

Implications of the UNSCEAR report “Attributing Health Effects to Ionizing Radiation Exposure and Inferring Risks” for the development of IAEA safety standards

Opinion of the Radiation Safety Standards Committee

Background

At its 35th meeting held in April 2014, the Commission on Safety Standards (CSS) requested the Radiation Safety Standards Committee (RASSC) to “prepare a policy/position paper on the UN General Assembly deliberation on the attribution of radiation effects and inference of risk and possible implications for the safety standards”.

At the 36th meeting of RASSC in June 2014, the request from the CSS was discussed, together with a background paper submitted by Argentina. RASSC noted that, while UNSCEAR has reported a summary of its findings to the UN General Assembly, its scientific report had not yet been published. RASSC therefore agreed to return to this issue once the UNSCEAR report was available. In the meantime, members and observers of RASSC were invited to provide written submissions with their views on this topic. RASSC also agreed that it was inappropriate for it to consider any issues related to compensation.

Submissions received from Belgium and Canada were discussed at the 37th meeting of RASSC in December 2014. At this time, RASSC also established an electronic Working Group to work with the Secretariat in preparing a draft response to the CSS. The membership of the Working Group is given in Annex 1. RASSC noted the intention of UNSCEAR to publish its report during 2015.

At the 38th meeting of RASSC in June 2015, Mr Malcolm Crick, Secretary of UNSCEAR, presented the background to and the conclusions of its report “*Attributing Health Effects to Radiation Exposure and Inferring Risks*”.

Summary of the UNSCEAR Report

The UN General Assembly resolution 62/100 of 17 December 2007 encouraged UNSCEAR to submit a report, at its earliest convenience, “to clarify further the assessment of potential harm owing to chronic low-level exposures among large populations and also the attributability of health effects”. The key findings were submitted in a report to the 2012 UN General Assembly. The two supporting technical annexes, “*Uncertainties in Risk Estimates for Radiation-induced Cancer*” and “*Attributing Health Effects to Ionizing Radiation Exposure and Inferring Risks*” were finalized in 2015 and have been published electronically.

The principal motivation for the development of the report was the confusion over the health impact of the Chernobyl accident. Various bodies, including some UN bodies, provided very different estimates of the number of cancers due to the radiation exposure following the accident, including statements to the effect that any increase in cancer rates were likely to be so small as to be undetectable. The intention of the report was to clarify assessment of potential harm from, and attributability of health effects to, ionizing radiation exposure and, as a consequence, to promote informed use of UNSCEAR reports.

The report makes a clear distinction between past and present actual observations of health effects in an individual or a population and the predicted risk of future health effects in an individual or a population. Clinical studies of actual cases and epidemiological studies of changes in the frequency of occurrence of health effects in exposed populations provide the scientific basis to test causal hypotheses, but to attribute observed outcomes to cause it is necessary to eliminate other possible causes. Inference of future risk can be based on the frequency distribution of a sufficiently large number of observations. In some cases, it may be necessary to fill gaps in observations by expert judgements/modelling. When estimating future risks, we can make confident predictions only where increased frequency of effects is deemed proven; where it is not deemed proven, we can make conditional predictions, based on assumptions.

When dealing with population studies, there are major challenges in overcoming statistical fluctuations and eliminating bias and confounding. For that reason it is not surprising that for adults a statistically significant increase in the frequency of radiation induced cancers is seen only from about 100 mGy upwards for low LET radiation. The lack of a specific biomarker for radiation-induced cancer means that other possible causes need to be considered.

The main conclusions of the report are as follows:

- (1) Observed deterministic effects in an individual can be unequivocally attributed to radiation exposure only if possible alternative causes can be excluded;
- (2) Observed stochastic effects in an individual cannot be unequivocally attributed to radiation exposure, because radiation exposure is not the only possible cause and presently there are no biomarkers specific to radiation exposure;
- (3) An observed increased frequency of stochastic effects in a population can be attributed to radiation exposure through epidemiological analysis, provided that the increased frequency is large enough to overcome inherent statistical uncertainties and bias and confounding can be accounted for;

- (4) In general, increases in frequency of health effects in populations cannot be attributed reliably to chronic exposure to radiation at typical global average background levels, because of (1) uncertainties associated with assessment of risks at low doses; (2) current absence of radiation-specific biomarkers for health effects; and (3) insufficient statistical power of epidemiological studies;
- (5) Although demonstrated in animal studies, an observed increase in the frequency of hereditary effects in human populations cannot presently be attributed to radiation exposure;
- (6) The 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;
- (7) Public health bodies need to allocate resources appropriately, and 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 is applied consistently, the uncertainties in the assessments are taken fully into account, and it is not inferred that the projected health effects were other than notional.

UNSCEAR identifies the following priorities for future work

- identification of specific radiation-induced biomarkers
- robust epidemiological studies involving cohorts exposed to very-low doses;
- better characterization of non-cancer effects; and
- a rigorous quantification of uncertainties.

Response from RASSC

In response to the Commission on Safety Standards, RASSC wishes to make the following points:

- (1) 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.

- (2) 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.
- (3) 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.
- (4) 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.
- (5) 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.
- (6) 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.

- (7) 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.
- (8) 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.

Summary

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.

ENDS

Annex 1

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