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Implications of the UNSCEAR 2012 Report to the UN General Assembly for the development of the IAEA safety standards

Comments on the draft CSS policy

Judgments on radiation protection standards in Europe and elsewhere are highly dependent, first of all, on scientific knowledge that is reviewed in cycles by national committees and by a committee of the United Nations (UNSCEAR) and, secondly, on the recommendations made by the International Commission on Radiological Protection (ICRP) that seeks to take into account of such scientific development. The IAEA basis safety standards GSR Part 3 (2014) reflects feedback and experience accumulated until 2010. The implementation of this holistic view on radiation safety and updating of the IAEA safety guides is under way.

The UNSCEAR report 2012 underlines the importance of the understanding of the uncertainties in the radiation risk assessment and communication of the risk to radiation experts, public and decision makers. It also highlights the challenges related to adequate data collection for the research needs after an accident based on experience gained after the TEPCO Fukushima Dai-ichi accident in March 2011. As a member of UNSCEAR Finland endorses the UNSCEAR 2012 report.

UNSCEAR 2012 report concluded that the science on radiation-induced cancer has not changed but UNSCEAR has made the uncertainties in risk assessment more visible, in particular for low doses. To reduce such uncertainties, the acquisition of new scientific knowledge through research is a crucial element in improving radiation protection standards for the public, radiation workers and medical patients. This often requires transnational collaboration. The need to pursue such research reducing uncertainties could be explicitly stated by CSS.

The UNSCEAR report has no direct and immediate implications for the IAEA safety standards . As safety standards are subject to ongoing critical evaluation and review, it is important to maintain an open mind on the appropriateness and adequacy of the IAEA safety standards in the future. In particular, as new scientific evidence becomes available, it may be necessary to review the scientific basis for the IAEA safety standards. In particular, it would be important to follow research on non-cancer effects, and their possible contribution to detriment.

Recently, the NEA Expert Group on Radiological Protection Science of the Committee for Public Health and Radiation Protection, CRPPH (OECD 2016, NEA No. 7265) reviewed the knowledge basis and concluded the current radiation protection system, with its focus on optimisation and a linear extrapolation of the risk observed at high-to-medium doses to low doses with no threshold, does not underestimate protection needs.

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Conclusions

1. UNSCEAR 2012 report concluded that the science on radiation-induced cancer has not changed but UNSCEAR has made the uncertainties in risk assessment more visible, in particular for low doses. The UNSCEAR report has no direct and immediate implications for the IAEA safety standards .
2. CSS could make a statement to support the radiation safety research based on the UNSCEAR 2012 report. There is a need
 - a. to reduce the uncertainties,
 - b. for the scientific data on non-cancer effects,
 - c. to ensure structured data collection immediately after major radiological accident considering both human health and environment,
 - d. to make use of digitalization and big data to improve decision making
 - e. to carry out research on stakeholder engagement and risk communication in a modern society.
3. CSS should encourage enhancing risk communication skills to address uncertainties related to low dose effects.

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Detailed discussion on the comments on the draft CSS policy

Judgments on radiation protection standards in Europe and elsewhere are highly dependent, first of all, on scientific knowledge that is reviewed in cycles by national committees and by a committee of the United Nations (UNSCEAR) and, secondly, on the recommendations made by the International Commission on Radiological Protection (ICRP) that seeks to take into account of such scientific development. The acquisition of new scientific knowledge through research is therefore a crucial element in improving radiation protection standards for the public, radiation workers and medical patients. During the last century of radiation protection, there has been an evolution of the system of protection, mainly driven by new knowledge on radiation effects but also by changes in the society, both in terms of societal values and technological development. Although current radiation protection standards are generally judged to be acceptably robust there remains considerable scientific uncertainty particularly with regard to health risks at low doses and/or low dose rates. Consequently upon these uncertainties, the issue of low dose risk is controversial in both scientific and political and public context.

The IAEA basis safety standards GSR Part 3 reflects feedback and experience accumulated until 2010. It has been subject to the rigorous review process and reflects the common understanding of several international organizations. The updating of the IAEA safety guides reflecting the current requirements document is under way. The IAEA safety standards follow ICRP recommendations that inter alia reflect the UNSCEAR assessment of the scientific knowledge.

