POLICY ISSUE
INFORMATION

July 1, 2005 SECY-05-0117

FOR: The Commissioners

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SUBJECT: STAFF COMMENTS ON THE FOUNDATION DOCUMENTS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

PURPOSE:

To inform the Commission of the staff's review of the draft "Foundation Documents" published for public comment by the International Commission on Radiological Protection (ICRP).

BACKGROUND:

The primary mission of the ICRP is to advance the science of radiological protection by providing recommendations and guidance on all aspects of protection against ionizing radiation. The Main Commission of the ICRP regularly examines the status of its recommendations and reviews scientific information to decide whether new recommendations are needed. The ICRP published a draft revised set of recommendations for public comment in June 2004. The U. S. Nuclear Regulatory Commission (NRC) provided numerous general and specific comments (SECY-04-0223 and SRM-SECY-04-0223). During the comment period, many comments, including those of the Commission, noted the lack of availability of the "Foundation Documents" which were to provide elaboration and support for the draft recommendations.

The ICRP has posted five Foundation Documents on its website (www.icrp.org), and has requested public comments. Comments are due by July 10 or July 24, 2005, depending on

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when the specific document was posted for comment. ICRP has requested that comments be submitted electronically via the ICRP website. All comments submitted will be available for viewing on the ICRP website, and will be considered in preparing the final versions of these reports. The ICRP Main Commission also intends to use these comments in the preparation of the next version of the draft recommendations. The next draft of the recommendations themselves is anticipated to be available for public comment in Spring 2006.

In SECY 04-0055, dated April 7, 2004, the NRC staff proposed a plan for evaluating radiation protection recommendations. As part of its proposal, the staff committed to continue participating in the revision process by providing comments on early draft documents directly to the ICRP.

The NRC staff Radiation Protection Steering Committee solicited comments on the ICRP Foundation Documents from its members' respective offices. The NRC staff has also contacted NRC's Advisory Committee on Nuclear Waste (ACNW); the Agreement States, the Organization of Agreement States; and the Conference of Radiation Control Program Directors; to make them aware of the opportunity to comment on the ICRP documents. The NRC staff will also be participating in efforts by the Interagency Steering Committee on Radiation Standards to coordinate high-level comments from Federal agencies.

The NRC staff participated in an ACNW meeting on June 16, 2005. During that meeting, the NRC staff discussed the draft Foundation Documents with the Committee, and identified the areas in which the staff was developing comments. The ACNW plans to prepare a letter report and forward it to the Commission. The NRC staff has incorporated the ACNW views into the staff consolidated comments, as appropriate.

DISCUSSION:

The staff reviewed each of the Foundation Documents. Much of the material is technical information and provides details in the particular topical areas. However, some aspects may eventually affect policy considerations, so the staff is making the Commission aware of these issues. Considering prior Commission guidance on ICRP activities, the staff has prepared a set of consolidated comments for each of the Foundation Documents, and is providing these for Commission information (Attachments 1 - 5, respectively).

Most of the comments that the NRC provided during the comment period on the draft recommendations are not resolved by the material in these Foundation Documents. It is noteworthy that several of the key areas of NRC's previous comments, such as on the use of constraints versus limits and exemptions from the system of protection, are not addressed by any of the published Foundation Documents.

The staff notes the following issues that are of interest to the Commission, and which are contained in the NRC staff comments that will be provided to ICRP.

- "Assessing Dose of the Representative Individual for the Purpose of Radiation Protection of The Public." This report updates information on the critical group, and extends the discussion to the use of probabilistic calculations of dose. The report also suggests a limited set of age groups as sufficient for characterization of doses in prospective, future calculations.

The draft report suggests several new positions. First, the report suggests the use of a 95 percent confidence level for assessing compliance when probabilistic approaches are used to assess dose to members of the public. The recommendation could be a very useful step in realistic calculations if clarified properly. However, the draft is inconsistent in the presentation of this concept, causing confusion about the precise recommendation being made. Second, the report suggests that a limited number of age groups can be used in the prospective, future assessment of doses that might occur at a facility. This is consistent with the type of approach the NRC staff has used in assessments.

- "The Optimization of Radiological Protection - Broadening the Process." This report updates information from several previous publications on optimization, and includes significant discussions of qualitative analysis and stakeholder interactions as part of the optimization process.

