Improved radiation safety in Finland with graded approach in the new regulatory framework

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Contents

• Finnish legislation and regulation
• Graded approach
• Categorization
The new Finnish radiation legislation and regulation

Legislation

– Radiation Act 859/2018 (into force 15th December 2018)

Regulation

– Governmental Decree on Ionizing Radiation 1034/2018
– Decree of the Ministry of Social Affairs and Health on Ionizing Radiation 1044/2018
– Decree of the Ministry of Social Affairs and Health on the limitation of public exposure to non-ionizing radiation 1045/2018

STUK Regulations

– 12 Regulations
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.
Graded approach 1/2

• Licensee’s responsibility is emphasized
  – Safety first (evaluated and documented)
  – Less detailed requirements
  – More possibilities to adjust the system to fit the needs of the operator

• New profession ‘radiation safety expert’
  – Helps with the design and implementation of the system
  – Advices with the requirements

• The role of STUK changes
  – ST-guides -series discontinued
  – Emphasis in the surveillance of the operators capabilities rather than specific requirements
Graded approach 2/2

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

• Categorization of exposures
  – Basis for targeting requirements and control
Categorization 1/2

Categorization is made by the licencee separately for:

• Types of exposure
  – Occupational, general public, medical

• Types of sources
  – Sealed sources
  – Unsealed sources in laboratories
  – Releases of radioactive substances
  – Heap disposal of waste
<table>
<thead>
<tr>
<th>Type of exposure</th>
<th>Category 3</th>
<th>Category 2</th>
<th>Category 1</th>
<th>Notice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational exposure</td>
<td>Effective dose ≤ 1 mSv</td>
<td>Effective dose ≤ 6 mSv</td>
<td>Effective dose &gt; 6 mSv</td>
<td>Effective dose refers to the annual effective dose to a worker (normal or potential exposure).</td>
</tr>
<tr>
<td>Public exposure</td>
<td>Effective dose ≤ 0,1 x mSv</td>
<td>Effective dose ≤ 0,3 mSv</td>
<td>Effective dose &gt; 0,3 mSv</td>
<td>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.</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>
<td>Effective dose &gt; 100 mSv, or localized or organ absorbed dose &gt; 10 Gy, or deterministic effects to the patient are possible.</td>
<td>Effective dose refers to the effective dose caused by one examination or operation to the patient.</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><strong>Unsealed sources in laboratory</strong></td>
<td>3</td>
<td>Activity ≤ k x 10 x exemption level</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Activity ≤ k x 10000 x exemption level</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Activity &gt; k x 10000 x exemption level</td>
</tr>
<tr>
<td>Coefficient depends on the type of practice:</td>
<td></td>
<td>work involving particular risks: k=0,1, work using normal chemical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>methods: k=1, simple work: k=10, storage: k=100.</td>
</tr>
<tr>
<td><strong>Releases of radioactive substances</strong></td>
<td></td>
<td>Effective dose ≤ 10 µSv</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effective dose ≤ 0,1 mSv</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effective dose &gt; 0,1 mSv</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effective dose refers to the annual effective dose to the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>representative person (normal or potential exposure).</td>
</tr>
<tr>
<td><strong>Sealed sources</strong></td>
<td></td>
<td>Activity ≤ HASS-level</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Activity ≤ 1000 x HASS-level</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Activity &gt; 1000 x HASS-level</td>
</tr>
<tr>
<td><strong>Heap disposal of waste</strong></td>
<td></td>
<td>$M \cdot \sum_{i} \frac{c_i}{CL_i} \leq 1000$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$M \cdot \sum_{i} \frac{c_i}{CL_i} \leq 10000$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$M \cdot \sum_{i} \frac{c_i}{CL_i} &gt; 10000$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Final disposal in a separate heap or among other waste generated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>by the practice.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Refers to radioactive waste and waste prescribed in section 78 point 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>of the Act.</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.
Categorization 2/2

• Categories provide a basis for applied requirements
  – Requirements of using Radiation safety expert; closely involved / available / when starting a new practice …
  – Interval of required clinical audits
  – Required extent of the safety assessment

• Categories affect the intensity of regulatory control
  – Licensing protocols (amendment, notifications…)
  – Interval and extent of the inspections
  – Also other factors affect to the intensity of regulatory control
STUK Regulation enacted under Radiation Act

1. SY/1/2018 on exemption and clearance levels
2. S/1/2018 on the investigation, assessment and monitoring of occupational exposure
3. S/2/2018 on a plan for radiation safety deviations and actions during and after radiation safety deviations
4. S/3/2018 on security of radiation sources licenced upon the Radiation Act
5. S/4/2018 the use of high-power laser equipment
6. S/5/2018 on the use of non-ionizing radiation in a cosmetic or other comparable procedure
7. S/6/2018 on radiation measurements
8. S/2/2019 on the radioactive waste and discharges of radioactive substances in the use of unsealed sources
10. S/4/2019 on the justification and optimization of medical exposure
To be published in June:
11. S/5/2019 on safety of radiation sources during the practice
12. S/6/2019 on obligations of undertakings