Application of the concept of graded approach in core regulatory functions - Finnish experience and feedback

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Graded approach: general principle

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.

The aim is to ensure that radiation sources requiring a safety license are under regulatory control throughout the life cycle of the source.
Mechanisms for graded approach 1/2

• Exemption from authorization
  – Practices causing minor exposure
  – Practices whose authorization would not increase safety

• The primary responsibility of the licensee is emphasized
  – Holistic risk management (earlier: compliance with detailed requirements)
  – Use of experts

• Safety assessment
  – Identification and prevention of risks
  – Optimization of protection
  – Form the basis for categorization of exposures and radiation sources

• Categorization of exposures
  – Basis for targeting requirements and control
Mechanisms for graded approach 2/2

• Flexibility of the system of licensing
  – The conditions for obtaining authorization and the information to be submitted in the application depends on the practice
  – Financial security only where potential radioactive waste treatment costs are significant
  – Procedures for amending a license or notifying of changes are proportional to the safety significance of the change
  – Clearance; reuse, recycling, other utilization, final treatment

• Inspection programme
  – Safety assessment, scale and nature of the practice
    • Contents and scope of the inspection
    • Frequency of regular inspections
  – Unannounced and re-inspection according to their impact to safety
Categorizations of exposures and sources

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 and 3 lowest radiation exposure, other detriment or activity of a source.
## Categorizations based on exposure

<table>
<thead>
<tr>
<th>Type of exposure</th>
<th>Category</th>
<th>Notice</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Occupational exposure</td>
<td>Effective dose ≤ 1 mSv</td>
<td>Effective dose ≤ 6 mSv</td>
</tr>
<tr>
<td></td>
<td>Effective dose refers to the annual effective dose to a worker (normal or potential exposure).</td>
<td></td>
</tr>
<tr>
<td>Public exposure</td>
<td>Effective dose ≤ 0,1 x mSv</td>
<td>Effective dose ≤ 0,3 mSv</td>
</tr>
<tr>
<td></td>
<td>Effective dose refers to the annual effective dose to the representative person (normal or potential exposure).</td>
<td></td>
</tr>
<tr>
<td>Medical exposure</td>
<td>Effective dose ≤ 0,1 mSv, and no deterministic effects to the patient.</td>
<td>Effective dose ≤ 100 mSv, and no deterministic effects to the patient.</td>
</tr>
<tr>
<td></td>
<td>Effective dose refers to the effective dose caused by one examination or operation to the patient.</td>
<td></td>
</tr>
</tbody>
</table>

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 on radiation sources

<table>
<thead>
<tr>
<th>Type of source</th>
<th>Category</th>
<th>Notice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsealed sources in laboratory</td>
<td>Activity $\leq k \times 10 \times$ exemption level</td>
<td>Activity $\leq k \times 10000 \times$ exemption level Activity $&gt; k \times 10000 \times$ exemption level</td>
</tr>
<tr>
<td></td>
<td>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: $k=100$.</td>
<td></td>
</tr>
<tr>
<td>Releases of radioactive substances</td>
<td>Effective dose $\leq 10 \mu$Sv</td>
<td>Effective dose $\leq 0,1 \text{ mSv}$</td>
</tr>
<tr>
<td></td>
<td>Effective dose refers to the annual effective dose to the representative person (normal or potential exposure).</td>
<td></td>
</tr>
<tr>
<td>Sealed sources</td>
<td>Activity $\leq \text{HASS-level}$</td>
<td>Activity $\leq 1000 \times$ HASS-level</td>
</tr>
<tr>
<td>Heap disposal of waste</td>
<td>$M \cdot \sum_{i} \frac{c_i}{CL_i} \leq 1000$ ja $c_i \leq 10 \times CL_i$</td>
<td>$M \cdot \sum_{i} \frac{c_i}{CL_i} \leq 10000$ ja $c_i \leq 100 \times CL_i$</td>
</tr>
<tr>
<td></td>
<td>Final disposal in a separate heap or among other waste generated by the practice.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refers to radioactive waste and waste prescribed in section 78 point 3 of the Act.</td>
<td></td>
</tr>
</tbody>
</table>

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.
What do the categorizations stand for?

