



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

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# The new Finnish radiation legislation and regulation

## Legislation

- Radiation Act 859/2018 (into force 15<sup>th</sup> 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

Leadership and Management of Safety

Radiation Protection of Workers and Members of the Public

Radiation Protection Education and Training

Planned Exposure Situations

Emergency Exposure Situations

Existing Exposure Situations

Natural Radiation

Non Ionizing Radiation

Regulatory Oversight

Enforcement

# 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 licensee **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

# Categorizations based on exposure

Type of exposure	Category			Notice
	3	2	1	
Occupational exposure	Effective dose $\leq 1$ mSv <sup>1</sup>	Effective dose $\leq 6$ mSv	Effective dose $> 6$ mSv	Effective dose refers to the annual effective dose to a worker (normal or potential exposure).
Public exposure	Effective dose $\leq 0,1 \times$ mSv <sup>2</sup>	Effective dose $\leq 0,3$ 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 $\leq 0,1$ mSv, and no deterministic effects to the patient.	Effective dose $\leq 100$ 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.

<sup>1</sup> 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.

<sup>2</sup> 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

Type of source	Category			Notice
	3	2	1	
Unsealed sources in laboratory	Activity $\leq k \times 10 \times$ exemption level	Activity $\leq k \times 10000 \times$ exemption level	Activity $> k \times 10000 \times$ 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	Effective dose $\leq 10$ $\mu\text{Sv}$	Effective dose $\leq 0,1$ $\text{mSv}$	Effective dose $> 0,1 \text{ mSv}$	Effective dose refers to the annual effective dose to the representative person (normal or potential exposure).
Sealed sources	Activity $\leq$ HASS-level	Activity $\leq 1000 \times$ HASS-level	Activity $> 1000 \times$ HASS-level	
Heap disposal of waste	$M \cdot \sum_i \frac{c_i}{CL_i} \leq 1000$	$M \cdot \sum_i \frac{c_i}{CL_i} \leq 10000$	$M \cdot \sum_i \frac{c_i}{CL_i} > 10000$	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.
	ja $c_i \leq 10 \times CL_i$	ja $c_i \leq 100 \times CL_i$	tai $c_i > 100 \times CL_i$	
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

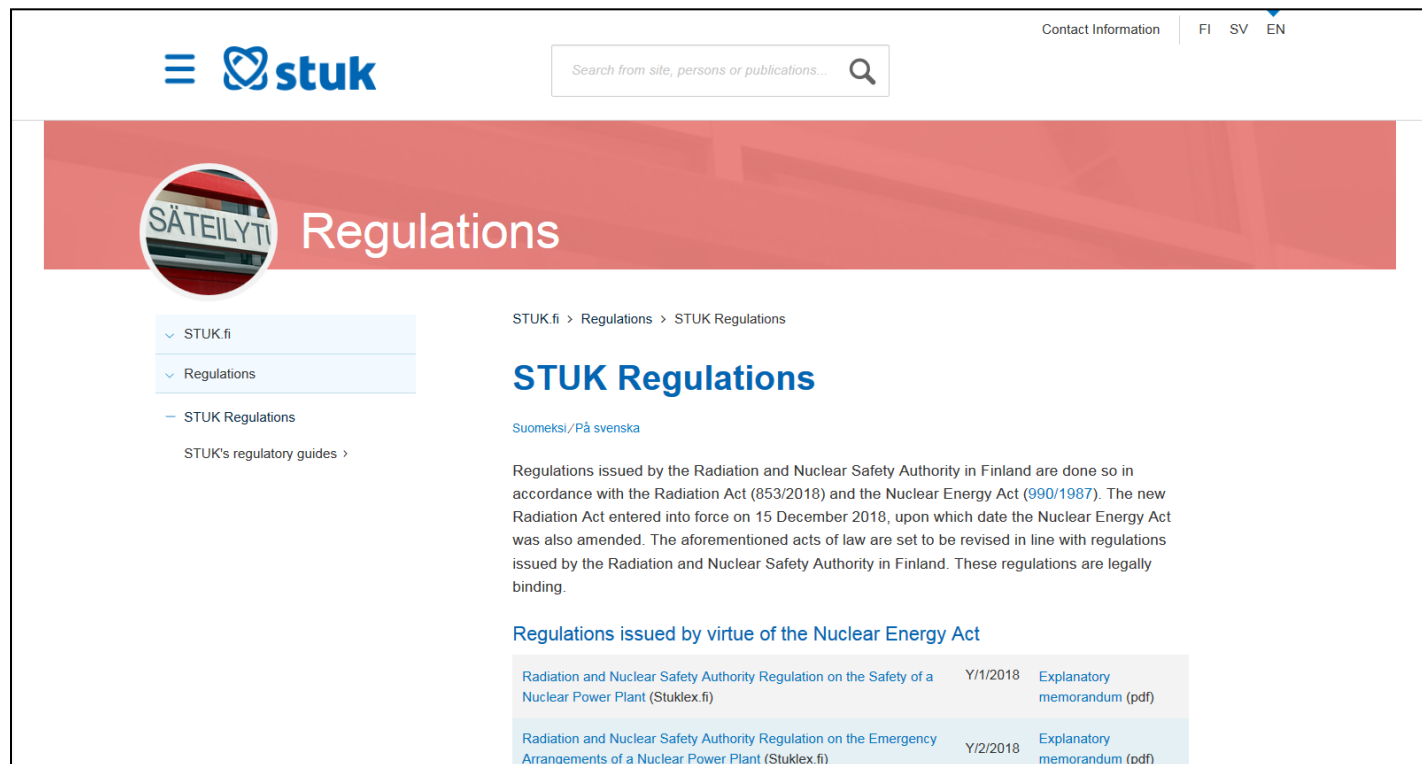
1. SY/1/2018 on exemption and clearance levels
2. S/1/2018 on the investigation, assessment and monitoring of occupational exposure
3. S/2/2018 on a plan for radiation safety deviations and actions during and after radiation safety deviations
4. S/3/2018 on security of radiation sources licenced upon 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
9. S/3/2019 on the practice exposing to natural radiation
10. S/4/2019 on the justification and optimization of medical exposure

# STUK Regulation enacted under Radiation Act

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



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## Regulations

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### STUK Regulations

Suomeksi/På svenska

Regulations issued by the Radiation and Nuclear Safety Authority in Finland are done so in accordance with the Radiation Act (853/2018) and the Nuclear Energy Act (990/1987). The new Radiation Act entered into force on 15 December 2018, upon which date the Nuclear Energy Act was also amended. The aforementioned acts of law are set to be revised in line with regulations issued by the Radiation and Nuclear Safety Authority in Finland. These regulations are legally binding.

#### Regulations issued by virtue of the Nuclear Energy Act

Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (Stuklex.fi)	Y/1/2018	Explanatory memorandum (pdf)
Radiation and Nuclear Safety Authority Regulation on the Emergency Arrangements of a Nuclear Power Plant (Stuklex.fi)	Y/2/2018	Explanatory memorandum (pdf)