



SOCIEDAD ESPAÑOLA DE PROTECCION RADIOLOGICA

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Spanish Society for Radiological Protection (SEPR) comments to the draft **Radiological Protection of People and the Environment in the Event of a Large Nuclear Accident**

SEPR members have been invited to comment on the draft through the member's forum. This note is summarizing the main points raised in the comments received.

The overall impression about the document is very positive. It is recognized the effort to address the complexity of nuclear accidents beyond radiation issues and the emphasis placed on stakeholder involvement along the different phases of the accident.

There are some detailed suggestions:

- Line 40) Perhaps psychological impact should be included within the cited "all impacts".
- Line 95) Suggestion to include "health" in this list of effects to consider for justification.
- Line 99) Suggestion to add "health" to economic, societal and environmental factors to consider for optimisation.
- Line 139) mention to "infrastructural" factors should be more explicit in mentioning hospitals and nursing homes for elderly.
- Line 187) "resumption of agricultural activities" should include a wider concept, like "resumption of agricultural and economic activities in general".
- In section 2.2.1 on radiation-induced health effects no mention is made to children, while they should deserve a special consideration.
It is also observed that no mention is made to the Acute Radiation Syndrome (ARS) when dealing with severe tissue/organ damage.
Although Table 2.1 is quite detailed, perhaps it could be replaced by a more complete reference in which to find the threshold dose values for tissue/organ damage.
- (§41) "In the longer term, other secondary health issues were observed in populations affected by the Chernobyl accident (Luccioni *et al.*, 2016)". Comment: while for Fukushima these secondary health effects are described in the text, this is not the case for Chernobyl. Perhaps some indication could be useful here.



- (§94) When discussing about dietary habits, it should also be mentioned that recommendations to the population should consider the full nutritional balance of the food basket, and not only look to the relative potential contamination of different foods.
- (§101) Some references could be useful in this paragraph. The following guidance from the U.S. FDA for instance: U.S. Food and Drug Administration. 2016. Radiation Biodosimetry Medical Countermeasure Devices. Guidance for Industry and Food and Drug Administration Staff (available at: <https://www.fda.gov/media/90385/download>).
- Line 1066 – the cited reference (Hayano, 2014) does not deal with diet adjustments. Better to place the reference earlier in the paragraph: “Measurements of internal contamination in children, including babies (Hayano, 2014)...”,
- With regard to subchapter 3.3 “Protection of emergency responders”, the Commission recommends a reference level less or equal to 100 mSv (incurred either acutely or in a year) to ensure adequate protection. However, it is pointed out (§119) that exposure under exceptional circumstances may reach values of some "hundreds" of mSv, and for these exceptional circumstances there is no recommendations regarding reference levels. It is suggested to develop some recommendation about the setting of reference values for situations in which relatively high doses can be received in a single action needed for life-saving or to avoid severe worsening of plant conditions.
- It is suggested to go deeper into aspects related to medical countermeasures, which may be necessary for emergency responders or for the population individuals more severely exposed. While, for instance, the U.S. FDA has a website dedicated to these kind of countermeasures (<https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/radiological-and-nuclear-emergency-preparedness-information-fda#mcms>), they are addressed neither in the main text nor in the Annexes.

Some recent interesting references are also, for instance:

- Vijay K. Singh & Thomas M. Seed (2017) A review of radiation countermeasures focusing on injury-specific medicinals and regulatory approval status: part I. Radiation sub-syndromes, animal models and FDA-approved countermeasures, International Journal of Radiation Biology, 93:9, 851-869, DOI: 10.1080/09553002.2017.1332438
- Vijay K. Singh, Melissa Garcia & Thomas M. Seed (2017) A review of radiation countermeasures focusing on injury-specific medicinals and regulatory approval status: part II. Countermeasures for limited indications, internalized radionuclides, emesis, late effects, and agents demonstrating efficacy in large animals with or without FDA IND status, International Journal of Radiation Biology, 93:9, 870-884, DOI: 10.1080/09553002.2017.1338782
- Vijay K. Singh, Briana K. Hanlon, Paola T. Santiago & Thomas M. Seed (2017) A review of radiation countermeasures focusing on injury-specific medicinals and regulatory approval status: part III. Countermeasures under early stages of development along with ‘standard of care’ medicinal and procedures not requiring regulatory approval for



use, International Journal of Radiation Biology, 93:9, 885-906, DOI: 10.1080/09553002.2017.1332440

- Andrea L. DiCarlo, David R. Cassatt, William E. Dowling, John L. Esker, Judith A. Hewitt, et. al. (2018). Challenges and Benefits of Repurposing Products for Use during a Radiation Public Health Emergency: Lessons Learned from Biological Threats and other Disease Treatments Radiation Research, 190(6): 659-676. <https://doi.org/10.1667/RR15137.1>
- Vijay K. Singh, Patricia L.P. Romaine, Victoria L. Newman and Thomas M. Seed (2016). Medical countermeasures for unwanted CBRN exposures: part II radiological and nuclear threats with review of recent countermeasure patents. Expert Opinion On Therapeutic Patents, 26:12, 1399–1408. <http://dx.doi.org/10.1080/13543776.2016.1231805>

- 3.4.1.3. Iodine thyroid blocking. The use of stable iodine to protect emergency responders should be also recommended. Although it could be thought that is implicit in this paragraph, it should be clearly mentioned either here or in subsections 3.3.1 and 3.3.2.

- With regard to chapter 5. EMERGENCY AND RECOVERY PREPAREDNESS, while it is true, as recognized in paragraph (§221), that the details of the preparation do not correspond directly to the Commission, guidance is being given in the text that is important and of great interest.

The text considers the emergency phase and the recovery, but it does not expressly discuss about the importance of the preparation of the intermediate or transition phase. The transition period and its proper management has been shown to be essential for the recovery and for the management of the health and well-being of those affected. However, in this chapter about preparedness, it is not mentioned and the actions are not differentiated. The objectives in terms of radiation protection, as well as the territorial and temporal scope of the intermediate phase, are very important and should be duly considered in chapter 5 as in the previous chapters of the document. The dimensioning of resources and the necessary planning of actions should be properly analysed in the text with due consideration to the essential role of optimization and stakeholder involvement.

Also in this chapter, some additional considerations about public communication in the preparedness phase would be acknowledged. A useful reference in this regard are, for instance, the educational videos of the U.S Centers for Disease Control and Prevention (available at: <https://www.cdc.gov/nceh/radiation/emergencies/protectiveactions.htm>).

- Regarding medical management of people exposed in nuclear or radiological emergencies, the draft is quite limited. These are some suggested relevant references:
 - Rojas-Palma, C., Liland, A., Næss Jerstad, A., Etherington, G., Pérez, M.R., Rahola, T., Smith, K. (eds.). 2009. TMT Handbook. Triage, Monitoring and Treatment of people exposed to ionising radiation following a malevolent act.



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- U.S. Department of Health and Human Services. 2019. Radiation Emergency Medical Management. REMM. Website accessible at: <https://www.remm.nlm.gov/>.
- (§227) "... involving stakeholders in implementation of the optimisation process". Why not in **Justification** too?

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