Applying the graded approach – Finland

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Graded approach in Finnish radiation legislation and regulations

Radiation Act (859/2018)

- Safety principles for ionizing and non-ionizing radiation safety
- Basis for all decrees and STUK Regulations

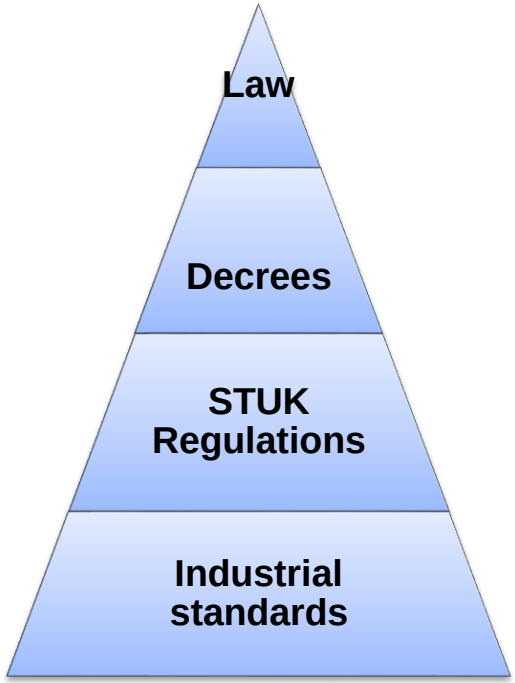
Decrees

- Government Decree on Ionizing Radiation (1034/2018)
- Decree on Ionizing Radiation by MoH (1044/2018)

STUK Regulations

- 11 Regulations

- Graded approach has been incorporated into legislation and regulation in different ways
- In this presentation examples are given on using categorization of exposures and grading the use of medical physics expert



Categorizations of exposures

Categorization is made **separately** for types of exposures:

- Occupational exposure
- Public exposure
- Medical exposure

A category may be 1, 2 or 3.

Category 1 corresponds highest ja 3 lowest radiation exposure.

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).
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 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.

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 and transparency
    – The licensee can easily conclude the categories by itself;
    – Easy to refer to in setting requirements;
    – Implementation of the graded approach is easy to be demonstrated.
  - Easily adjustable in regulations by changing categories when necessary

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.
- A radiation safety expert must also be used: With exceptions
  - 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

- Exceptions in category 3: A radiation safety expert must at least be used <u>when advice is required</u>:
  - 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.

Radiation safety expert is not required in the practice that is exempted from a saety licence, for example in a use of closed x-ray equipment or in education and training with exempted radiation sources.

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.

Clinical auditing

Medical exposure	Category 3	Category 2	Category 1
		INTERNAL AUDIT IN EVERY 4 YEARS COMPLEMENTARY TO SELF ASSESSMENTS	
		EXTERNAL AUDIT IN EVERY 8 YEARS	**EXTERNAL AUDIT IN EVERY 6 YEARS**
		Radiography Diagnostic nuclear medicine	**Radiotherapy Interventional cardiac radiology**

In category 3 dental imaging only self assessments are required.

Use of a medical physics expert 1/2

1. The undertaking must ensure that a medical physics expert is closely involved in radiotherapy practices, excluding established radionuclide therapy.
2. 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.
3. 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 needed.