### **ICRP 103 and Authorization and Inspection Processes**

### Helena Janžekovič

### Introduction

As a rule, radiological protection tackles nearly everyone in the modern times, i.e. while spacecraft exposures seem to be at least nowadays related to relatively small scientific, touristic and other groups, nearly everyone is confronted with at least medical exams using x-rays. However, as ionizing radiation cannot be identified by human senses the concepts related to radiological protection might pose significant challenges. Furthermore, as the radiation protection evolves also required safety measures to be in place in particular situation evolve.

It should be noted that nowadays the implementation of ICRP 103 [1] is as a rule a huge endeavour. In countries with somehow old legislation established as a rule when very first nuclear reactors were constructed there, e.g. decades ago, updating of legislation takes place. Typically several tens of documents are updated, e.g. strategies, laws, regulations, guides and emergency plans. Moreover, such changes lead further to changes in procedures to be in place at regulatory authorities, designers of sources and equipment, operators, technical support organizations, qualified experts, just to mention few parties involved in assuring radiation safety.

But the implementation of the ICRP 103 is even much bigger challenge in countries with relatively new radiation safety regulatory framework, e.g. countries which are struggling to put in place their very first complete regulatory framework. They are already overloaded with planned exposures situations; e.g. medical practices are taking place and operators of industrial facilities already operate facilities with radiation sources. Very often they are confronted also with existing exposures situations, e.g. contamination of areas due to past activities such as operation of mines which were abandoned decades ago. In addition, in parallel emergency preparedness and response shall be developed. In later case international community might help as has been demonstrated several times in the last decades.

#### **Regulatory Control**

The key of effective and efficient regulatory regime of radiation and nuclear safety is based on graded approach, i.e. understanding of the complexity of the risk to humans and environment related to the particular exposure situation and to assure that protective measures to be in place reflect this complexity. Graded approach is used by all parties involved. As an example, while a use of electron capture detectors is associated with only few safety measures and less strict regulatory control, building, operating and decommissioning of a new nuclear power plant requires complex regulatory framework assuring that siting, designing, construction, operation and decommissioning including management of radioactive waste and spent fuel are going to be in line with radiological principles.

Authorization and inspections are two of the main core processes of regulatory authorities. Very often inspections are the most visible part of the regulatory authority activities. Both processes are focused on the regulatory authority decisions which are unambiguous, namely:

- the regulatory authority issues or declines to issue an authorization,
- inspector's assessment confirms that either legally binding requirements are in place or incompliances exist.

The ICRP concepts shall support these very clear decision-making processes. The implementation of the ICRP 103 in legal system within EU Member States (MSs) implementing EU BSS [2] as well as IAEA MSs which is still taking place, reveals some of the key issues within ICRP 103 which require further

evaluation or guides. Namely, in authorization, review and assessment and in particular during inspection process it seems that some of the concepts are only poorly understood by operators, regulatory staff, qualified experts and other involved in assuring radiation safety. Inspectors are confronted on a daily basis with concepts which require additional explanations and guides. Moreover, it seems that implementation of some concepts in legal systems might require more attention and further practical recommendations and guides are beneficial. The list of such concepts includes e.g.:

- relation between justification and optimization principle,
- practical implementation of justification principle in non-medical exposures,
- justification principle and disused sources,
- implementation of dose constraints for members of the public,
- optimization bellow reference levels,
- implementation of radiation safety concepts and COVID-19

A list of concepts shall be longer and might include practical implementation of justification in emergency exposure situations, regarding evacuation as needed in the Fukushima accident.

# **Open Issue 1 - Justification Principle and Optimisation**

Justification principle as stated requires that "any decision that alters the radiation exposure situation should do more good than harm". ICRP 103 further explain application of the justification in:

- planned exposure situation,
- emergency and existing exposure situations.

The process of justification takes into account assessment of good and harm. In planned exposure situation different risks are assessed, among them radiation risk and associated detriment. On the other hand the optimization principle also addresses the radiation detriment, i.e. it can be high or low depending on the optimisation process. After optimisation process the harm can be used somehow back into the justification process. Therefore the implementation of optimization principle might influence justification process and as such justification and optimisation principles are linked. Further recommendations on such influence are welcomed.

