Biological and Epidemiological Information on
Health Risks Attributable to Ionizing Radiation:
A Summary of Judgments for the Purposes
of Radiological Protection of Humans
Task Group Report of Committee 1

The U.S. Nuclear Regulatory Commission (NRC) would like to thank the International Commission on Radiological Protection (ICRP) for the opportunity to provide comments on the FD-C-1, Biological and Epidemiological Information on Health Risks Attributable to Ionizing Radiation: A Summary of Judgments for the Purposes of Radiological Protection of Humans. The opportunity to submit and review other stakeholder comments on Commission documents is greatly appreciated.

General Comments:

1. During its review of the draft 2005 Recommendations, the NRC observed that "the technical basis to support a recommendation to modify the tissue weighting factors and nominal risk coefficients is not adequately presented. Furthermore, it is unclear how the nominal risk coefficients proposed can be applied to the global community if they are based in part on early cancer diagnosis and treatment success." The ICRP was encouraged to clearly elaborate the underlying basis for selection of the tissue weighting factors, and explain how these factors could be applied to any global population in a clear and transparent manner. The NRC regrets that this has not been achieved.

2. The NRC staff continues to believe that additional time should be taken to allow a review of the BEIR VII report when it becomes available. The NRC staff recommends that the ICRP not attempt to complete a revision of this foundation document in the short time period before the ICRP meeting in Geneva, as implied by the "Summary of the 2005 Paris Meeting" provided on the ICRP web site, and instead recommends that ICRP take sufficient time to thoroughly consider and revise the report.

Specific comments:

1. NRC Comment #60, Page 66, Paragraph A11, submitted January 7, 2005.

   "The composite population used in Annex A is different from population used in ICRP 60 as is the methodology to determine the nominal risk coefficient. Additional information is needed to ascertain whether or not the tissue weighting factors and the nominal risk coefficients are applicable to the US population."

   It is not clear how a composite of three Japanese cities, one Chinese city and three Euro-American countries is representative of a global population. The committee should justify how the cancer rates for Shanghai (population 16 million) are representative of China with a population of 1.3 billion. Similarly, the committee should demonstrate how the cancer rates for three Japanese cities and one Chinese city are representative of India with a population of 1.1 billion. The committee should discuss the uncertainties associated with transferring the unweighted average cancer rate proposed by the committee to any country. The formulation of the detriment adjusted nominal probability

coefficients is not readily transparent. Hence, state regulators may be inclined to use country-specific cancer incidence/mortality information and not adopt the ICRP recommended coefficients or tissue weighting factors.

2. NRC Comment #62, Page 72, Tables A1 and A2, submitted January 7, 2005.

"The presentation of nominal risk and detriment is neither transparent nor clear. By deviating from the methodology described in Publication 60, a more exhaustive explanation of where numbers were obtained and how values are computed is required. For example, it is not clear how the data for nominal risk coefficient (cases per 10,000 Person Years per Sv) were derived. The data for lethality coefficients (column 3) should be referenced. The ICRP should explain how the lethality coefficients cited in this table are appropriate for third world countries with less sophisticated cancer diagnostic and treatment capabilities. Since the cancer nominal risk and hereditary detriments have decreased relative to the Publication 60 values, a complete explanation of the methodology used to develop these numbers is needed for all Commission stakeholders to review and hopefully adopt. Otherwise, each national authority will consider adopting methodologies and values that are representative for their country."

This foundation document does not provide additional information that clarifies this comment. On the contrary, additional questions are raised. The values cited in Table 4-1 differ from the corresponding table in Annex A of the draft 2005 Recommendations. Committee 1 acknowledges this with footnote a to Table 4-1. The changes result in different tissue weighting factors for breast, kidney, gonads, and remainder tissues. There was no change to the gonadal detriment, but the tissue weighting factor increased from 0.05 to 0.08. Justification for these changes appears warranted. ICRP did not present a technical basis for setting q_{min} to 0.1. The Commission should provide sufficient technical basis so that its' recommended risk and detriment coefficients that are traceable, understandable, reproducible and have generic applicability."

