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


The Commission on Safety Standards (CSS), at its 35th meeting held in April 2014, requested the Radiation Safety Standards Committee (RASSC) to prepare a policy/position paper on the possible implications for the development of safety standards, of the 2012 Report of UNSCEAR to UNGA. The RASSC paper was submitted to CSS’ 39th Session, in April 2016. RASSC concluded as follows:

“RASSC considers that the UNSCEAR report “Attributing Health Effects to Ionizing Radiation Exposure and Inferring Risks” has no direct and immediate implications for the IAEA safety standards. As such, the UNSCEAR report reinforces the appropriateness of, and sound scientific basis for, the IAEA safety standards.

Looking to the future

The UNSCEAR report raises questions about communication with the public on issues such as exposure, health effects and future risks. It is important that radiation protection professionals better explain the sources of radiation to which the public are exposed and the magnitude of these exposures. The associated health risks, the uncertainties in the risk estimates and the system that is in place to protect against these risks also need to be explained. Both actual risks and perceived risks need to be addressed and put in context with the many beneficial uses of radiation in modern society.

As the 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.”

Some CSS members raised comments on the conclusions and considered that it could not be ruled out that there were implications of the UNSCEAR report on the safety standards. Although the standards were intended to be used in a prospective manner, providing requirements and guidance on radiation protection based on probabilities of occurrence of events, a great interest lay in retrospective attribution of effects, and it was in distinguishing these two approaches that problems arose in understanding and communication, even among experts. CSS agreed on the following action item:

39.01 The CSS Chair, with the assistance of volunteers from the CSS members, to prepare, on the basis of the RASSC contribution paper, a CSS policy on the implications of the UNSCEAR report “Attributing Health Effects to Ionizing Radiation Exposure and Inferring
Issues considered

It can be concluded from the UNSCEAR report that there is a fundamental epistemological difference between radiation effects and radiation risk, between attributing effects and inferring risk and on a number of related concepts. Recognizing such differences is fundamental for the process of establishing radiation and nuclear safety standards. The UNSCEAR evaluations provide a significant part of the scientific basis for the establishment of international safety standards under the aegis of the IAEA. The purpose of this paper is to promote a discussion on how the current system of international safety standards taking such differences into account.

The RASSC paper provides a factual summary of Annex A to the UNSCEAR 2012 Report. The paper identifies eight different areas, which are broadly relevant to the UNSCEAR Report as well as to the safety standards. Appendix 1 to this Discussion paper builds on the RASSC paper to further stimulate a discussion on how the safety standards should accommodate the existing scientific understanding of health effects and risks from ionizing radiation; and how the protective regime can be communicated to stakeholders, either these are regulatory agencies, members of the occupationally exposed workforce and their representatives, or members of the public.

Appendix 2 to this discussion paper reproduces the relevant content of the UNSCEAR 2012 Report to the UN General Assembly.
**Appendix 1 Issues identified by RASSC in its opinion paper; and draft CSS policy**

