REPORT
from the findings from the review of the Safety Standards in
Emergency Preparedness and Response against the UNSCEAR 2012 Report on
Attributing Health Effects to Ionizing Radiation Exposure and Inferring Risks

Introduction

Based on the recommendation from the CSS Working Group on Scientific Annex A of the UNSCEAR 2012 Report: Attributing Health Effects to Ionizing Radiation Exposure and Inferring Risks\(^1\), at its 42nd meeting held 1-3 November 2017, the CSS requested the Safety Standard Committees (SSCs) to determine which safety standards, currently under development and already published, could be strengthened in respect to addressing the following:

- Retrospective attribution\(^2\) of radiation health effects to radiation exposures;
- Prospective inference of health risks from radiation exposures; and
- Prediction of notional health effects for comparative purposes (e.g. use of collective dose);

and for the SSCs Chairs to report on progress to the CSS meetings in 2018.

In response to this request, EPreSC members, supported by the Secretariat, reviewed the safety standards in nuclear or radiological emergency preparedness and response (EPR Safety Standards), both published and under development, against the conclusions of the UNSCEAR 2012 report summarized in Appendix 1.

Approach adopted for the review

The EPR Safety Standards that were subjected to the review are briefly described in Appendix 2. Considering that aspects of interest for the review against the UNSCEAR 2012 Report appear as cross-cutting areas in the several EPR Safety Standards, the review was organized around the following three main areas:

- Protection strategy for a nuclear or radiological emergency;
- Emergency arrangements at the preparedness stage; and
- Communicating radiation risks and radiological health hazards in perspective in EPR;

and looked into the specifics of how conclusions of UNSCEAR 2012 Report were considered to provide for effective emergency preparedness and response commensurate with the associated health risks.

The first area deals primarily with the emergency response criteria that provide basis for taking effective protective actions and other response actions in a nuclear or radiological emergency as well as with the approach to ensuring justified and optimized protection at doses that are lower than the internationally agreed criteria. This area concerns primarily the following EPR Safety Standards: GSR Part 7, GSG-2 and GSG-11.

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\(^2\) In this context, attribution refers to the ascribing of an outcome — in particular a health effect — to radiation exposure: an outcome may be an individual outcome (such as the occurrence of a health effect in an individual) or a collective outcome (such as a change in the frequency of occurrence of health effects in a population or a group).
The second area deals primarily with the emergency arrangements that are warranted in the EPR Safety Standards to be made at the preparedness stage to avoid or minimize radiation induced health effects in a nuclear or radiological emergency. This area concerns primarily the following EPR Safety Standards: GSR Part 7, GS-G-2.1 (DS504) and TS-G-1.2 (DS469).

The third area concerns the way radiological health hazards and radiation risks are put in perspective in a nuclear or radiological emergency to support the effective implementation of the protection strategy as well as to mitigate the non-radiological consequences of either the emergency itself or emergency response actions taken. This area concerns primarily the following EPR Safety Standards: GSR Part 7, GSG-2 and DS475.

These three areas are embedded in the requirements and guidance provided in all EPR Safety Standards irrespective of their format and have implications on the way the requirements and the guidance are formulated. Hence, no specific review, for example against each overarching requirement in GSR Part 7, was considered as needed.

Summary of findings

**Protection strategy for a nuclear or radiological emergency**

The safety requirements in EPR (GSR Part 7 and Section 4 of GSR Part 3) call for the governments to develop, justify and optimize protection strategy for a nuclear or radiological emergency for taking protective actions and other response actions effectively in a nuclear or radiological emergency so that the emergency response goals can be achieved. As part of the protection strategy, generic criteria need to be developed (in terms of projected doses and doses that are received) so that once they are exceeded protective actions and other response actions, either individually or in combination, are taken. The establishment of such internationally agreed generic criteria within the IAEA safety standards was initially accomplished with the publishing of GSG-2 (at a safety guide level) and then brought at a safety requirements level with incorporating the criteria in GSR Part 3 and GSR Part 7. The most comprehensive set of the generic criteria is included in Appendix II of GSR Part 7.

The internationally agreed generic criteria for taking protective actions and other response actions reflect adequately the conclusions of UNSCEAR 2012 Report. Namely, the criteria are grouped in two sets: the first set of generic criteria is associated with doses received within a short period of time (acute exposures) for which protective actions and other response actions are expected to be undertaken under any circumstances to avoid or minimize severe deterministic effects and the second set of generic criteria is associated with doses at which protective actions and other response actions need to be taken to reduce the risk of stochastic effects.