In its 2012 report, UNSCEAR has addressed the attribution of health effects to different levels of exposure to ionizing radiation. The attributability depends on exposure level so that the link is easier to prove at high doses but inferring risks at low doses (generally below 0.1 Gy) is not reliable because of scientific uncertainties. At individual level, it is possible to attribute health effect to radiation at high acute doses (above 1 Gy or more) causing tissue reactions or “deterministic effects”. Ionising radiation also induces cancer across a wide dose range. Cancer is stochastic effect: radiation causes an increase in cancer on top of a spontaneous incidence. Such increase could be attributed to radiation exposure only through an epidemiologic analysis, in the population level, when doses are sufficiently high (above 0.1 Gy). In rare cases only it is possible to attribute an individual cancer case to a particular radiation exposure, like it was in the case of thyroid cancers induced by radioiodine in young children after the Chernobyl accident (compared against a very low background incidence). Ionising radiation is defined as weak carcinogen by the WHO. Even at high doses, not all exposed persons get cancer. At the lowest dose range (below 100 mGy), epidemiological studies suffer of lack of statistical power and associations in population studies not statistically significant. In epidemiological studies, there are uncertainties related to dosimetry and modifying factors such as genetic and epigenetic factors, age, sex, other exposures and lifestyle (eg. smoking). The radiation-induced increase is thought to be in proportion to the spontaneous incidence (relative risk). Transferability of risk from one population to another is complicated by the population characteristics and confounding factors.

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As for hereditary effects, there is currently no direct evidence attributing hereditary effects to ionizing radiation exposure in humans, partly because of large variations in the spontaneous background of such effects. However, the link is well established in animal studies.

Understanding of risk

The UNSCEAR analysis in Annex A considering the issue of *Attributing health effects to ionizing radiation exposure and inferring risks* was underpinned by Annex B of the 2012 Report, *Uncertainties in Risk Estimates for Radiation-induced Cancer*. However, in addition to cancer, non-cancer effects are receiving more and more scientific attention. Currently, their occurrence and possible mechanisms at low levels of dose and dose rate remain uncertain. The ICRP has recommended a lower threshold for cataracts, but more research is needed for circulatory and other non-cancer effects. Until recently, it was thought that there is a threshold and radiation doses below 5 Gy produce no substantial circulatory disease risk. However, evidence is emerging that ionising radiation doses under 5 Gy may also increase the long-term risk of circulatory diseases and a threshold dose below 0.5 Gy cannot be excluded. Tissue reactions such as cataracts and circulatory disease apparently have both deterministic and stochastic features, depending on dose and latency period (high dose, short term effects behaving like deterministic effects and lower dose effects manifesting after long latency having stochastic nature). By time, this may impact the IAEA safety standards.

All possible efforts have to be taken to lower uncertainties in evidence based research after a major radiological accident. The EU project SHAMISEN (Nuclear Emergency Situations, Improvement of Medical and Health Surveillance) that will end in 5/2017 and financed by OPERRA (Open Project for European Radiation Research Area) has identified draft recommendations to enhance understanding and communications of risks for different areas of interest, such as health surveillance, dose assessment and communication & training. For further details see <http://www.crealradiation.com/index.php/en/shamisen-home>.

Understanding of risk as such is elementary for the CSS policy and it is useful to reflect the UNSCEAR report and see if it calls for changes. Overall, it can be concluded on the UNSCEAR 2012 report that the science on radiation-induced cancer has not changed but UNSCEAR has made the uncertainties in risk assessment more visible, in particular for low doses. To reduce such uncertainties, the acquisition of new scientific knowledge through research is a crucial element in improving radiation protection standards for the public, radiation workers and medical patients. The need to pursue such research reducing uncertainties could be explicitly stated by CSS.