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<td>1</td>
<td>Understanding of risk</td>
<td>The Report summarizes the available information and state of knowledge regarding the attribution of health effects and the inference of risks associated with exposure due to ionizing radiation. The report provides considerable clarification on the uncertainties in the assessment of such risks, particularly for low doses, and is addressed primarily to the scientific community rather than to the general public.</td>
<td>The effects of radiation against which the standards shall provide protection and safety are categorized in two types: (i) those that produce tissue reactions mainly due to the killing of cells by radiation exposure, termed ‘deterministic effects’; and, those that derive from transformation of cells, termed ‘stochastic effects’. Attribution of radiation effects requires knowledge and scientific attestation: Individual attribution through diagnosis by qualified pathologists; collective attribution by means of epidemiology. The issue of counterfactuality has to be addressed, i.e. would the effect (in an individual or in a population) have been manifest in the absence of radiation exposure? The attestation should also address uncertainties of epistemic and statistical nature, as well as individual risk factors. Knowledge, on both radiopathology and radio-epidemiology, has epistemological limitations, namely boundaries associated with the methods, validity, and scope of the relevant sciences. Below relatively high levels of radiation doses, deterministic effects cannot be diagnosed in the exposed individuals and below lower levels of radiation doses, stochastic effects cannot be estimated in the exposed populations. These levels of dose above which effects can be attributed to the exposure represent a division line between knowledge (at higher doses) and assumption (at lower doses). <strong>Radiation health effects are changes in the health status that can be proved to be an unequivocal result of radiation exposure on either an individual person, or collectively on a cohort.</strong> Conversely, radiation risks are plausible but uncertain prospective detrimental outcomes of radiation exposure situations; these outcomes and their chance of occurrence can be estimated on a collective basis but not readily for individuals. Standards aimed at protecting against radiation need to clarify the distinction between individual protection and collective protection. <strong>Safety standards should state clearly what effects they are addressing; what risks they are designed to manage; and what level of protection they afford individuals and populations.</strong></td>
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<td>2</td>
<td>Understanding of risk</td>
<td>The report contains no information that significantly changes the understanding of risk. It is recognized that there is no such thing as absolute certainty in this regard, and that there are still unanswered scientific questions. Radiation protection therefore needs to be based, to some extent, on probabilistic analysis. It is appropriate, therefore, to consider whether the absence of scientific certainty is adequately addressed in the development of the IAEA safety standards.</td>
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<td>3</td>
<td>Communication: perception of risk</td>
<td>There is considerable evidence that the public views radiation risks very differently from the way that radiation protection professionals view them. This is particularly apparent in the aftermath of an accident involving the release of radionuclides to the environment. In communicating to the public regarding the measures for radiation protection, the challenge will be not only to explain the science and principles on which they are based, but to also address their concerns and beliefs.</td>
<td>As stated with regard to 1 and 2 above, risk can be can be inferred as varying degrees of probability, or expressed differently with varying degree of certainty. This process is prospective in nature. Risks cannot be proved. Inference is based on assumptions based on professional judgments on the likelihood of occurrence, based on observations in the past, i.e. retrospective analysis. On occasions, such assumptions involve a high degree of certainty and effectively become predictions; sometimes, however, they reflect a degree of belief and associated uncertainties, of qualified experts. The process of attribution of effects, and inference of risks, is driven by the norms and values of science. These may be different from the norms and values of society in general. The perception of risks, and the relative importance of the uncertainties, is going to be modified by a variety of societal factors affecting the acceptability of activities that give rise to the risks. The standards must not defend policy but enable development of policies based on evidence and acknowledging uncertainties. Safety standards should communicate ‘what is safe’ in a way that takes into account what is known and what is inferred, i.e. what can be proven in retrospective analysis of attribution, what can be the predicted health outcomes and what are inferred outcomes. They should support policy makers and enable people to make their own informed choices. They should allow for, and stimulate, informed decision making regarding protective measures and remediation in case of accidents or severely disruptive natural events, before such exposures occur, in a transparent manner. This will allow for societal values to be fully considered in the decision making.</td>
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<td>Communication: evidence and values</td>
<td>Scientific evidence is one of the cornerstones of radiation protection and, as a consequence, also of the IAEA safety standards. The concept of “values” is also important and this includes ethical considerations such as equity, consent, judgement, engagement with interested parties and more general societal issues. Therefore, a range of societal issues needs to be considered, and given an appropriate weighting, in different situations. Such considerations need to be transparently documented, including their weight relative to the scientific evidence considered, in setting standards.</td>
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<td>5</td>
<td>Science, values and policy in development of the safety standards</td>
<td>It is essential that the IAEA safety standards continue to be evidence-based, taking account of the weight of the scientific evidence and its implications. Scientific evidence and values are both reflected in the IAEA safety standards. Reflecting an international consensus on the relative importance of the science, values and policy considerations in the development of safety standards, as part of the standard-setting process, is to be encouraged.</td>
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| 6  | Precaution and conservatism | Because of the lack of certainty regarding the risks following radiation exposure, in particular for low doses, one of the key elements of establishing standards for radiation protection is the adoption of a precautionary approach. In practice, this 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, considerably over-estimate the actual doses received. In circumstances where additional doses are within the range of doses due to natural background radiation, the need for such conservatism is much reduced. | Precaution and conservatism are concept that cannot be understood or discussed in isolation from the extent of certainty or belief in attribution and inference. It is linked to ethics and societal values underpinning protective ambitions but may also lead to undesirable societal and health consequences. Radiation protection approaches the issue by application of the principles of justification and optimization.  

*It may be necessary to reflect further on how consideration of retrospective attribution and prospective inference relates to justification and optimization.* |
| 7  | Stability and regulatory predictability | The stability of the safety standards is important for their credibility and public acceptance. In general, the standards are robust and effective in achieving an appropriate balance between the protection of people and the environment from possible harmful effects and the many uses of radiation that benefit society. Major changes to the standards are not without consequences and need to be justified; the impact of reduced stability must be carefully balanced against the improvements in protection that are expected to ensure an overall net benefit. | Regulatory stability and predictability is as important as the evidence base for the regulatory system. Thus, the regulatory system needs to be able to absorb evolving concepts and science in a manner that allows for adjustments and avoids major disruptions.  