- Prescribe risk at very general level
  - Categories are **not** comparable with each other as a measure of risk
- Provide basis for targeting requirements and regulatory control
- Benefits:
  - Clarity, transparency and easy updating of regulations (if needed)
    - The licensee can easily conclude the categories by itself;
    - Easy to refer to in setting requirements;
    - Updating the tables is easy (if needed);
    - Implementation of the graded approach is easy to see and to demonstrate.
Examples on the application of graded approach

- Use of Radiation Safety Expert (RSE)
- Qualification of Radiation Safety Officer (RSO)
- Use of Medical Physics Expert
- Clinical Auditing
- Dose constraints
- Revisiting a safety assessment
- Inspections
Use of radiation safety expert 1/2

• The undertaking must ensure that the radiation safety expert is:
  – closely involved in the radiation practice if the category of the occupational or public exposure is 1 or 2;
  – available for the radiation practice when the category of the occupational or public exposure is 3. [With exceptions]

• A radiation safety expert must also be used:
  – at the commencement of a new radiation practice;
  – when changing a radiation practice in such a way that the category of the occupational or public exposure can change;
  – in the event of a problem detected in the radiation protection of workers or members of the public;
  – in connection to the discontinuation of a radiation practice which involves the handling of radioactive substances (waste and decommissioning)
Use of radiation safety expert 2/2

• By way of derogation from what is provided in subsection 1 and 2, a radiation safety expert must at least be used when advice is required:
  – in dental x-ray imaging by using panoramic tomography x-ray equipment, cephalostats or dental x-ray equipment for imaging with an intraoral imaging receptor;
  – in veterinary x-ray examinations conducted with dental x-ray equipment;
  – the use of shielded x-ray equipment in industry;
  – in an aviation practice requiring a safety licence.

RSE is not required in the practice that is exempted from a safety licence, for example in a use of a closed x-ray equipment or education and training with exempted radiation sources.
Qualification of a radiation safety officer 1/2

- In health care and veterinary medicine radiation practices, a master’s degree as referred to in the Universities Act from a suitable field of mathematics and natural science, engineering, medicine, dentistry or veterinary medicine, in accordance with the nature of the practices and the risks involved.
  - Exception 1: a radiographer for native radiography (not in CT) at primary healthcare service provider.
  - Exception 2: a suitable university degree for installation, maintenance and repair of radiation sources used in health care
Qualification of a radiation safety officer 2/2

• A radiation safety officer shall have a master’s degree as referred to in the Universities Act from a suitable field of matematic and natural science or engineering:
  1) on the use of an accelerator in research and isotope production;
  2) on the use of unsealed sources, excluding low-risk practices;
  3) on the use of nuclear energy.

• In other practices the radiation safety officer shall possess training suitable for the practice.
Use of a medical physics expert 1/2

- The undertaking must ensure that a medical physics expert is closely involved in radiotherapy practices, excluding established radionuclide therapy.

- A medical physics expert must be used in any radionuclide therapy other than that referred to in subsection 1 as well as in interventional radiology, computerized tomography and other practices causing high medical exposure.

- In practices other than those referred to in subsection 1 and 2, a medical physics expert must be used at the commencement of the practice and the expert must be available during the practice.
Use of a medical physics expert 2/2

• By way of derogation from what is provided in subsection 3, dental x-ray imaging in health care by using panoramic tomography x-ray equipment, cephalostats or dental x-ray equipment for imaging with an intraoral imaging receptor are subject to the use of a medical physics expert, provided that advice is required.

