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WHITE PAPER
FOR THE
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CONSIDERING THE IMPLICATIONS OF THE UNSCEAR REPORT ON 'ATTRIBUTING HEALTH EFFECTS TO IONIZING RADIATION EXPOSURE AND INFERRING RISKS' FOR THE DEVELOPMENT OF IAEA SAFETY STANDARDS

BACKGROUND

At the 42nd meeting of the IAEA's Commission on Safety Standards (CSS) in November 2017, the commission requested the IAEA to organize a Consultancy Meeting (CM) to consider the implications for the development of the IAEA Safety Standards of the reporting by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) on *Attributing Health Effects to Ionizing Radiation Exposure and Inferring Risks*. [1]UNSCEAR had submitted its conclusions to the United Nations General Assembly (UNGA), which at its 67th session welcomed 'with appreciation the scientific report on attributing health effects to radiation exposure and inferring risks requested by the General Assembly in its resolution 62/100 of 17 December 2007 and the report on uncertainties in risk estimates for cancer due to exposure to ionizing radiation.' The IAEA Safety Standards, which are an essential part of the radiation and nuclear safety international regime are based on the scientific estimates of UNSCEAR and the International Commission on Radiological Protection (ICRP).

This white paper:

- Describes the IAEA Safety Standards and its relation to the UNSCEAR estimates
- Provides an overview of UNSCEAR regarding the issue of attributing health effects to ionizing radiation exposure and inferring risks report
- Looks at the ICRP recommendations in relation to the prospective inference of radiation risk (mainly contained in ICRP Publication 99 and confirmed in the current ICRP recommendations in ICRP Publication 103)
- Notes the actions undertaken by the CSS since 2014 on the issue
- Discusses the potential implications of the new UNSCEAR estimates on the developments of the IAEA Safety Standards
- Explores possible courses of action for incorporating the relevant conclusions into IAEA Safety Standards.

UNSCEAR Estimates & This Consultancy

The 2012 UNSCEAR report imply a clear distinction between two types of radiation exposure situations:

[1] UNITED NATIONS SCIENTIFIC COMMITTEE ON THE EFFECTS OF ATOMIC RADIATION, Report of the United Nations Scientific Committee on the Effects of Atomic Radiation, 59th Session, United Nations, New York (2012), http://www.un.org/en/ga/search/view_doc.asp?symbol=A/67/46. . (See in particular §25.)

(i) situations for which an observed health effect could be explicitly attributed to radiation exposure (this is the case for deterministic effects, such as erythema and other radiation syndromes) or in populations through radio-epidemiological assessments (such as statistically significant increases in the background prevalence of malignancies following high dose, high dose-rate exposures in large populations), and are therefore attributable to the situation, and

(ii) situations for which stochastic health effects that are known to be associated with radiation exposure cannot be explicitly attributed to radiation exposure because radiation exposure is not the only cause and there are no biomarkers that are specific to radiation exposure.

The purpose of the CM is to initiate an analysis of the relevant IAEA Safety Standards, including the Safety Fundamentals, and to identify whether there is a need to refine them with respect to:

- Retrospective attribution of radiation health effects to past radiation exposures
- Prospective inference of health risks from radiation exposures
- Prediction of notional health effects for comparative purposes (e.g., use of collective or population dose)

The current IAEA Safety Standards do not make any distinction between these two situations. The consultancy is expected to advise the CSS whether this continued approach is acceptable or should be reviewed and eventually revised.

SCIENTIFIC BASIS OF THE IAEA SAFETY STANDARDS

As noted by the November 2017 CM on Attribution, the scientific basis of the IAEA Safety Standards is rooted on the estimates of UNSCEAR and the recommendations by ICRP. The Nov 2017 CM noted that IAEA's SPESS process addresses interactions with other international organizations and states that "The findings of UNSCEAR and the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP) are taken into account in developing the IAEA safety standards." The CM also noted that the IAEA Safety Fundamentals had been issued in 2006, before the most recent recommendations of the ICRP, and consequently agreed that there may be a need for the safety standards to adequately reflect the concepts of attributability, inference of risk and use of collective dose, to reflect the lessons learned from the latest international scientific evaluations, and to ensure that these concepts are adequately addressed.