  The report reflects attempts to "broaden" the process through the consideration of more than just the collective dose, factors beyond normal exposure and dose, and the use of stakeholders in the process. The report recommends that a matrix of dose attributes be used in optimization decisions because it would provide more complete information than a single calculation of collective dose. The report also suggests that other insights, such as implications for accident risks, are an appropriate part of optimization, as is the involvement of stakeholders. However, the draft does little to clarify the practical implementation of the approach suggested. In summary, the report reflects material that does, in fact, "broaden the concept of optimization" from that presented in previous ICRP publications, but it does not appear to add any new information that would be useful to NRC. The recommended additions are already part of many "as low as reasonably achievable" analyses conducted within industry. Earlier NRC comments on the topic remain valid.

  One additional issue of concern in the report regards the statements that "Best Available Technology Not Entailing Excessive Costs (BAT)" is the equivalent of Optimization for purposes of exposure of the public, and effluents. The staff believes this is inappropriate, even given the caveat of "not entailing excessive costs." BAT is generally regarded as a technology-driven approach, not an optimization of protection, and thus may be an input to, but not equivalent to, optimization. Staff identified this issue during the 2004 review of the ICRP draft Recommendations document, and comments on the Foundation Document are consistent with comments previously approved by the Commission.

- "Biological and Epidemiological Information on Health Risks Attributable to Ionizing Radiation: A Summary of Judgements for the Purposes of Radiological Protection of Humans." This report provides the background and information supporting ICRP's discussions of radiation exposure versus risk. The report builds upon the materials posted in December, 2004, in a draft ICRP report entitled "Low Dose Extrapolation of Radiation-Related Cancer Risk."

The report presents information that would be essential for the NRC staff in order to develop any changes in the NRC regulatory framework after the ICRP recommendations

are completed. However, the previous NRC comment that additional time should be allowed for review and consideration of the BEIR VII report remains valid. Changes in tissue weighting factor (W_T) values between this Foundation Document and those described in the draft Recommendations, apparently caused by revised considerations for several tissues (breast, gonads, kidney), also raise concerns about the stability and predictability of the basis for these recommendations.

- "Basis for Dosimetric Quantities Used in Radiological Protection." This report provides the background information on the development and selection of radiation weighting factors and tissue weighting factors to be used in the calculation of effective dose (formerly referred to as dose equivalent).

  The report recommends several changes, which include adopting new radiation weighting factors for protons and neutrons, and new tissue weighting factors used in the calculation of effective dose. The recommendations are tied to the information in the Biological and Epidemiological report described above. New terminology is introduced in an effort to make the system of radiological protection more coherent and understandable. The NRC staff has identified only specific technical comments to improve the clarity and understandability of the report.

- The Concept and Use of Reference Animals and Plants for the Purposes of Environmental Protection." This report is the next in the series related to environmental protection, and builds upon ICRP Publication 91 by outlining a possible set of reference animals and plants that could be characterized and used in assessments of environmental impacts.

  The report does not appear to change the current NRC view regarding Protection of the Environment. Much of the material presented is a description of the current state of knowledge on radiation effects in various species, and the issues that need to be studied and resolved. As such, the document is a statement of a research program, not a foundation for making policy commendations. The Commission's earlier views, as articulated in a Staff Requirements Memorandum dated May 13, 2004, in response to SECY-04-0055, are fully reflected in the NRC staff comments.

The ICRP has indicated that the next version of the draft Recommendations would be completed after the finalization of the Foundation Documents and should be ready for Main Commission consideration in the early part of 2006. The staff believes that the ICRP should take additional time to respond to comments that will be received before preparing the next draft of the recommendations. ICRP has also indicated that it will likely solicit stakeholder comments on the draft Recommendations for a second time. This is expected to occur in the Spring 2006. The most likely consequence of this schedule will be that the publication of the new ICRP Recommendations will be delayed until at least late 2006, if not longer. The staff will continue to monitor the ICRP's activities, review documents if and when they become available,

and provide comments directly to the ICRP. In addition, the staff will continue to participate in other forums, such as Expert Groups of the Nuclear Energy agency, to express NRC's views on the ICRP documents.

COMMITMENTS

Listed below are the actions or activities committed to by the staff in this paper:

1. Provide the attached comments, as NRC staff comments, via the ICRP website, on or before the comment due date for each respective document.