• Any non-medical imaging with a health care equipment is subject to subsection 3 and 4.
Clinical auditing 1/2

• Clinical auditing consists of **internal** and **external** audits

• Implementation based on safety assessment and **category of medical exposure**
## Clinical auditing 2/2

<table>
<thead>
<tr>
<th>Category 3</th>
<th>Category 2</th>
<th>Category 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>INTERNAL AUDIT IN EVERY 4 YEARS</strong></td>
<td><strong>EXTERNAL AUDIT IN EVERY 8 YEARS</strong></td>
</tr>
<tr>
<td></td>
<td><strong>INTERNAL AUDIT IN EVERY 4 YEARS</strong></td>
<td><strong>EXTERNAL AUDIT IN EVERY 6 YEARS</strong></td>
</tr>
<tr>
<td></td>
<td><strong>INTERNAL AUDIT IN EVERY 4 YEARS</strong></td>
<td><strong>EXTERNAL AUDIT IN EVERY 6 YEARS</strong></td>
</tr>
<tr>
<td>Radiography</td>
<td><strong>EXTERNAL AUDIT IN EVERY 8 YEARS</strong></td>
<td><strong>EXTERNAL AUDIT IN EVERY 6 YEARS</strong></td>
</tr>
<tr>
<td>Diagnostic nuclear medicine</td>
<td><strong>EXTERNAL AUDIT IN EVERY 8 YEARS</strong></td>
<td><strong>EXTERNAL AUDIT IN EVERY 6 YEARS</strong></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td><strong>EXTERNAL AUDIT IN EVERY 6 YEARS</strong></td>
<td><strong>EXTERNAL AUDIT IN EVERY 6 YEARS</strong></td>
</tr>
<tr>
<td>Interventional cardiac radiology</td>
<td><strong>EXTERNAL AUDIT IN EVERY 6 YEARS</strong></td>
<td><strong>EXTERNAL AUDIT IN EVERY 6 YEARS</strong></td>
</tr>
</tbody>
</table>

In ordinary dental practices self assessments are enough
Dose constraints

Radiation Act, Section 25
Setting of dose constraints and constraints for potential exposure

The responsible party shall establish in advance the dose constraints and constraints for potential exposure to be used within the practice unless the Radiation and Nuclear Safety Authority has, pursuant to section 10, confirmed constraints generally applicable to the practice in question.

Dose constraints for occupational exposure of an outside worker shall be established in cooperation with the employer of the outside worker.

The constraint for potential exposure of workers and the members of the public shall be set in advance for radiation safety deviations referred to in section 26 (Safety assessment), which may cause significant radiation exposure.
Dose constraints

A dose constraint for occupational exposure shall not exceed:

1) 0.3 mSv, when occupational exposure category is 3;
2) 6 mSv in aviation.

A dose constraint for public exposure shall not exceed 0.1 mSv.

Exceptions possible if justified.

Dose constraints for room and storage shielding design and construction shall not exceed:

– 6 mSv/a for worker in controlled area
– 0.3 mSv/a for any worker outside of the controlled or supervised area.
Constraints on potential occupational and public exposure

• The potential occupational exposure from a single event shall not exceed 100 mSv except for a highly unlikely event whose occurrence probability can not practically be reduced further.

• If the potential occupational exposure from a single event is greater than 6 mSv, the anticipated number of events shall not be more than 1 in 10 years.

• The potential public exposure from a single event shall not exceed 10 mSv except for a highly unlikely event whose occurrence probability can not practically be reduced further.

• The potential public exposure from a single event shall not exceed 1 mSv, if the number of anticipated exposed persons can be more than 100 except for a highly unlikely event whose occurrence probability can not practically be reduced further.

• If the potential public exposure is greater than 0,3 mSv the number of events shall not be more than 1 in 10 years.
Revisiting of a safety assessment

- A safety assessment has to be revisited for occupational, public and medical exposure in a period of
  - 2 years in category 1;
  - 3 years in category 2;
  - 5 years in category 3.

- Revisiting also needed if the practice has been changed, there is a safety deviation or because of experience from other similar practices, safety research or development of technologies.
Inspections

- From fixed periods of 2-8 years towards risk based approach taking into account among others
  - safety assessment, especially categorization of exposures
  - results of regulatory questionnaires
  - history of the licensee (such as results from previous inspections, resent changes in the licence)

- Thematic inspections with a limited scope (focused inspections) instead of full scope inspections

- Inspection results will be published as summaries and distributed to all licensees.