The UNSCEAR 2012 report addresses the attribution of health effects to different levels of exposure to ionizing radiation, and reaches the following two main conclusions:

- Increases in the incidence of hereditary effects in human populations cannot at present be attributed to radiation exposure; and
- Increases in the frequency of occurrence of health effects in populations cannot be reliably attributed to chronic exposure to radiation at levels that are typical of the global average background levels of radiation (~several mSv/year)

These conclusions may have significant influence in the future development of IAEA Safety Standards. *>>The February CM should expand on this point in the final paper presented to the CSS.*

In addition to addressing the attribution of health effects to different levels of exposure to ionizing radiation, UNSCEAR also analyzed uncertainties in the *prospective* risk estimates for cancer due to exposure to ionizing radiation (that are used in the IAEA Safety Standards). We highlight only a few factors that UNSCEAR noted can dominate the uncertainty in projecting risk:

- Transfer of risk estimates from one population to another
- Transfer of risk estimates from population to individuals
- Extrapolation from acute to chronic and fractionated exposures
- Extrapolation from moderate- or high-dose to low-dose exposures
- Non-linear dose responses over the dose range of interest
- Extrapolation to different radiation types
- Absorbed dose values in the population of interest

RECOMMENDATIONS OF THE ICRP

ICRP recommends that at radiation doses below ~100 mSv in a year, the increase in the incidence of stochastic effects is assumed to occur with a small probability and in proportion to the increase in radiation dose over the background dose. This is the fundamental assumption of inference of risk providing the bases for the IAEA Safety Standards. Use of this so-called linear-non-threshold (LNT) model is considered by ICRP and Regulatory Authorities to be the best practical approach to managing risk from radiation exposure, commensurate with the *precautionary principle*.[2] In sum, ICRP considers that the LNT model remains a prudent basis for radiological protection at low doses and low dose rates.

ICRP has not yet revised its last recommendations, which were issued in 2007 as ICRP Publication 103. The prospective inference of radiation risk in the 2007 recommendations are based on an ICRP estimate published in 2005 as ICRP Publication 99. The current version of the IAEA Basic Safety Standards (BSS) is based on recommendations of ICRP Publication 103.

DELIBERATIONS OF THE CSS & OPINION PAPER FROM RASSC

Since April 2014, the CSS, and more recently RASSC, have considered the implications of the UNSCEAR estimates on attributing health effects to ionizing radiation exposure and inferring risks and requested RASSC to prepare a policy/position paper on the possible implications of the UNSCEAR report for the development of IAEA safety standards. Later that year, the CSS requested additional review by RASSC and recommended that the IAEA should use the language of UNSCEAR, so rather than “activities that give rise to radiation risks” (the current language of the Safety Standards) to use instead “activities from which one can infer radiation risks”, which presented a subtle difference. In November 2015, RASSC informed the CSS that discussions had been held on attribution of health effects and inference of risk, but that it did not have a report on the issue and recommendations for the Commission at that time.

In 2016, RASSC produced a report on the issue for discussion at the 39th meeting of the CSS.[3] It judged that the UNSCEAR report “Attributing Health Effects to Ionizing Radiation Exposure

[2] The *Precautionary principle* in basic terms is that there is an expectation that no radiation exposure shall be given without expectation of some benefit. By definition, UNESCO (2005) states that: “When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.”

[3] *http://www-ns.iaea.org/committees/files/CSScomments/1706/AgendaItem4.3RASSCE-WG-FINALresponsetotheCSS.pdf*

and Inferring Risks" might have no direct and immediate implications for the IAEA safety standards. It was noted that the UNSCEAR report reinforces the appropriateness of, and sound scientific basis for, the IAEA safety standards.

After CSS discussion and deliberations, in November 2016, the CSS decided to establish a Working Group (WG) of CSS members 'to consider the implications of the UNSCEAR report "Attributing Health Effects to Ionizing Radiation Exposure and Inferring Risks" for the development of IAEA Safety Standards. This WG met in November 2017 and discussed the views on the implications of the report that were submitted in advance of the meeting and also discussed the Secretariat's independent assessment. At that meeting, there was broad agreement among participants that there was a need for the Safety Standards to adequately reflect the concepts of attributability, inference of risk and use of collective dose, to reflect the lessons learned from the latest international scientific evaluations, and to ensure that these concepts are adequately addressed. A two page summary of the WG's conclusions is attached as Annex 1 to this white paper. Other pertinent documents on this issue can be found at *http://www-ns.iaea.org/committees/csscomments/default.asp?fd=1706&dt*= .

