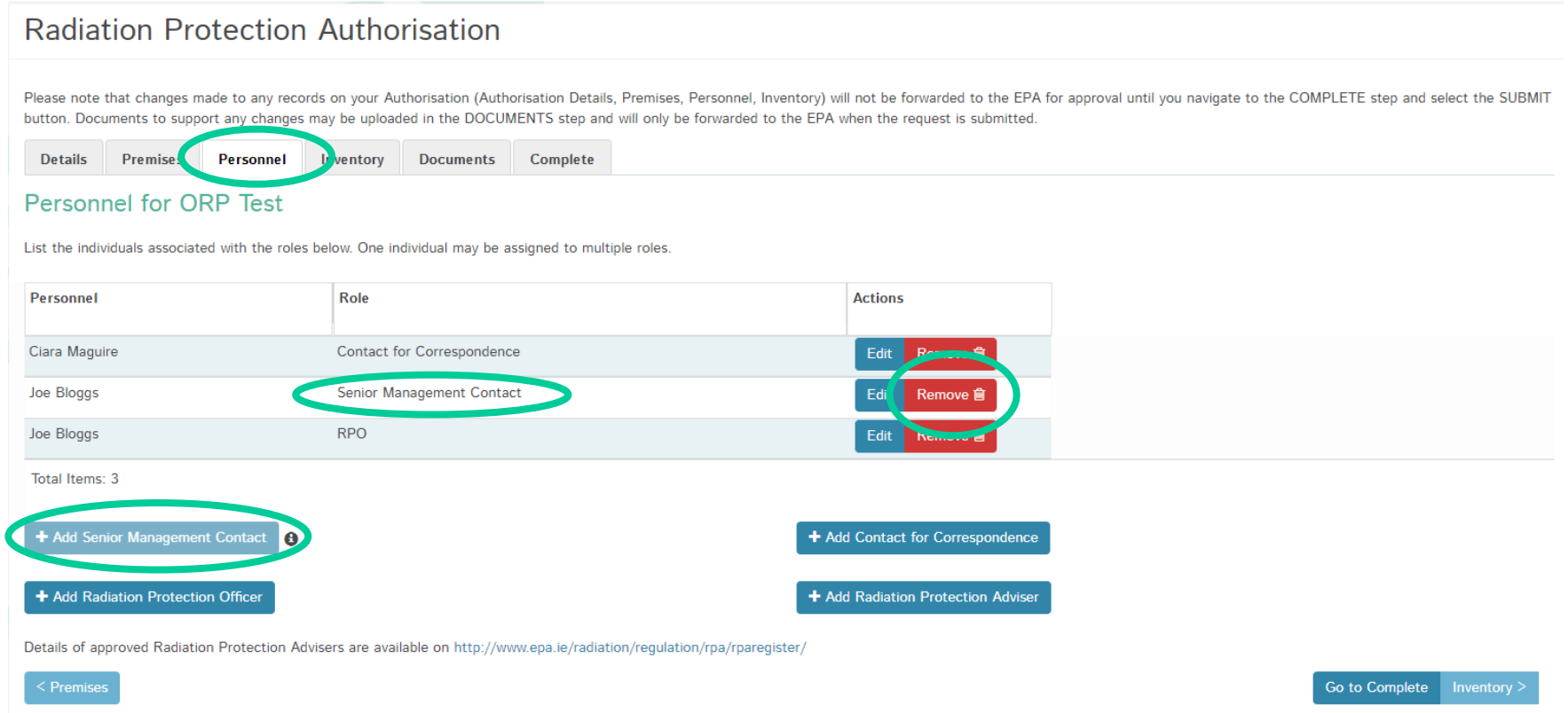
How to amend your Authorisation



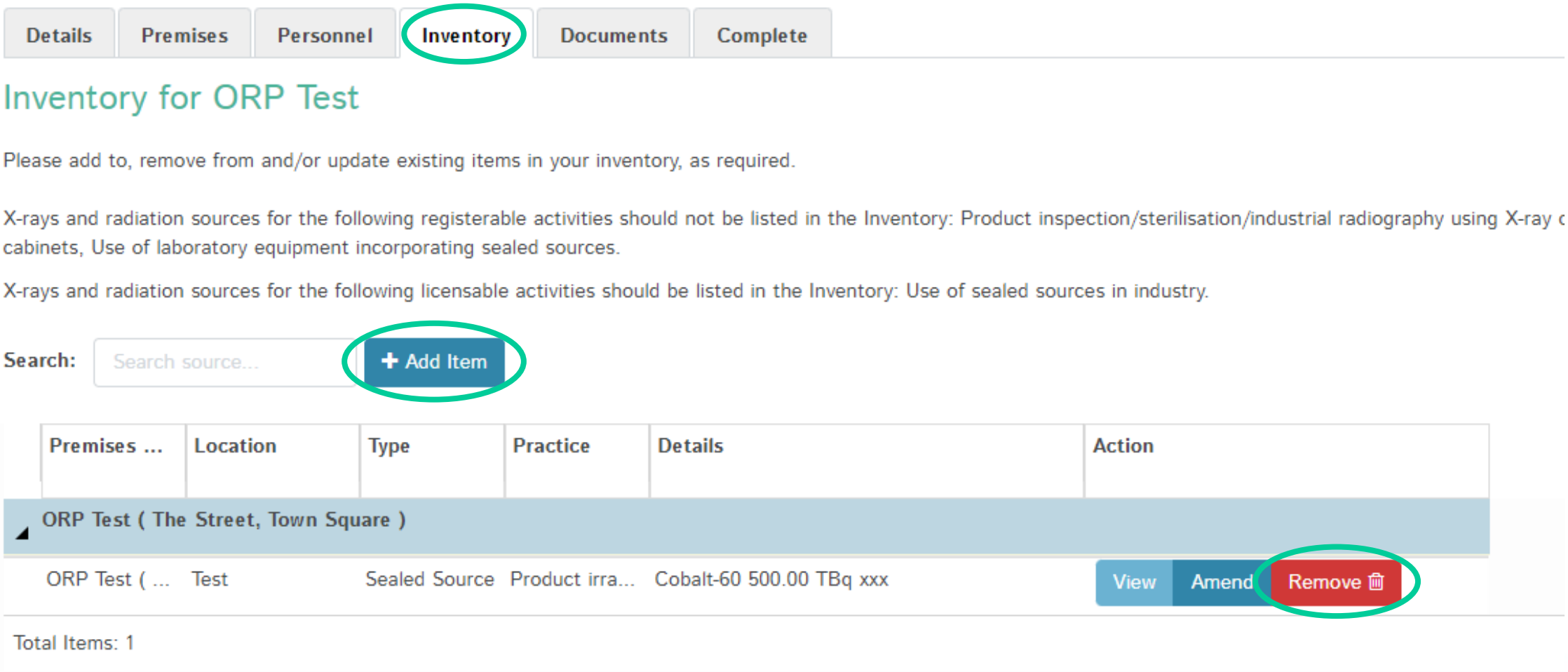
How to amend your Authorisation



How to amend your Authorisation - Personnel



How to amend your Authorisation - Inventory



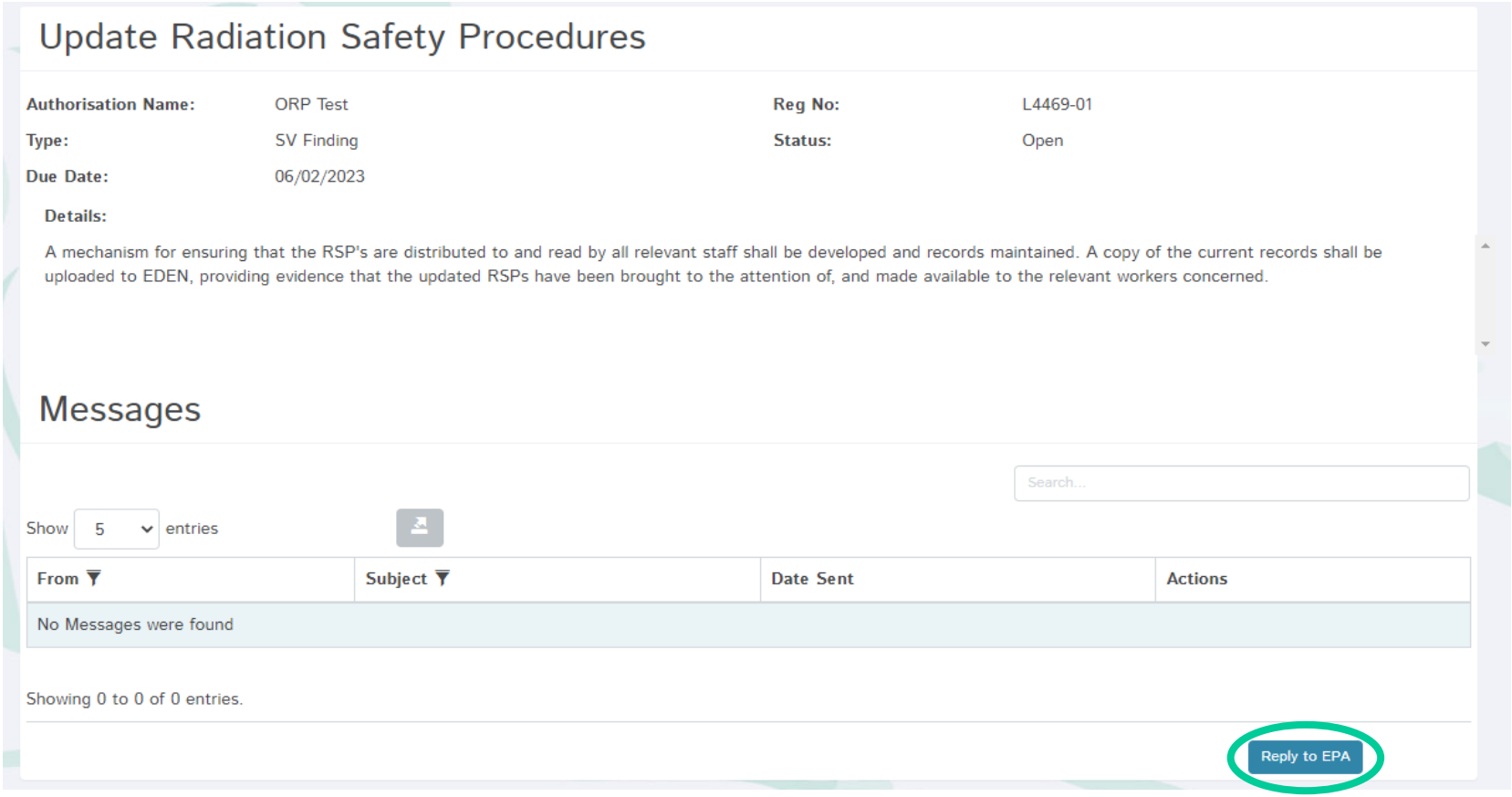
View Inspection Findings