In the draft 2005 Recommendations q_{min} was set equal to 0.1 with the understanding that the result was not sensitive to the value chosen. Yet, in the foundation document new values were selected for skin and thyroid. Given the increase in melanoma, a value of zero for skin does not seem appropriate. No justification for the selection of a q_{min} value of 0.2 for thyroid is provided.

4. The development of radiation protection recommendations excluded much peer-reviewed/published data because the knowledge of the biological effects being examined is "currently insufficient for radiological protection purposes". This rationale was applied to both induced genomic instability, bystander signaling, and adaptive responses as well as the risk of non-cancer diseases. Although the NRC agrees with this sentiment, greater justification is warranted in the foundation document. Conversely, data that has not yet been submitted for publication is cited three times; lines 1540-1541, 1583, and 1930-1931. It appears that this unpublished data was considered by Committee 1 when it choose to increase the tissue weighting factor for breast. This data should not be considered until the material is published in a peer-reviewed journal.

Recommend delaying the finalization of this foundation document until Japanese atomic bomb survivor cancer incidence data are published in a peer-reviewed journal. Similarly, NRC recommends delaying the finalization of this foundation document until the National Academies BEIR VII document is published and available for ICRP Committee 1 and stakeholder review.

5. Lines 1164-1166. Delete "The Task Group is also aware of unpublished data that also tend to support a lowering of this threshold dose. Until these new data are available for review".

   Consistent with comment #4 above, unpublished data that is not available to open peer review and public examination should not be addressed in this foundation document. Similarly, no Committee or Commission recommendations should be derived using unpublished data.

6. Table 3.4, page 32. The estimated threshold (1% incidence) for cataract (visual impairment) was reduced from 3 to 1.5 Gy based on new evidence. Yet, the threshold for annual dose rates for visual impairment (table 3.1) remain unchanged. Either the value in Table 3.1 should be reduced or the original value in Table 3.4 should be retained for consistency.

7. Chapter 5. The Committee should consider expanding their review and discussion of non-cancer diseases after radiation exposure. Additional evidence of non-cancer effects of radiation exposure was observed among nuclear power industry workers by Geoffrey Howe et al. A strong positive and statistically significant association between radiation dose and deaths from arteriosclerotic heart disease including coronary artery disease was observed among US workers (Howe et al, Radiation Research, 162, 517-526 (2004)). The average cumulative radiation exposure to these workers was 25.7 mSv. Additional information is available from the Chernobyl liquidators. In particular, Ivanov has published several articles on cardiovascular disease among the nearly 61,000 Russian emergency workers. Data for Japanese atomic bomb survivors suggests that there is a threshold that needs to be exceeded before a non-cancer effect is demonstrated. If this observation is valid, the Committee should address the impact this might have (if any) on developing radiation protection recommendations for low dose exposures.

8. Table A1, page 61. Corrections:
   ICRP 60 values for Lethality (column 5) referencing data from Table B-19, ICRP 60: lung - 0.95 not 0.87; skin 0.002 not –. ICRP 60 values for Relative Life Lost (column 6) referencing data from Table B-20): oesophagus - 0.77 not 0.65.

9. Lines 647-650. An example of a late tissue reaction with a long progression period would be helpful here, even though provided later, in lines 869-875.

10. Lines 655-660. This summary discussion is hard to follow/understand. Perhaps use of an equation (e.g., cell survival, $S = \exp^{-(\alpha D + \beta D2)}$ and/or a few more words would help here, even though provided later, in lines 892-911.

11. Line 1123. The expression RBE_M (maximum RBE) is used in the text, but not defined.

12. Lines 1170-1171. Should define equivalent dose (Sv) and radiation weighted dose (Gy), since both are used here.

13. Lines 1990-1991. It would be useful if an explanation were provided to justify why there is a gender-specific relative detriment for the thyroid, as for other listed organs (breast, ovary, gonads).

14. Line 2690. Incorrect wording. Should read (or equivalent): For a <u>one-generation radiation exposure</u> [not "one-time increase in mutation rate"] which produces a one-time increase in mutation rate....

15. Line 2694. "s" is used, and no range for "s" is provided, but the range appears to be $0<s<1$, where s = the selection coefficient.