POTENTIAL IMPLICATIONS FOR THE IAEA SAFETY STANDARDS

UNSCEAR has stated that radiation effects cannot be attributed *retrospectively* to radiation exposure situations delivering low radiation doses usually at low dose rates. In particular, UNSCEAR estimated that increases in the incidence of health effects in populations cannot be explicitly attributed to chronic exposure to radiation at levels that are typical of the global average background levels of radiation, namely of the order of few mSv per year. UNSCEAR does recognize however that radiation risk can be inferred for *prospective* radiation exposure situations. Because at those low doses such effects are not explicitly attributable, any *prospective* inference of risk should be subjective, i.e., a 'degree of belief' among experts).

The current IAEA Safety Standards use the ICRP recommendations as a basis for its requirements on inference of radiation risk. The ICRP inference of risk is quantified as a detriment-adjusted nominal risk coefficient for stochastic effects after exposure to radiation at low dose rate.

The detriment-adjusted nominal risk coefficients do not introduce any weighting or difference between the probabilities of effects that are attributable to radiation exposure and those which are subjectively postulated but are not objectively attributable. They implicitly presume that these effects can still be prospectively inferable by using epidemiological information from exposure situations at high dose and relatively high dose-rate and quantitative uncertainty analysis.

As a consequence, the current Safety Standards give equal weighting to radiation effects that are attributable and to effects that are not explicitly attributable, but which under some assumptions their prospective occurrence might be inferable. The consequences of this current approach can be significant. For instance, the justification of an emergency intervention in situations involving low radiation doses, such as evacuation or relocation or even resettlement, which may involve harm to those affected, is judged against a theoretical radiation detriment that is not attributable.

REVIEWING THE SAFETY FUNDAMENTALS

IAEA's Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements of the IAEA Safety Standards. Ten fundamental principles are recognized: responsibility for safety; role of government; leadership and management for safety; justification of facilities and activities; optimization of protection; limitation of risks to individuals; protection of present and future generations; prevention of accidents; emergency preparedness and response; and, protective actions to reduce existing or unregulated radiation risks.

Except for the principles for responsibility for safety, role of government, leadership and management for safety, all the others Safety Fundamentals may be affected by considerations of objective attribution of effects versus subjective inference of risks. Each of these are highlighted below:

Principle 4: Justification of facilities and activities

This principle states that ***facilities and activities that give rise to radiation risks must yield an overall benefit***. This wording differs slightly but significantly from the ICRP recommended wording for its justification principle, namely any decision that alters the radiation exposure situation should do more good than harm. While the ICRP formulation includes decisions that are aimed at reducing the radiation dose (e.g., intervention in emergencies), the Fundamentals' formulation seems to be limited to increases in radiation exposure only.

This principle's implementation might benefit from some clarification on whether prospective estimates of radiation exposure that might lead to inferable but not explicitly attributable effects should have the same weighting as those leading to inferable and attributable effects.

Topics for discussion and possible action:

- The IAEA might wish to consider revising this requirement in order to include the justification of activities aimed at reducing radiation risk.
- A paragraph might be added suggesting to give a different weighting to radiation risks created by exposure situations involving doses for which radiation effects are attributable than to those involving lower doses.

Principle 5: Optimization of protection

This principle states that ***safety measures are considered optimized if they provide the highest level of safety that can reasonably be achieved.*** Again, this formulation differs slightly but significantly from the ICRP recommended wording for its optimization principle, which is described with the meaning that the level of protection should be the best under the prevailing circumstances, maximizing the margin of benefit over harm, and specifically defined as the process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable, economic and societal factors being taken into account.

This principle's implementation might benefit from clarification on whether prospective estimates of radiation exposure that might lead to inferable but not explicitly attributable effects should have the same weighting than those leading to inferable and attributable effects.

Topics for discussion and possible action:

- The IAEA might wish to consider revising this requirement in order to make it coherent and consistent with the ICRP recommendations and with the BSS wording.
- A paragraph might also be added suggesting to give a different weighting to radiation risks created by exposure situations involving doses for which radiation effects are attributable than to those involving lower doses.

Principle 6: Limitation of risks to individuals

This principle states that ***measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm***. This formulation is different and perhaps clearer than the ICRP formulation which states the total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the Commission.

Topics for discussion and possible action:

- This principle appears to be wider and more grounded than the ICRP equivalent. At this time no action is recommended for revising this principle. The Fundamentals clearly indicate that justification and optimization do not in themselves guarantee that no individual bears an unacceptable risk of harm. Consequently, doses and radiation risks must be controlled within specified limits (e.g., restrictions).

Principle 7: Protection of present and future generations

This principle of protection states that **people and the environment, present and future, must be protected against radiation risks.** There is no equivalent principle in the ICRP recommendations; it may be that ICRP considers this principle as embedded into the previous ones.