2. Provide the attached comments to other Federal Agencies through the Interagency Steering Committee on Radiation Standards to coordinate high level comments.

/RA by Martin J. Virgilio Acting For/

Luis A. Reyes
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Attachments:
1. NRC Staff Comments on Representative Individual Foundation Document
2. NRC Staff Comments on Optimization Foundation Document
3. NRC Staff Comments on Physics Foundation Document
4. NRC Staff Comments on Biology Foundation Document
5. NRC Staff Comments on Environment Foundation Document

Assessing Dose of the Representative Individual
for the Purpose of Radiation Protection of The Public
Task Group Report of Committee 4

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 draft Foundation Document "Assessing Dose of the Representative Individual for the Purpose of Radiation Protection of The Public". The opportunity to submit and review other stakeholder comments on Commission documents is greatly appreciated.

General Comments:

1. This Foundation Document offers useful concepts and material. However, the presentation suffers from repetition, and slightly different formulations for the same concept, leading to confusion. Significant improvement can be achieved by removing some of the duplication and assuring that there is coherence in the presentation language.

2. The definition of "representative individual" is inconsistently presented at various points. The presentation differs in, for example, Paragraphs S9, 23, and the details of Paragraphs 60 - 70. Thus, the text is very ambiguous on the proper approach to take on identifying and calculating the dose to the representative individual. It is not clear if the "representative individual" is an average or maximum. At times the text suggests approaches akin to the average member of the critical group. However, in other portions the text clearly articulates for approaches akin to a maximum exposed individual. A clear, single definition that avoids the maximum is necessary.

3. For probabilistic risk assessment, the document suggests that if the 95 percentile of the dose distribution is within a factor of 3 of the limit, compliance has been demonstrated. This is useful guidance, but a clear point of compliance or algorithm for compliance would be helpful. At the least, the ICRP should advise regulators to make the compliance algorithm clear.

4. Scattered throughout the text are references to "95% of the population" without clear indication of which population (the critical group population? the general population?). For the "95% of the population," it appears that this is in reference to the general population. However, in the context currently in the text, the general reader will assume that compliance will be demonstrated using the 95% of the dose distribution calculated for the representative individual. In an analysis of critical group's behavior and potential exposure, the proper quantile to estimate the dose to the representative individual (assuming it is meant to be similar to the average member of the critical group) will vary depending on the overall level of conservatism of the analysis and uncertainties present. In a properly done analysis of the critical group, it may be very appropriate to use the mean dose from the distribution as the estimate of the representative individual. If the critical group is defined properly, the mean dose of the critical group's dose distribution should satisfy the additional criteria being discussed in the ICRP document that 95% of the general population will have doses less than this mean dose. The ICRP document

should discuss clearly the difference between the selection of the compliance point on the dose distribution of the critical group's analysis and the compliance point on the general population dose distribution.

5. The NRC staff agrees with the stated ICRP position in Paragraph 46 that "...the goal should be to perform a realistic evaluation of the dose." However, the stated goal appears to be inconsistent with the additional guidance in Section 2.5. For example, paragraph 49 describes screening methods and other paragraphs describe deterministic methods with conservative assumptions on habits. In fact, the goal of any analysis is to ensure that real dose to the population will be below the dose constraint. This can be accomplished by highly unrealistic assessments, such as screening analyses, or with ultra-realistic probabilistic analyses with the common factor being that the compliance measure does not underestimate the dose. Thus there should be clarification of how the guidance relates to the overall goal, and to the concepts of realism, homogeneity, and sustainability.

6. The NRC staff agrees with the general thrust that a small set of age categories are sufficient for prospective dose evaluations. It should be clear that when the calculation is prospectively addressing hypothetical individuals the smaller set of ages apply. When actual individuals and populations have been identified and can be characterized to some degree, the more detailed age coefficients are appropriate.

7. 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. Paragraph S2. The third sentence should be corrected to read, "In setting its dose constraint for the public, the Commission recognizes the inherent variability in estimated annual effective dose to members of the public and the transient nature of many extreme exposure situations."

2. Paragraph 9. The statement is made that guidance on the protection of future individuals in the case of disposal of long-lived radionuclides is provided in ICRP 81. Is this statement intended to imply the current guidance document does not apply to disposal, or that this document provides additional guidance?