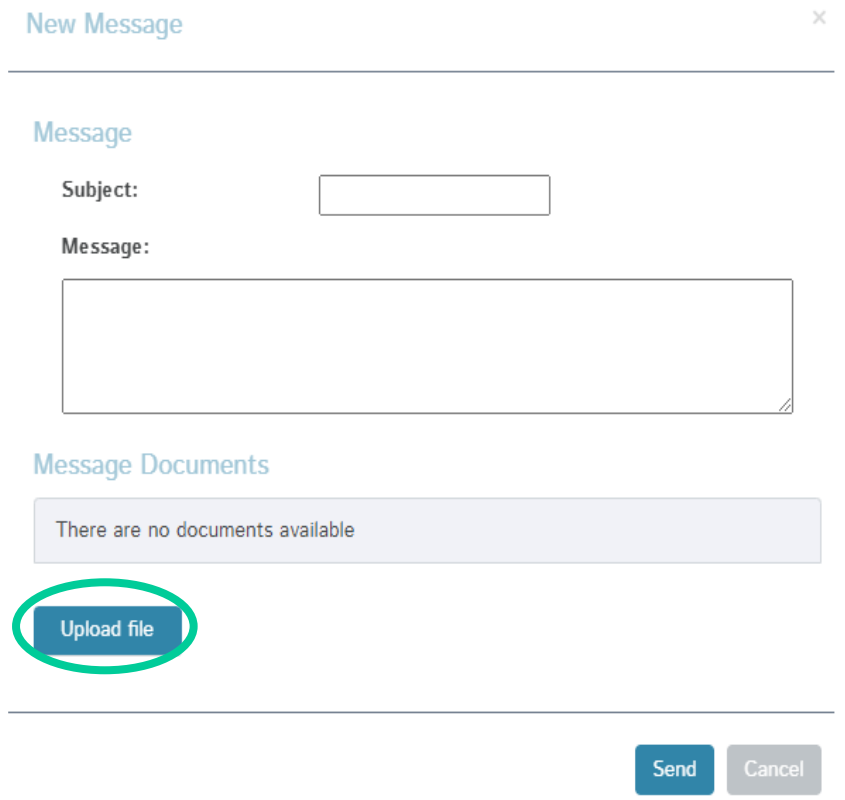
Apply	Notify/Manage	EPA Services
My Applications	My Authorisations	Beaches
Amend/Change Authorisation	Returns	Catchments
New Authorisation	Incidents	EPA Water Maps
Review Authorisation	Compliance	SEA GIS
Amend Radiation Authorisation	Site Visits	
Renew Radiation Authorisation	Radiation Authorisation Dashboard	
New Radiation Authorisation	Pay Fee	
	Findings and Recommendations	
	Radiation Site Visits	
	Download Certificate of Authorisation	
	Environmental Performance Report	

EDEN FAQs

View Inspection Findings

View Inspection Findings





Technical Issues?

Online Contact Form

ORPedensupport@epa.ie