



Experiences in applying the general principle of justification

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Experiences in implementing justification principle in Finland

Radiation Act (859/2018)

- **Section 24 Justification assessment concerning new types of or existing practices**

The undertaking shall demonstrate that a new type of radiation practice subject to a safety licence is justified. The same applies to existing radiation practices if new important information on the efficiency, possible consequences or alternative methods or techniques of the practice is obtained.

- List of justified and not justified use of radiation

<https://stuk.fi/en/prerequisites-for-a-safety-licence>

- This presentation does not address the justification of medical exposure and non-medical imaging

Purpose and contents of the list

- Most commencing practices are similar to those exist already in Finland and are still considered justified.
- Implementation of graded approach: not warranted to repeat similar justification assessments for each individual application
- Purpose of the list is to help applicants to consider the need for a justification assessment when starting a new use of radiation.
- Concerns practices in which there is nothing abnormal compared to other same type of practices, for example in terms of
 - purpose of the use of radiation and radiation sources used,
 - the radioactive waste or discharges generated,
 - the working procedures, or
 - the arrangement related to radiation safety and security.

Justified practices

- Use of radiation exempted from safety license
- Use of radiation sources (sealed and sealed sources and devices containing them, as well as electrically emitting devices):
 - Use in research when the radiation is not directed at a human being
 - Use in the calibration and checking of radiation meters
 - Use in education as a teaching, demonstration and training tool
 - Trade, import, export and transfer
 - Installation, maintenance, repair and manufacture
 - Transport

Justified practices

- Use of sealed sources and electrically emitting devices:
 - Control and monitoring of industrial processes
 - Quality control of raw materials, products and waste
 - Analysis of material properties
 - Industrial radiography and similar imaging where radiation is not applied to humans
 - Irradiation of products, excluding foodstuffs
- Use of unsealed sources
 - Tracer tests in industrial processes, except in water supply systems whose water is used for domestic purposes

Justified practices

- Use of electrically emitting radiation equipment
 - In the manufacture of radioisotopes
 - Ion Implantation
 - Veterinary imaging
 - Security checks when radiation is not directed at humans
- Treatment and disposal of radioactive waste¹⁾

¹⁾The assessment of the justification of practice must also take into account the waste generated and the exposure arising from waste management (Government Decree § 2(4)). When a practice is justified, the treatment and disposal of radioactive waste resulting from the activity is also justified.

Not justified practices

- Intentional use of radioactive substances in the following products and the import, export and transfer of such products:
 - Foodstuffs within the meaning of the Foodstuffs Act
 - Feed within the meaning of the Feed Act
 - Cosmetic products within the meaning of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products
 - Jewellery and other similar personal accessories
 - Toys within the meaning of the Toy Safety Act (1154/2011)
 - Tracer tests in water supply systems whose water is used for domestic purposes
- Use of a high-activity sealed source without considering the possibility of using an electrically emitting device or other alternative technology instead

Rejected applications

- Placing radiation sources removed from smoke alarms into a work of art
- Some cases where pre-discussions with the applicant resulted to not to apply for a license because of high probability for rejection

- Some views for the future system of radiation protection
 - Is justification a fundamental principle or just a constraint within the process of optimization?

Background

- The current system of protection introduces the principles of justification, optimization, and dose limits as separate issues and **to be applied in a distinct sequence:**
 - 1) assess justification,
 - 2) if justified, optimize protection
 - 3) ensure that dose limits are not exceeded.
- In practice, the regulators need to apply them much more “flexibly”.

The current system process: Only theory, not implemented in practice

- The principles cannot be implemented, in practice, in the manner foreseen by the current system of protection i.e. separately and in the distinct sequence, because:
 - Justification assessment requires knowledge on the exposures (in order to assess the harms) which always includes assumptions on the optimization of protection. So, there is always some a-priori optimization taking place before justification is assessed.
 - The current system “checks” the compliance with the dose limits after the justification assessment. In practice, this never happens.
 - No regulatory body would make a decision stating that “the proposed practice is justified but rejected because the dose limits may be exceeded”.
 - A regulator would make a decision stating that “the proposed practice is not justified because the dose limits may be exceeded”.

Implementation in practice

- So, in practice, the factual sequence of applying the principles are:
 - Planning phase optimization, which is done in conjunction with conducting the safety assessment of the planned practice.
 - This includes selection among different possible options affecting radiation protection such as selection of an appropriate source for the intended practice, shieldings, work procedures etc.
 - Checking that foreseen exposures do not exceed the dose limits, considering the outcome of the planning phase optimization.
 - Assessing the justification (more good than harm) of the intended practice, considering the outcome of the planning phase optimization.

Reassessment of justification

- There is a need also to reassess the justification of the practice where
 - 1) significant changes to practice are planned,
 - 2) other factors, on basis of which the justification of the practice was concluded, changes.
- Reassessment is done against an ongoing practice i.e. for a practice for which protection is assumed to be optimized under the prevailing circumstances.
 - Justification (as well as dose limits) is “a constraint” or “game stopper” in the process of optimization

Conclusions

- Optimization of protection is the key for the process and dose limitation and justification are just two distinct boundaries within which the process of optimization should remain.
- Dose limits and justification are de facto used as specific “game stoppers” or as specific boundaries for the process of optimization of protection.
- This means that optimization of protection is the only overarching fundamental principle for radiation protection.

Summary/Suggestion

- As part of revising the system or radiation protection initiated by the ICRP, optimization of protection should be defined as the only fundamental principle for radiation protection.
 - Having only one fundamental principle which is guiding everything through the whole process could simplify the system for protection and make it easier to apply and understand.
- Role of justification and dose limitation should be changed from fundamental principles to “boundaries/constraints/game stoppers” to be used within the process of optimization.
- This would ultimately not be a major change to the current system (or what it has intended to be): the same elements would remain; optimization, dose limitation and justification
 - only their role would change to what they de facto already are in their practical implementation