Some Finnish experiences in implementing the graded approach

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Graded approach to regulation provided by the BSS directive

- Graded processes and mechanisms for regulatory control
  - Scope
  - Exemption
  - Notification and authorization (registration and licensing)
  - Clearance
  - Inspection programme
- Graded requirements for radiation protection and safety
  - Categorization of workers
  - Categorization of working areas
  - Categorization of radioactive sources
  - Etc.

Graded approach to regulatory control

Radiation Act, 11 §

Taking into account the risks in regulatory control

In supervising compliance with the obligations under this Act, the Authority shall take into account:

1) the nature and extent of the exposure situation;
2) risks associated with radiation exposure and radiation sources;
3) the impact that control may have on reducing risks and improving radiation safety.

Graded approach to regulatory control

- There is a wide spectrum of different types of practices
  - Wide spectrum of graded requirements and procedures are needed
- Division to notification, registration and licensing is not enough;
  - Safety requirements need to vary depending on the type of practice
  - Further grading needed, especially with licensed practices
  - “Graded approach” is not a synonym with “division to N/R/L”!

- Categorization of practices is needed for better implementation of a graded approach.

Categorizations of practices

Categorization is made **separately** for:

- Types of exposure
  - Occupational exposure
  - Public exposure
  - Medical exposure
- Types of sources
  - Sealed sources
  - Unsealed sources in laboratories
  - Releases of radioactive substances
  - Heap disposal of waste
- Category may be 1, 2 or 3.
  - Category 1 corresponds highest ja 3 lowest radiation exposure, other detriment or activity of a source. Category is E, if the type of exposure or source does not occur in the practice.

Categorizations based on exposure

Type of exposure	Category			Notice
	3	2	1	
Occupational exposure	Effective dose ≤ 1 mSv [1]	Effective dose ≤ 6 mSv	Effective dose > 6 mSv	Effective dose refers to the annual effective dose to a worker (normal or potential exposure).
Public exposure	Effective dose ≤ 0,1 x mSv [2]	Effective dose ≤ 0,3 mSv	Effective dose > 0,3 mSv	Effective dose refers to the annual effective dose to the representative person (normal or potential exposure). For the purpose of categorization, the exposure to a wrong patient is considered as unintended medical exposure.
Medical exposure	Effective dose ≤ 0,1 mSv, and no deterministic effects to the patient.	Effective dose ≤ 100 mSv, and no deterministic effects to the patient.	Effective dose > 100 mSv, or localized tai or organ absorbed dose > 10 Gy, or deterministic effects to the patient are possible.	Effective dose refers to the effective dose caused by one examination or operation to the patient.

[1] The category is 3 if the practice may cause occupational exposure but it is so small that workers do not need to be classified as occupationally exposed workers. The category is E if the practice does not cause occupational exposure.
[2] The category is 3 if the practice may cause public exposure. The category is E if the practice does not cause public exposure.

Categorizations based radiation sources

Type of source	Category			
	3	2	1	Notice
Unsealed sources in laboratory	Activity ≤ k x 10 x exemption level	Activity ≤ k x 10000 x exemption level	Activity > k x 10000 x exemption level	Activity is the maximum activity handled at a time.
	Coefficient depends on the type of practice: work involving particular risks: k= 0,1, work using normal chemical methods: k=1, simple work: k=10, storage: k=100.			
Releases of radioactive substances	Efective dose ≤ 10 µSv	Effective dose ≤ 0,1 mSv	Effective dose > 0,1 mSv	Effective dose refers to the annual effective dose to the representative person (normal or potential exposure).
Sealed sources	Activity ≤ HASS-level	Activity ≤ 1000 x HASS-level	Activity > 1000 x HASS-level	
Heap disposal of waste	$M \cdot \sum_i \frac{c_i}{CL_i} \leq 1000$ ja $c_i \leq 10 \times CL_i$	$M \cdot \sum_i \frac{c_i}{CL_i} \leq 10000$ ja $c_i \leq 100 \times CL_i$	$M \cdot \sum_i \frac{c_i}{CL_i} > 10000$ tai $c_i > 100 \times CL_i$	Final disposal in a separate heap or among other waste generated by the practice. Refers to radioactive waste and waste prescribed in section 78 point 3 of the Act.
	where M is the mass of the waste in tons, c_i is the activity concentration of nuclide i in the waste in units kBq/kg and CL_i is the clearance level of nuclide i in units kBq/kg. All nuclides i in the waste are included in the summation.			