The generic criteria that aim to avoid or minimize severe deterministic effects are associated with doses that, based on the UNSCEAR 2012 Report, can result in deterministic health effects in an individual that could be unequivocally attributed to radiation exposure. Hence, these criteria provide a basis for taking precautionary protective actions and other response actions within the protection strategy before or shortly after the release or exposures occur, primarily based on observables or plant conditions. Taking effectively such precautionary protective actions will ensure that no deterministic effects that could be attributed to radiation exposure are to be observed in any individual. Should doses at this level be assessed to have been received, then they provide basis for identifying the need for medical examination and screening followed, as required, by medical treatment.

The generic criteria that aim to reduce the risk of stochastic effects are associated with doses that, based on the UNSCEAR 2012 Report, can result in an increased incidence of stochastic effects in a population that could be attributed to radiation exposure through epidemiological analysis although
radiation induced cancers cannot be unequivocally attributed to radiation exposure on an individual basis. Hence, these criteria provide a basis for taking urgent and early protective actions and other response actions within the protection strategy either based on observables or plant conditions or based on monitoring results. Taking effectively such urgent and early protective actions will ensure that no increase in the incidence of cancers that could be attributed to radiation exposure will be observed in a population. Should doses at this level be assessed to have been received, then they provide basis for identifying the need for subjecting individuals for health screening and for longer-term medical follow-up to detect early and, hence, treat effectively specific radiation induced cancers.

GSR Part 7 and GSG-11 address also protection to be provided at doses lower than the above-discussed internationally agreed generic criteria (i.e. at low doses and low dose rates at which the UNSCEAR Report clearly indicates that increases in the incidence of health effects in populations cannot be attributed reliably to radiation exposure). Namely, in this context GSR Part 7 and GSG-11 emphasize the need for thorough justification and optimization to ensure that (1) the actions taken do more good than harm, social and economic factors being considered and (2) the protection is the best under the prevailing circumstances which is not necessarily the option with the lowest dose. In such circumstances (particularly expected later in the response to emergency), GSG-11 emphasizes the inappropriateness to consider disruptive public protective actions such as evacuation or relocation as implementation of remedial actions, for example, might be more efficient. Complying with this approach within the protection strategy will ensure that the best protection is provided to those in need while still it is ensured that no harm is caused that can outweigh the benefit from the protection options implemented. Should doses at this level be assessed to have been received, there will be no need for subjecting individuals to any medical follow-up in relation to early detection and effective treatment of radiation induced cancers.

In the current framework reflected in the EPR safety standards, the concept of collective dose is not used as a basis for decision-making on public protective actions in a nuclear or radiological emergency.

GSR Part 7 further requires that the pre-set protection strategy is implemented safely and effectively in an emergency response through implementation of pre-established emergency arrangements for taking effectively the necessary protective actions and other response actions as described above as well as those actions that (1) aim to mitigate non-radiological consequences and (2) ensure effectiveness of taken protective actions is reassessed as information becomes available so that the protection strategy could be revised and unjustified actions discontinued.

The above-discussion focuses on the protection of the public. The Safety Standards in EPR (GSR Part 7, Section 4 of GSR Part 3, GSG-2 and GSG-11 primarily) apply similar approach in ensuring adequate protection of emergency workers that considers the doses that might be incurred by emergency workers in the emergency response and associated health risks. Namely, based on these standards emergency workers are to be subject to the stringent requirements for occupational exposure in planned exposure situation stipulated in Section 3, GSR Part 3 unless they have been tasked with undertaking specific actions aimed at (1) saving human life or preventing serious injury, (2) preventing severe deterministic effects or the development of catastrophic conditions that could significantly affect people and the environment, and (3) averting a large collective dose. For these exceptional circumstances, among other provisions, emergency workers are to be subjected to guidance values to indicate the need to restrict their further exposure during the emergency response. In this context, the first two set of actions allow for emergency workers to receive doses higher than those at which an incidence of radiation induced cancers could be attributed to radiation exposure through epidemiological analysis but below those at which severe deterministic effects could be unequivocally attributed to radiation exposure. Exceeding doses at which severe deterministic effects could be unequivocally attributed to radiation exposure could be possible for emergency workers only if the benefits to others clearly outweigh the health risks of the emergency
working undertaking the action and that the emergency worker volunteers to take the action while understanding and accepting the associated health risks.