(1) The main issues addressed by this principle are that: (i) safety standards apply not only to local populations but also to populations remote from facilities and activities; and (ii) where effects could span generations, subsequent generations have to be adequately protected without any need for them to take significant protective actions.

Topics for discussion and possible action:

- The IAEA might consider adding an additional footnote(s) to this principle indicating that the doses to be incurred by populations located far away from the origin of the exposure, either in distance or in time, are expected to be low, namely in the range of doses for which radiation effects are not explicitly attributable. It perhaps can also be suggested that a different (lower) weighting should be given to these exposures.

Principle 8: Prevention of accidents

This principle states that ***all practical efforts must be made to prevent and mitigate nuclear or radiation accidents.*** The principle is summarized into three main actions, namely: to prevent the occurrence of failures or abnormal conditions (including breaches of security) that could lead to such a loss of control; to prevent the escalation of any such failures or abnormal conditions that

do occur; and to prevent the loss of, or the loss of control over, a radioactive source or other source of radiation.

The principle notes that the primary means of preventing and mitigating the consequences of accidents is defense in depth. The objectives of defense in depth are: (a) to compensate for potential human and component failures; (b) to maintain the effectiveness of the barriers by averting damage to the facility and to the barriers themselves; and (c) to protect workers, members of the public and the environment from harm in accident conditions in the event that these barriers are not fully effective.

Whether the prevention of accident be achieved through the 'defense in deep' principle or by considering restrictions to 'potential exposures' it is not clear that the same efforts should be employed for preventing doses leading to attributable effects than for low doses.

Topics for discussion and possible action:

- The IAEA might wish to consider to provide some explanatory material to help implementing this principle taking into account the difference between doses for which the effects are *attributable* and those for which they are only *inferable.*

Principle 9: Emergency preparedness and response

This principle states that ***arrangements must be made for emergency preparedness and response for nuclear or radiation incidents***.

The ICRP recommendations refer to emergency exposure situations that are defined as unexpected situations such as those that may occur during the operation of a planned situation, or from a malicious act, requiring urgent attention and which include consideration of emergency preparedness and emergency response. Emergency preparedness should include planning for the implementation of optimised protection strategies which have the purpose of reducing exposures, should the emergency occur, to below the selected value of a '*reference level"* that represents the level of dose or risk, above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimisation of protection should be implemented. [*Note*: the chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration.] During emergency response, the reference level would act as a benchmark for evaluating the effectiveness of protective actions and as one input into the need for taking further actions.

The relevant BSS requirements for preparedness and response for emergencies states that the government shall ensure that protection strategies are developed, justified and optimized at the planning stage, and that emergency response is implemented in a timely fashion. In line with the ICRP recommendations, it requires that the development of a protection strategy that shall include setting a reference level expressed in terms of residual dose, typically an effective dose in the range of 20–100 mSv that includes dose contributions via all exposure pathways.

Topics for discussion and possible action:

- Any revision of the principle on emergency planning and response (EPR) would be a large undertaking and require the valuable input from EPR experts. It is in emergencies where a mixture of exposure situations occurs involving doses for which effects are clearly attributable to the situation and doses for which effects are

not explicitly attributable. One possible course of action would be to request the advice of an ad hoc group of experts to address this issue for this principle.

Principle 10: Protective actions to reduce existing or unregulated radiation risks

This principle states that ***protective actions to reduce existing or unregulated radiation risks must be justified and optimized.***

This principle is understood to be linked to existing exposure situations which are those that already exist when a decision on control has to be taken, such as those caused by natural background radiation.

Topics for discussion and possible action:

- The IAEA might consider adding an additional footnote(s) to this principle indicating that the doses to be incurred by populations located far away from the origin of the exposure, either in distance or in time, are expected to be low, namely in the range of doses for which radiation effects are not explicitly attributable. It perhaps can also be suggested that a different (lower) weighting should be given to these exposures.

SUMMARY

Once the CM completes its work on the review of the IAEA Safety Fundamentals with regard to the estimates on attribution of radiation effects and the recommendations on inference of radiation risks, the IAEA may wish to review and eventually revise the relevant Safety Requirements and Guides.

Topics for discussion at the CM:

- Should the CM recommend RASSC review and review by the other Standards Committees?

- What priority (how important) is it to make these changes? The CM should articulate this clearly. Can they be incorporated as the standards are periodically reviewed and updated? Or should some be involved in a preferential (higher priority) way?