*The safety standards could be more able to achieve the objectives of stability and predictability, and of adaptability to scientific developments, if careful consideration is made to:*  

- radiation effects vis-à-vis radiation risks  
- retrospective situations vis-à-vis prospective situations  
- attribution of effects vis-à-vis inference of risk  
- individual diagnosis vis-à-vis collective evaluation  
- frequency of occurrence vis-à-vis degree of belief of incidence |
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<td>Collective dose</td>
<td>The concept of collective dose is also highlighted in the UNSCEAR report. Indeed it is the misuse of this concept in the aftermath of the Chernobyl accident that was one of the principal motivations for the preparation of the report. Collective dose can be used to compare the outcome of different optimization strategies but it is not appropriate for use either in epidemiological studies or in risk projections. Specifically, the calculation of fatal cancers based on collective doses involving trivial exposures to large populations is inappropriate and should not be undertaken. It is important that the correct use of collective dose is emphasized in the IAEA safety standards.</td>
<td>Collective dose is a valuable tool for comparative purposes. It is not possible to prescribe against calculation based on small individual doses and a large number of individuals; the 2012 UNSCEAR GA Report indicated situations where this may be of assistance in decision making. However, if such calculations are made, it is imperative that the assumptions underpinning the calculations, as well as the associated uncertainties are communicated to the receiving audience. In many cases, it will have to be concluded that the information value of such calculations is very limited. The aggregated collective dose may have to be broken up into dose bands, in order to form a more informed view on the potential or plausible health implications. 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.</td>
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Appendix 2 The UNSCEAR 2012 Report to the UN General Assembly

In the report informing the General Assembly of its fifty-ninth session (Official Records, Sixty-seventh GA session, Supplement No. 46, Document A/67/46), UNSCEAR inter alia addressed the attribution of health effects to different levels of exposure to ionizing radiation, and reached the following conclusions:

(a) An observed health effect in an individual could be unequivocally attributed to radiation exposure if the individual were to experience tissue reactions (often referred to as “deterministic” effects), and differential pathological diagnosis were achievable that eliminated possible alternative causes. Such deterministic effects are experienced as a result of high acute absorbed doses (i.e. about one gray or more), such as might arise following exposures in accidents or in radiotherapy;

(b) Other health effects in an individual that are known to be associated with radiation exposure — such as radiation-inducible malignancies (so-called “stochastic” effects) — cannot be unequivocally attributed to radiation exposure, because radiation exposure is not the only possible cause and there are at present no generally available biomarkers that are specific to radiation exposure. Thus, unequivocal differential pathological diagnosis is not possible in this case. Only if the spontaneous incidence of a particular type of stochastic effect were low and the radiosensitivity for an effect of that type were high (as is the case with some thyroid cancers in children) would the attribution of an effect in a particular individual to radiation exposure be plausible, particularly if that exposure were high. But even then, the effect in an individual cannot be attributed unequivocally to radiation exposure, owing to competing possible causes;

(c) An increased incidence of stochastic effects in a population could be attributed to radiation exposure through epidemiological analysis — provided that, inter alia, the increased incidence of cases of the stochastic effect were sufficient to overcome the inherent statistical uncertainties. In this case, an increase in the incidence of stochastic effects in the exposed population could be properly verified and attributed to exposure. If the spontaneous incidence of the effect in a population were low and the radiosensitivity for the relevant stochastic effect were high, an increase in the incidence of stochastic effects could at least be related to radiation, even when the number of cases was small;

(d) Although demonstrated in animal studies, an increase in the incidence of hereditary effects in human populations cannot at present be attributed to radiation exposure; one reason for this is the large fluctuation in the spontaneous incidence of these effects;

(e) Specialized bioassay specimens (such as some haematological and cytogenetic samples) can be used as biological indicators of radiation exposure even at very low levels of radiation exposure. However, the presence of such biological indicators in samples taken from an individual does not necessarily mean that the individual would experience health effects due to the exposure;

(f) In general, 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. This is because of the uncertainties associated with the assessment of risks at low doses, the current absence of radiation-specific biomarkers for health effects and the insufficient statistical power of epidemiological studies. Therefore,
the Scientific Committee 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;

(g) The Scientific Committee notes that public health bodies need to allocate resources appropriately, and that this may involve making projections of numbers of health effects for comparative purposes. This method, though based upon reasonable but untestable assumptions, could be useful for such purposes provided that it were applied consistently, the uncertainties in the assessments were taken fully into account, and it were not inferred that the projected health effects were other than notional.