However, for actions aimed at averting a large collective dose, emergency workers may incur doses that approach those at which an incidence of radiation induced cancers could be attributed to radiation exposure through epidemiological analysis. The actions associated with these tasks do not apply the concept of large collective dose per se but they are associated with those actions that aim to reduce the risk of stochastic effects among affected population by keeping the doses below the above-discussed generic criteria that are associated with doses that, based on the UNSCEAR 2012 Report, can result in an increased incidence of stochastic effects in a population that could be attributed to radiation exposure through epidemiological analysis (although radiation induced cancers cannot be unequivocally attributed to radiation exposure on an individual basis).

**Emergency arrangements at the preparedness stage**

GSR Part 7 stipulates that the goal of emergency preparedness is “to ensure that an adequate capability is in place within the operating organization and at local, regional and national levels and, where appropriate, at the international level, for an effective response in a nuclear or radiological emergency.” Such capability relates to various arrangements (including plans, procedures, tools, training, exercises, etc.) needed to be made at the preparedness stage. The above-mentioned arrangements for ensuring effective implementation of the protection strategy are part of these arrangements and include, *inter alia*, specification of emergency planning zones and distances for facilities in emergency preparedness categories I and II. The arrangements set up at preparedness stage for the areas covered with the emergency planning zones and distances aim to ensure effective implementation of precautionary, urgent and early protective actions and other response actions even when very limited information is available. The four emergency planning zones and distances defined in GSR Part 7 are:

- A precautionary action zone (PAZ) for the area in which the focus should be on taking precautionary protective actions to avoid or minimize severe deterministic effects and associated arrangements;
- An urgent protective action planning zone (UPZ) for the area in which the focus should be on taking urgent protective actions to reduce the risk of stochastic effects and associated arrangements;
- An extended planning distance (EPD) for the area in which the focus should be on taking early protective actions to reduce the risk of stochastic effects and associated arrangements which include those for conducting timely monitoring and assessment;
- An ingestion and commodities planning distance (ICPD) for the area in which the focus should be on taking actions for ensuring food and commodities safety and associated arrangements.

The level of required preparedness for these areas is determined based on the doses that are expected to be incurred by the affected population in absence of any protective action and the urgency associated with implementation of effective public protective actions to ensure no radiation induced health effects occur. In this regard, account was taken of the generic criteria discussed above and the findings of the UNSCEAR 2012 Report so that the level of pre-planned arrangements is detailed for the PAZ and UPZ in comparison to the EPD and ICPD, with a priority of the response given to PAZ over UPZ. This is reflected in GSR Part 7 and in associated guidance such as GS-G-2.1 as well as in other technical tools. In this way, the generic criteria discussed above and the findings of UNSCEAR 2012 Report allow implementation of staggered emergency response focusing firstly on those in danger of sustaining deterministic effects and then on those in danger of an increased risk for radiation induced cancers with planning that is more specific and detailed (as reflected in plans,
procedures, exercises etc.) in the same line of priorities. More deliberate assessments and informed decisions are then foreseen to lead to justified and optimized actions for the rest of affected population, if needed at all, and arrangements that are more flexible are expected to accomplish this.

Similar approach is adopted for radiological emergencies with the establishment of inner cordon off area as required in GSR Part 7 which allows giving priority to actions for those that may be exposed to doses at which radiation induced health effects that could be attributed to radiation exposure either as an individual outcome or as a collective outcome could be observed.

In addition, to support the development of effective emergency arrangements at the preparedness stage, GSR Part 7 calls for performing a hazard assessment to provide a basis for a graded approach to emergency preparedness. The hazard assessment allows for identification of hazards and potential consequences of an emergency associated with various facilities, activities and sources (including associated health effects due to exposure to radiation) so that the emergency arrangements that need to be made at preparedness stage are commensurate with these hazards. Thus, the generic hazard assessment provided in GSR Part 7 and associated guidance (GS-G-2.1 primarily) resulting in grouping various facilities and activities in different emergency preparedness categories and assigning different requirements to be applied for them, weights similarly the radiation induced health effects that can be attributed to radiation exposure and the radiation risks that can be inferred to give different weight to arrangements to be made for different categories. In ensuring a graded approach for initiating adequate level of emergency response, GSR Part 7 and associated safety guides (GS-G-2.1 and GSG-2 primarily) also call for establishing of emergency classification system. The level of response warranted for each emergency class that would call for example for activating an emergency response within the above-discussed emergency planning zones and distances uses a graded approach that sets priorities similarly as discussed above. This approach ensures that activities carried out at preparedness stage at different levels and the actions taken in response through different arrangements are prioritized in the same way as discussed above (greatest attention and urgency be given firstly on those in danger of sustaining deterministic effects and then on those in danger of an increased risk for radiation induced cancers before others are considered).