3. Paragraph 23. The ICRP is introducing a new concept (i.e., "representative individual") who "receives the highest dose" as a means to protect the public. A lot of discussion in the guidance is devoted to addressing what is meant by "highest dose" - ICRP must clearly describe what is meant by highest - subsequent comments will identify potential inconsistencies in the text. NRC staff recommends that the concept continue to parallel the average member of the critical group, and not become a theoretical highest exposure.

4. Paragraph 42, introduces the term "committed effective dose." A footnote should be added to clarify if, and when, this is a 50-year or 70-year committed effective dose.

5. Paragraph 61. The representative individual is meant to be the "...average habits of a small number of individuals representative of those most exposed...", which is consistent with prior definitions of the average member of the critical group. However, paragraph B44 would appear to require calculation of the dose the maximally exposed individual. NRC staff agree with the concept expressed in Paragraph 61, and not the calculation of a maximum exposure.

6. Paragraph 74, refers to "committed dose." In this paragraph it would appear to be a 70 year calculation. But Paragraph 56 would appear to suggest a 50 year calculation. The guidance should be clarified and made coherent.

7. Appendix A, page A-2, paragraph A7, indicates the methodology used for the report is based on intake pathways for milk, green vegetables, and beef and the data is from the UK. Were pathways for other products considered, e.g., poultry and fish? Data should be provided for other meat products that are more likely to be ingested by a hypothetical individual who is representative of the public in a particular region.

8. Appendix A, Page A-6, Table 2. The ratio's vary considerably, and the report indicates that the 1-year individual is not necessarily representative of this age-span, 0 to < 6-years. A greater articulation of the use and impacts of these tables is desirable.

9. Appendix B, in general, is difficult to understand and needs to be simplified before members of the public can be expected to reasonably participate in the evaluation of this report.

Editorial comments:

1. Paragraph S2, third sentence, "In setting its the dose constraint..." The word "the" should be removed.

2. Paragraph 26, last sentence, "...where it is not merely sufficient to meet dose the dose constraint,..." The first "dose" should be removed.

3. Paragraph 35, sentence 1 should be corrected to delete the word "retrospectively" that is redundant

4. Paragraph 75, second line, "...with the dose the dose constraint..." The first "the dose" should be removed.

5. Paragraph 84, sentence 1, change "that" to "than."

The Optimization of Radiological Protection
- Broadening the Process
Task Group Report of Committee 4

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 draft Foundation Document “The Optimization of Radiological Protection - Broadening the Process”. The opportunity to submit and review other stakeholder comments on Commission documents is greatly appreciated.

General Comments:

1. The optimization principle is a well established concept in radiological protection. However, the broadening of the principle to a "process" is presented in an unclear and difficult-to-implement framework, if, in fact, this is the broadening that ICRP refers to. The NRC staff recognizes that some of these concepts go beyond the statements made in previous ICRP publications, and appreciates ICRP endorsing concepts and approaches that have become part of our expectation of a good program.

2. The text reverts between optimization as a tool in decision making (DM) and as a more lofty process having a foundation in the inclusion of stakeholders and non-quantitative considerations such as social equity. It is not clear how these qualitative social considerations are factored into the decision making. The result is a report which is difficult to understand, and appears to contribute little to the current understanding and use of optimization. The report does not resolve any of the issues previously raised in comments on the draft recommendation last year.

3. The NRC supports considering optimization as more than simple dose reduction. Many programs already incorporate consideration of accidents and other potential exposures in decisions on safety in a licensee's operational program. Care must be exercised to correctly state the relationship between optimization and the concept of safety culture. "Safety Culture" is a term and concept that is continuing to grow and mature within the nuclear safety community. While optimization may be seen as being complementary to, and overlapping with safety culture, it is not obvious that optimization requires "the adoption of a safety culture..". The present text seems circular and opaque. Rather than implying that a safety culture is an outcome of optimization, it might be better to describe those characteristics and attitudes that constitute a safety culture, and the role played by optimization in achieving those objectives.