The effects of radiation are currently classified in two categories: deterministic effects (eg. skin burns) and stochastic effects (cancer, hereditary effects). The protection principles are to prevent deterministic effects and to limit stochastic effects. The UNSCEAR report has no direct and immediate implications for the IAEA safety standards. As safety standards are subject to ongoing critical evaluation and review, it is important to maintain an open mind on the appropriateness and adequacy of the IAEA safety standards in the future. In particular, as new scientific evidence

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becomes available, it may be necessary to review the scientific basis for the IAEA safety standards. In particular, it would be important to follow research on non-cancer effects, and their possible contribution to detriment.

Communication; Science, values and policy in development of the safety standards

The system of protection is based not only on science but also on values and experience. The values are addressed by the ethical and societal principles for protection: protecting the individual, justification and optimisation. The communication of the risks both with the public and among stakeholders is important. Both actual risks and perceived risks need to be addressed and put in context with the many beneficial uses of radiation in modern society. In addition to science, also values underlying the safety standards need to be transparent. According to IAEA procedures for the safety standards they should support policy makers and enable people to make their own informed choices. Sometimes protective actions may come with health risk like it was the case with evacuation of elderly people and hospitalized patients after the Fukushima accident. Good decisions call for societal considerations in addition to radiation risk.

An example of recent approaches for better risk communication is the European RICOMET project. The next conference will take place at the IAEA premises in June 2017. For further information see <http://www.rec.org/event.php?id=150>

An other example on research on risk communication and improved collection of health data is the recommendations and procedures for preparedness and health surveillance of populations affected by radiation accidents developed by Euratom SHAMISEN project to be completed in May 2017. <http://www.crealradiation.com/index.php/shamisen-home>

Precaution and conservatism

Precautionary approach applies when scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds, in terms of plausibility, for concern about undesired effects. As a consequence, the dose assessment methodologies applied in radiation protection tend to be conservative and, in many situations, overestimate the actual doses received.

Recently, the NEA Expert Group on Radiological Protection Science of the Committee for Public Health and Radiation Protection, CRPPH (OECD 2016, NEA No. 7265) reviewed the knowledge basis and concluded that the cancer risk from ionising radiation, at low dose (defined as <100 mGy of absorbed dose) and low dose rate (defined as <5mGy/hr of absorbed dose), can be described as having a linear relationship with doses down to 50-100 mSv (of an equivalent or effective dose), and that for children and in utero exposures this could be valid at even lower doses. Thus, the current radiation protection system, with its focus on optimisation and a linear extrapolation of the risk observed at high-to-medium doses to low doses with no threshold, does not underestimate protection needs.

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Stability and regulatory predictability

The role of UNSCEAR is to review the scientific evidence on the sources, levels and effects of ionising radiation. UNSCEAR does not give any opinions on radiation protection standards. The ICRP system of protection is based not only on science (incl. UNSCEAR) but also on values and experience on practise. The IAEA safety standards follow ICRP recommendations.

The radiological protection system has to be protective but also pragmatic, avoiding excessive costs or unnecessary complexity.

Collective effective dose

As, due to scientific uncertainties, the increases in the incidence of health effects in populations cannot be attributed reliably to chronic exposure to radiation at levels that are typical of the global average background levels of radiation, UNSCEAR does not recommend multiplying very low doses by large numbers of individuals to estimate numbers of radiation-induced health effects within a population exposed to incremental doses at levels equivalent to or lower than natural background levels. If such projections of numbers of health effects are made for comparative purposes, uncertainties in the assessments should be taken fully into account and the projected health effects should be inferred as notional.

At present there is no experience feed back on the incorrect use of the collective dose in the IAEA safety standards. As stated the safety standards should define the applicability of the concept of collective dose in different circumstances and for different purposes, and outline its practical usefulness as well as its limitations.

Conclusions

- UNSCEAR 2012 report concluded that the science on radiation-induced cancer has not changed but UNSCEAR has made the uncertainties in risk assessment more visible, in particular for low doses. The UNSCEAR report has no direct and immediate implications for the IAEA safety standards .
- CSS could make a statement to support the radiation safety research based on the UNSCEAR 2012 report. There is a need
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 - to make use of digitalization and big data to improve decision making
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- CSS should encourage enhancing risk communication skills to address uncertainties related to low dose effects.