**Communicating radiation risks and radiological health hazards in perspective in EPR**

GSR Part 7 requires that governments develop at the preparedness stage and implement during the response a system for putting radiological health hazards in perspective to support informed decision-making regarding justified protective actions and addressing effectively the primary public concerns regarding potentially harmful health effects. DS475, the Safety Guide addressing public communication in EPR that is under development, aims to provide guidance and recommendations to Member States how to implement this requirement at national level. In developing such guidance and recommendations, a dedicated consultancy meeting was held in 2018 to discuss possible implications from the UNSCEAR 2012 Report as well as to ensure its conclusions are reflected adequately when providing, in an emergency, simple, easily understandable and scientifically correct messages on potential harmful health effects.

The guidance and recommendations provided in DS475 on the development of the system for putting radiological health hazards in perspective consider the recommendations of the UNSCEAR 2012 report in terms of how attributability of health effects, inference of risks and prediction of notional health effects for comparative purposes can and cannot be used particularly in public communication strategies. It elaborates an example system comprising of three (color-coded) levels that can be used to translate technical data obtained, for example, from monitoring or assessment into simple language in relation to potential harmful health effects. In addition, it allows associating each level with the health effects that can or cannot be attributed to radiation exposure, in line with
the UNSCEAR 2012 Report, the need for implementing protective actions and other response actions based on the above-discussed generic criteria and the need for any medical action.

Finally, DS475 discusses how risk calculations performed for each level of the example system can or cannot be used in public communication. The aim of this guidance is to ensure that clear message is given regarding the incorrectness of making inferences of expectations of numbers of health effects in an affected population from any theoretical risk calculations at low doses and low dose rates and using them in public communication. Use of such theoretical calculations of potential numbers of health effects in public communication during or following past emergencies resulted in inappropriate projections being made of potential numbers of deaths among large numbers of people exposed to radiation at relatively low levels. This gave rise to widespread anxiety and other deleterious non-radiological consequences and the impression that the impact of the emergency was far more severe than what the actual impact was. DS475 aims to prevent this from happening again.

Conclusions

Based on the findings of the review, the following conclusions can be drawn:

- Most of the EPR Safety Standards, published or under development, such as GSR Part 7, GSG-2, GSG-11 and DS475 already adequately consider and reflect the conclusions of UNSCEAR 2012 Report. At present, the review did not reveal any need for them to be strengthened in future to better address the implications from the UNSCEAR 2012 report. However, although GSG-2 does not call for immediate revision based on the findings of this Report, it will be worth that its next revision considers extending its scope to deal with the aspects related to protection strategy and its justification and optimization in more details while addressing explicitly how findings of UNSCEAR 2012 Report were considered as discussed in this Report. In addition, current GSG-2 may be improved by providing further clarity on how guidance values for restricting further exposures of emergency workers in the response and associated actions relate to the findings of the UNSCEAR 2012 Report and the international generic criteria.

- The revision of GS-G-2.1 (DS504) provides opportunity to strengthen the guidance and recommendations therein for consistency with the latest EPR Safety Standards (GSR Part 7, GSG-2, GSG-11, DS475) taking into account the UNSCEAR 2012 Report when providing specific guidance on effective emergency preparedness and response that is commensurate with the associated health risks. This should be accomplished during the on-going revision of GS-G-2.1 in line with approved DPP.

- The revision of TS-G-1.2 (DS469) addresses an area that is more of a generic nature making use of the concepts already provided in the most up to date EPR Safety Standards (GSR Part 7, GSG-2, GSG-11, DS475) with focus on practical arrangements as applicable for transport emergency. Thus, no implications are foreseen from UNSCEAR 2012 report warranting further consideration.
Appendix 1
Summary of the conclusions of the UNSCEAR 2012 Report on Attributing Health Effects to Ionizing Radiation Exposure and Inferring Risks

The following is a summary of the conclusions of the UNSCEAR 2012 Report that were considered in the review:

- In case of high doses and high dose rates, deterministic effects in an individual could be unequivocally attributed\(^3\) to radiation exposure if possible alternative causes could be eliminated;
- Stochastic effects in an individual 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;
- An increased incidence of stochastic effects in a population could be attributed to radiation exposure through epidemiological analysis — provided that the increased incidence was sufficient to overcome inherent statistical uncertainties;
- An increase in the incidence of hereditary effects in human populations cannot at present be attributed to radiation exposure (although demonstrated in animal studies);
- Increases in 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 radiation induced health effects and the insufficient statistical power of epidemiological studies.