Licensing is the only form of authorisation

Radiation Act, 48 §
Section 48 Safety license and its granting

The use of radiation requires a licence (safety licence), unless otherwise provided in this Act. Other radiation practices require a safety licence if separately laid down in the law.

Flexible grading can be achieved through categorization of practices and its consideration in:

- Safety requirements in legal provisions
- The in-depth of information to be provided with an application
- The in-depth of review and assessment processes

Graded appraoch in safety assessments

STUK Regulations S/6/2019

- Coverage of a safety assessment
  - The safety assessment must be carried out as a review specific to a practice and place of use.
  - The assessment may nevertheless be carried out as an appliance-based review applicable to the type of practice in question, provided that only radiation appliances whose radiation safety in use is based primarily on the appliance's structural properties are used in the practice.
  - However, the safety assessment must be carried out as a review specific to the practice and place of use if the appliance-based review indicates that the category of occupational or public exposure is 1 or 2.

Graded approach in safety assessments

STUK Regulation S/6/2019

- Conducting and reviewing a safety assessment
  - The safety assessment must be carried out prior to the commencement of the practice and it must be reviewed in terms of occupational, public, and medical exposure:
    1) every two years, if the category of radiation exposure is 1;
    2) every three years, if the category of radiation exposure is 2;
    3) every five years, if the category of radiation exposure is 3.

Inspections

- Previously STUK made inspections on-site at regular intervals (1 – 8 years) covering each facility
- All new licensees are inspected soon after they start the activity

- Now inspections mainly based on some theme e.g
  - Justification
  - Cardiology
  - Safety culture

