

Topic 3. – Non-Cancer Effects Summary of discussions:

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What does science tell us? Epidemiology

- Epidemiology:
 - There is definite evidence that radiation induces circulatory disease, but the shape of the dose response relationship is subject to debate:
 - For low doses, there is a fair amount of uncertainty. A small threshold dose is suggested, but a linear extrapolation cannot be ruled out.
 - Based on current knowledge, experts from the group agree on a threshold about 0.5 Gy.
 - NB. *'It is unclear from available evidence whether or not the threshold is the same for acute, fractionated, and chronic exposures'*, ICRP 118.
 - Excess risk is in the same order of magnitude that cancer effects for exposure > 0.5 Gy i.e. ~5% per Gy.

What does science tell us? Radiobiology

- Radiobiology:
 - Mechanisms of circulatory disease after irradiation are not clear, but there are known mechanisms that might apply in different dose ranges.
 - Lots of research is currently carried out (Europe, Japan, etc.) so as to improve knowledge regarding these mechanism(s). These ‘may’ contribute to the interpretation of the ‘most appropriate’ dose response curve, especially for low doses.

Questions (from Ted) regarding the RP System

- How much additional risk is suggested by new studies?
- Implication for the additional detriment due to these effects?
- Is evidence sufficient to require precautionary approach?
- Importance of consistency in approach given precedent of cancer risk regulation?
- How should this risk be taken into account in overall risk management?
- At what level is risk sufficient to warrant changes in current protection paradigm for workers and for the general public?

Questions regarding the RP System - 1

- Difficulty to manage uncertainties based on new scientific evidences:
 - Researchers/Scientists need to develop more studies so as to provide more reliable answers (e.g. decrease uncertainties):
 - Improve understanding of mechanisms,
 - Improve epidemiology,
 - Choice of dose-response curve model is a key issue (logistic model, others?)
 - Need to reach agreement.
 - But:
 - What is today the position of a regulator or other stakeholders regarding the management of such uncertainties?
 - What about prudence and precaution?

Questions regarding the RP System - 2

- **IF** cardiovascular disease is considered as a deterministic effect with a threshold dose at 0.5 Gy:
 - **Is prevention** of such effect relying on a ‘limitation’ of whole body exposure to the current limit (20 mSv.y^{-1}) for workers (considering Whole Body Exposure and **25 years** of work) with emphasis on optimization to reduce annual exposure for such workers?
 - See for instance management of cataract exposure following the decrease of the associated threshold.
 - *‘We need to consider workers and the public’*
 - What about people who are chronically exposed in contaminated territories?

Questions regarding the RP System - 3

- If management of cardiovascular disease is based on a LNT dose response relationship:
 - Radiation detriment is a central element of our RP System and it refers to a **representative individual** with the aim to ‘**nominalise**’ the information.
 - Preliminary calculations outline a potential increase in radiation detriment as presented in Plenary Session 2 in the order of 20-50%.
 - Need to better address the way to take into account ‘deterministic effects’ in the definition of the detriment (*‘We have forgotten something!’*).
 - What is the link(s) between this increase and current ‘numeric values’ in the ICRP System?

Questions regarding the RP System - 4

- **IF** management of cardiovascular disease is based on a LNT dose response relationship (continue):
 - Issues of imputation are also implied e.g. a very delicate question:
 - *‘What are we going to say in 10 years to a Fukushima worker who develops cardiovascular disease’?*

Questions (compared to Cancer) regarding the RP System - 5

- ICRP 9 (1966): ‘The mechanism of the induction by radiation of leukaemia and other types of malignancy is not known. Such induction has so far been clearly established after doses of more than 100 rads [1 gray], but it is unknown whether a threshold dose exists below which no malignancy is produced. [...] As the existence of a threshold dose is unknown, it has been assumed that even the smallest doses involve a proportionately small risk of induction of malignancies. [...] The Commission is aware that the assumptions of no threshold and of complete additivity of all doses may be incorrect, but is satisfied that they are unlikely to lead to the underestimation of risks’.
- Where are we now with deterministic effects, compared to 1966 for cancer?

Synthesis - 1

- New epidemiological evidence suggests that chronic exposure at levels as low as 500 mSv can cause excess of risk of stroke and heart disease. A cautious attitude is needed in the interpretation of epidemiological studies because of confounding factors.
- Current biological understanding provides mechanisms that might apply in different dose ranges.
- There are many models used in the literature, but the most appropriate model which is likely the “logistic model” has not been used, although it has been used a lot for tissue injury after radiotherapy treatments

Synthesis - 2

- The group recognizes that:
 - According to current knowledge, it is relevant to ‘put the issue on the table’ and to address it in a transparent and clear way,
 - The RP system will not change tomorrow: **time** is needed for a shared reflection to clarify the issue,
 - The RP System is sufficiently robust so that major conceptual changes are not expected.

Synthesis - 3

- Recommendations:

1. *'In order to ensure our ethical values fully apply we have to clarify the issue of the detriment due to deterministic effects'*. This must be achieved in close cooperation with experts from the radiation protection community and from all fields.

'ICRP is recommended to have a Task Group on the detriment associated with deterministic effects. The time is approaching for having a review and a report on this issue'

2. Synthesis of available knowledge - in particular radiobiology inputs - is needed (more assistance from UNSCEAR would be helpful).
3. Need to maintain research efforts so as to provide more reliable answers (e.g. decrease uncertainties):
 - Improve understanding of mechanisms,
 - Improve epidemiology.

Synthesis - 4

- Additional point:
 - Efforts are still needed to find more ways to spread the message of ICRP recommendations in the context of the wider range of Safety issues in daily life.