4. The NRC has previously commented on the draft 2005 Recommendations with regards to the introduction of the “best available technology not entailing excessive costs” (BATNEEC). We believe that BATNEEC, is not equivalent to optimization. In normal usage, best available technology is a very different conceptual framework, starting from a technology base, and then determining if can be practically and economically introduced on a wide scale. Success is generally not judged on the basis of a minimization of dose or released quantity of material, but rather on whether the technology is the best available, irrespective of how well current or previous technologies may be working to reduce exposures. It is not obvious how this is consistent with the optimization framework. Furthermore, while

BATNEEC also results in minimizing exposures in the occupational setting and minimizing accident potentials, such an outcome is highly unlikely.

5. The NRC has previously commented on the ICRP Draft Recommendations statements on the role of stakeholders. This document was understood to be the elaboration and explanation of those statements. Unfortunately, this expectation is not fulfilled. For example, it is unclear how the ICRP envisions that stakeholder involvement be incorporated into the optimization of radiation exposures for a given practice. Once an activity or practice is justified and authorized by a national authority, the controls and decisions, employed to ensure dose is optimized, are carried out at an operational level. It would be impractical to accommodate input from all stakeholders into each of these operational decisions during the conduct of the particular practice. There should be a distinction drawn between an overall (or high level) optimization/ALARA scheme, specific for each practice, and the day to day implementation of that scheme. The Foundation Document, in the end, does not seem to add significantly to the concept of stakeholder involvement beyond now acknowledging its importance.

6. The tone of this Foundation Document can be read to imply that an effective ALARA program (or Optimization in general) always results in a decreasing dose trend. Optimization itself means that doses should only be lowered to the point where the cost of lowering them further exceeds the safety return from the incrementally lower doses. Furthermore, the influence of avoidance of accidents and other factors may lead to an optimum where the occupational doses are not the minimum, but the overall risk is minimized. This must be clarified further.

7. Terminology interferes with understanding in this document. Terms seem to be used interchangeably, and this confuses the reader. For example, characteristics, considerations, factors, parameters, elements, attributes, and constraints - to name a few - seem to be used in multiple contexts, if not as synonyms. Likewise, dose constraints, dose restrictions and dose limits are used loosely. It is vital to provide a glossary.

8. 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.

<u>Specific Comments:</u>

1. Abstract; 3rd para. It is not clear what is meant by disaggregation nor how it replaces the usefulness of the collective dose. This issue also is present in multiple places within the text.

2. Page 7, first paragraph, states, "Exclusion and Exemption levels should not, de facto, be considered as relevant endpoints to optimisation." The Foundation Document is not clear, here or elsewhere, on the reason for this assertion. In fact, it would appear that

the exclusion and exemption levels are, at least, reasonable benchmarks, since they imply that the associated risk is so small that further efforts are not likely to be cost effective. Clearance levels should be included in the discussion regarding the relevant endpoints to optimisation.

3. Page 9, paragraph 5 does not contribute anything to the discussion, and should be deleted.

4. Page 9, paragraph 6. How is the disaggregated dose handled within the optimization process? Is the disaggregated dose actually a vector that results from optimization in a multi-dimensional stochastic analysis? Is the stakeholder involvement addressed in this type of analysis? Finally, what are the results of the optimization compared to? A single number? A distribution of constraints?

5. Page 15, Chapter 3, paragraphs (21) - (24), appear to focus on exposure of the public, although it does not say so. Some of the discussion would not be applicable to occupational exposures. For example, considering as a single source for optimization to be a power plant would not be meaningful if the exposed people are workers in that power plant. It is suggested that this discussion be clarified, first regarding the populations being considered and second, regarding application of optimization within these sources (power plant, hospital) for workers and the role of constraints in such cases. This becomes particularly confusing when a worker is exposed to multiple sources within the organization, such as a power plant or hospital. Separate subsections for public, workers, and emergency response could be useful.

6. Page 16, Figure(1), the third diagram, "Controllable Existing Situations," should be re-examined. Many controllable exposure situations may be such that the constraint is above the existing exposure. It may be helpful to state the situations to which each figure corresponds in the figure description.

7. Page 17, paragraph 27. Text should be added to this section to give examples of how optimization analyses have been used to determine the need for mitigation to reduce the total risk (i.e., reduce the probability, as well as the consequences) of severe accidents. An example in the US, is the Severe Accident Mitigation Analysis (SAMA) performed for reactor licensees. The probability-weighted consequences of various accident scenarios are used in a cost-benefit analysis to determine whether mitigation should be required.