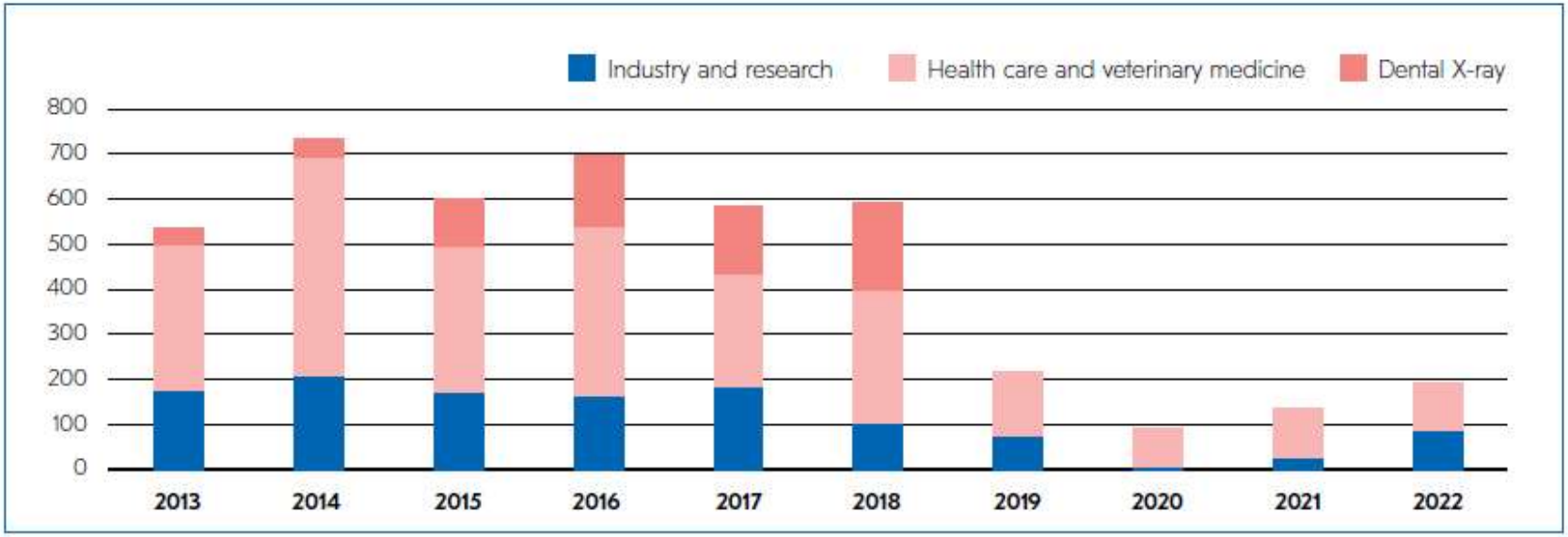

FIGURE 4. Numbers of on-site inspections in 2013–2022. From 2019, dental x-ray examinations have been included in the section "Health care and veterinary medicine".

Further examples

- Regulatory control projects (based on inspections):
  - Undertakings storing sealed sources
  - Undertakings engaged in trade in radiation sources
  - Mobile sealed source appliances
- Own-check survey addressed to industry and research

- Guidance, communication, webinars etc. are more intensively used for enhancing knowledge and understanding
  - Overall responsibility for safety
  - radiation protection and safety and related requirements

Graded enforcement policy (examples)

Enforcement measure		Typical situation
Reminder		Failure to comply with the statutory obligation to notify STUK
Request for clarification		Often the first action when you become aware of a deviation or suspicion of such a deviation. Used when more detailed information is needed.
Obligation to correct a non-compliance		
	Entry in the control register	The deviation is very small and non-urgent from a safety point of view or requires monitoring and possible development before it is raised with the operator.
	Notification to the operator	The safety significance of the deviation is not high, and the operator can be expected to correct the non-compliance without an appealable binding decision
	Request to correct the deviation	When an operator can be expected to correct the non-compliance without an appealable binding decision, but a deadline should be set for taking corrective action.
	Appealable binding decision	The deviation is significant from a safety point of view, the operator has previously failed to correct the non-compliance or, or there is reason to suspect that the operator may not otherwise correct the deviation.

Graded enforcement policy (examples)

Enforcement measure	Typical situation
Setting a conditionally imposed fine or a threat of commissioning or suspension	Set in conjunction with an appealable binding decision. The imposition is to be considered if there is a significant or urgent non-compliance or if there is reason to suspect that the operator will not otherwise comply with the decision and if the operator has not complied with a previous decision.
Suspension or restriction of operations	When the activity is not in accordance with the Radiation Act or it may cause obvious adverse health effects.
Revocation of a safety license	When the conditions for granting a license are not met or the licensee has repeatedly or essentially violated the conditions of the license or the provisions of or regulations issued pursuant to the Radiation Act.

Examples of other areas where graded approach is implemented in Finland

- Competence requirements and the extent of the use of RPEs, MPEs and RSOs
- Incident reporting
- Periodity for clinical audits
- Security requirements

What implementation of a graded approach to regulatory control needs?

- **Provisions** in legislation and regulations which incorporate / allows for the implementation of a graded approach
  - Requirements related to the regulatory control conducted by the Regulatory Body
  - Requirements related to radiation protection and safety and related obligations of the undertakings
- **Regulatory processes** which are well defined in the Regulatory Body's management system and consider the graded approach
  - Registration/licensing process/processes,
  - Inspection programmes
  - Enforcement policy
- **Supporting guidance**
  - Comprehensive rationales/explanations of all legal provisions
  - Expectations of the regulatory body
  - Practice specific application forms
- **Competence**
  - Regulatory staff
  - Licensees staff