# Open Issue 2 - Practical Implementation of Justification Principle in Non-Medical Exposures

Regulatory authorities for radiation and nuclear safety are confronted with applications related to radiation sources used for new purposes such as:

- non-medical exposures related to sport activities,
- non-medical exposures related to a control of weight.

The assessment of "good and harm" in justification process requires:

- identification of relevant stakeholders,
- communication assuring transparent justification process,
- foreseen re-evaluation of justification when needed, etc.

When regulatory body is confronted with "first of that kind" application the justification process might be very challenging. Even identification of relevant stakeholders might be an issue. Further practical recommendations on justification principles as well as on re-evaluation of justification are very welcomed. The globalisation of the world also lead to further harmonization of implementation radiation protection in particular areas.

# **Open Issue 3 - Justification Principle and Disused Sources**

In the past regulatory frameworks were very often oriented to the beginning of a lifecycle of a particular facility and activity with radiation sources e.g., to initial authorization process. However, justification principle is applicable during all life phases of facility and activity with radiation sources e.g., managing ageing nuclear power plants and disused sources.

In particular, the risk due to orphan sources has been identified as one of the main regulatory issues in last decades. Disused sources which become orphan sources are tackling nearly event country in the world. The national strategies have been developed [3] as well as specialised emergency response including detectors to identify orphan sources in cargo. Such systems require substantial workload of several authorities and other stakeholders. Further advice on justification of exposures related to disused sources are welcomed in order to empower safe management of such sources before becoming orphan sources.

## **Open Issue 4 - Implementation of Dose Constraints for Members of the Public**

Dose constraints are not to be used as "regulatory limit". But the regulatory authority sets the control on the doses of members of the public associated with a particular source, e.g. uranium mine, nuclear power plant or nuclear medicine department in a hospital. As a rule, this control is established through authorization process setting legally enforceable "public dose limits related to a particular facility" which is usually well below 1 mSv/y. Once such public dose is legally enforceable it is the regulatory limit, i.e. doses above the limit are not tolerated and in case of violations enforcement actions leading to corrective actions conducted by the operator follow. Misunderstanding of such dose limit might have severe legal consequences. Therefore, further recommendations are needed on this issue.

#### **Open Issue 5 - Optimization bellow Reference Levels**

The implementation of reference levels e.g., in Radon Action Plan, and associated regulatory regime is always a challenge for a regulatory authority. Several factors contribute to complexity of regulatory approach:

- lack of reliable data related to measurements and dose assessment as a basis to develop effective regulatory regime,
- changes in dose calculations, e.g. calculation of doses due to radon and its decay products,
- several new stakeholders involved in regulatory regime,
- changes in physical characteristics of objects, etc.

In light of mentioned complexity, it should be noted that it is often forgotten that optimization shall take place also bellow reference levels. Further recommendations seem to be needed.

#### **Open Issue 6 - Implementation of Radiation Safety Concepts and COVID-19**

The implementation of ICRP 103 in regulatory practice has been challenged and it is still challenged due to the COVID-19 pandemic. Changes included several activities:

- risk assessment have been changed,
- inspections are largely influenced,
- authorization of needed medical equipment has been a subject of changes,
- management of exiting exposure situations was postponed, etc.

Analysis of lessons learned from the pandemic time and its influence on implementation of ICRP concepts might be useful. Also, it might be useful to take lessons learned and to better prepare

radiation safety framework for such stressful situations. In particular, it might be interesting to answer the question: What can we learn from the pandemic when addressing public perception of new and somehow abstract concepts?

# Conclusion

Practical recommendations on application of challenging concepts assist regulatory authorities as well as whole radiological community to better implement the overall framework of radiological protection. The implementation of new recommendations takes several decades before they are seen to be fully implemented by operators and all other involved in assuring radiation safety. The changes in radiological protection shall be taken with a great caution, in particular as COVID-19 pandemic is teaching us that changes in protective actions even fully justified by the science might initiate unexpected behaviour leading even to neglecting scientific facts.

# References

[1] ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).

[2] EU, 2014. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, OJ L 13, 17.1.2014, p. 1–73.

[3] IAEA, 2011. National Strategy for Regaining Control over Orphan Sources and Improving Control over Vulnerable Sources, IAEA Safety Standards Series No. SSG-19, IAEA, Vienna.