The UNSCEAR Report also:

- “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”.
- “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 was 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”.
Appendix 2
A Brief Overview of Safety Standards in Nuclear or Radiological Emergency Preparedness and Response

The following EPR Safety Standards were subjected to the review:


  A General Safety Requirements publication that was issued in 2015. It establishes the requirements for an adequate level of preparedness and response for a nuclear or radiological emergency. This publication addresses Principle 9 of the Safety Fundamentals publication No. SF-1 issued in 2006.


  A General Safety Requirements publication that was issued in 2014. It addresses limited aspects of emergency preparedness and response in its Section 4 and Schedule IV that are also covered in GSR Part 7. Due to the limitation of the requirements contained in this publication and their coverage in GSR Part 7, no specific judgements were considered necessary in the review regarding this publication.


  A General Safety Guide that was issued in 2007 and is currently under revision (DS504). It provides detailed guidance and recommendations to support the implementation of selected safety requirements contained in the earlier edition of GSR Part 7, i.e. GS-R-2 issued in 2002. Its revision aims at (1) ensuring consistency in terminology and concepts with GSR Part 7, (2) removing outdated guidance or guidance which has been addressed in more recent EPR related safety standards, either in place or under development as well as other recently published Safety Standards and Nuclear Security publications, (3) ensuring appropriate cross-references are given to various EPR related safety standards, (4) providing more detailed guidance on a number of requirements in GSR Part 7, such as those for infrastructure, which are essential for an effective emergency response capability, and (5) addressing all the five emergency preparedness categories with common guidance. Its completion is expected in 2022.
- **FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, INTERPOL, OECD NUCLEAR ENERGY AGENCY, UNITED NATIONS OFFICE FOR THE COORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, WORLD METEOROLOGICAL ORGANIZATION, ARRANGEMENTS FOR THE TERMINATION OF A NUCLEAR OR RADIOLOGICAL EMERGENCY, IAEA SAFETY STANDARDS SERIES NO. GSG-2, IAEA, VIENNA (2011):**

  A General Safety Guide publication that was issued in 2011 and provided basis for the criteria for taking emergency response actions provided in GSR Part 3 and GSR Part 7. It presents a coherent set of generic criteria that form a basis for developing operational criteria needed for decision-making concerning emergency response actions as well as default operational criteria for use in emergency preparedness and response alongside with plain language explanations that address the risk to human health of radiation exposure.

- **FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, INTERPOL, OECD NUCLEAR ENERGY AGENCY, UNITED NATIONS OFFICE FOR THE COORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, WORLD METEOROLOGICAL ORGANIZATION, ARRANGEMENTS FOR THE TERMINATION OF A NUCLEAR OR RADIOLOGICAL EMERGENCY, IAEA SAFETY STANDARDS SERIES NO. GSG-11, IAEA, VIENNA (2018):**

  A General Safety Guide that was issued in 2018. It provides guidance and recommendations on emergency arrangements to be made for enabling the transition from an emergency exposure situation to either a planned exposure situation or an existing exposure situation and the subsequent termination of the emergency. It supports the implementation of relevant requirements in GSR Part 3 and GSR Part 7 including in relation to development and implementation of effective protection strategy during the transition phase of the emergency.

- **INTERNATIONAL ATOMIC ENERGY AGENCY, ARRANGEMENTS FOR COMMUNICATION WITH THE PUBLIC IN PREPAREDNESS AND RESPONSE FOR A NUCLEAR OR RADIOLOGICAL EMERGENCY, IAEA SAFETY STANDARDS SERIES NO. GSG-XX, IAEA, VIENNA (UNDER DEVELOPMENT, ID NUMBER: DS475):**

  A General Safety Guide under development. It provides guidance and recommendations on arrangements for public communication in preparedness for and response to a nuclear or radiological emergency to support implementation of relevant safety requirements contained in GSR Part 7 and GSR Part 3. As part of this publication, guidance and recommendations are provided on how to develop and implement a system that puts radiological health hazards in perspective in a nuclear or radiological emergency and an example system to do so is proposed. Its completion is expected in 2019.

- **INTERNATIONAL ATOMIC ENERGY AGENCY, PREPAREDNESS AND RESPONSE FOR AN EMERGENCY DURING THE TRANSPORT OF RADIOACTIVE MATERIAL, IAEA SAFETY STANDARDS SERIES NO. SSG-XX, IAEA, VIENNA (UNDER DEVELOPMENT, ID NUMBER: DS469, REVISION OF TS-G-1.2):**

  A Specific Safety Guide under development. It provides guidance and recommendations on preparedness and response for a nuclear or radiological emergency during the transport of radioactive material in support of the implementation of safety requirements of GSR Part 7 as applicable for this type of emergency and of relevant provisions of SSR-6.