8. Page 18, paragraph 30. Before the last sentence add: "Non-radiological risks/impacts should also be considered as part of the optimization process. These may include such things as injuries or deaths attributed to chemical or biological hazards, heat or cold stress, transportation accidents, etc."

9. Page 18, Paragraph 31. What is the phrase "..particular attention is given by the Commission to..." mean. Should this be read as meaning that the following items should be given more weight in an analysis, or is this intended as a reminder that the items should not be forgotten?

10. Page 18, paragraph 31, last sentence. How does stakeholder participation achieve comprehensive identification of relevant attributes? It is an aid to help identify relevant attributes, but is there some innate aspect of stakeholder participation that guarantees a comprehensive list?

11. Page 18, paragraph 32. List of attributes. It is not clear how individual benefit fits with the reduction of individual dose. Is the intent of the social considerations and values to account for improvement in standard of living provided by the practice? The text is not clear how these would be rated. Likewise, for environmental considerations, there is nothing specific in the text which relates to the inclusion of such considerations in the list.

12. Page 19, List of Attributes. Suggest adding non-radiological impacts to the list of categories, and “presence of multiple sources of exposure” to the pre-existing conditions category.

13. Page 19, Table, section entitled, "Social considerations and values," it is important to add what is usually the most important factor in stakeholder involvement, namely the level of risk the stakeholders consider acceptable under the exposure circumstances. Equity addresses this implicitly but not adequately.

14. Page 20, paragraphs 33 - 47. Only some of these paragraphs relate to the "key characteristics related to the dynamics of the optimization process." For example, para 38 discusses the procedure for assessing protection options; it doesn't relate to either optimization or its characteristics. Likewise for paras 41 and 44. The relationship should be clarified, or the material presented differently.

15. Page 20 Much of the text describing optimization as a frame of mind in (34), (46), and (47) is redundant.

16. Page 23, paragraphs 48 - 54. These paragraphs describe the benefits of including active stakeholder involvement in generic decision making; irrespective of any connection to optimization. No connection is apparent from the text.

17. Page 24, paragraph 51. It is not clear that everyone is a stakeholder. Some distinction has to be made between those who have vested interests and those uninterested or unaffected individuals.

18. Page 24, paragraph 54. Suggest adding "Notwithstanding the direct involvement of particular stakeholders in the process, the optimization decisions made by those responsible for radiological protection should be based on consideration of impacts on all stakeholders."

19. Page 24, paragraph 55. This text addresses the endpoints of the stakeholder involvement process more so than optimization. It also appears that the endpoint is an arbitrary decision by the decision maker that it is over.

20. Page 25, Paragraph 59. The meaning of the phrase "kept above the constraint" in the last sentence is not obvious, and should be clarified. If the optimization process,

including stakeholder input, results in selection of a level greater than a normal exposure constraint, it should still be considered acceptable. In part, the difficulty here is the meaning of the concept of constraint for existing or emergency situations.

21. Page 26, paragraphs 60 - 69. Chapter 5 points out the shortcomings of collective dose computations without offering any approach that provides added value; i.e., do the trend histograms provide anything more towards the decision of compliance? Annexes 1 and 2 support the shortcomings of traditional collective cost/benefit quantitative approaches, but provide little in alternatives and how these alternatives can be used for decision making.

22. Page 26, paragraphs 60 - 69. Collective dose is not treated in this document consistently with the treatment in section 5.8 of the Committee 2 draft document. Specifically Committee 2 refers to collective dose as an "instrument for optimisation," and gives a list of matrix parameters. The issue of how collective dose and the parameter matrix are used in optimization should be clarified in this document, and between the ICRP Foundation Documents.

23. Page 27, paragraph 67. The use of a collection of matrices to reflect different attributes, characteristics, etc... to perform optimization for public exposure seems to little more than organization of the collective dose calculation as a multi variable equations, with all the characteristics, parameters, attributes, etc... taken up as matrix entries. Eventually, the public detriment needs to be compared to the single valued dose constraint, so the matrices must somehow be reflected as a single number for comparison purposes. It is not clear how this "consolidation" of attributes, radionuclides, characteristics, parameters, etc... converge to a single value, or even a range of values for the comparison purposes. Annex 2 does not provide this clarification.

24. Page 27, Paragraph 69. (And Table on Page 19) In this paragraph, and other places, gender is given as one of the individual characteristics for defining exposure conditions. The dose and risk calculations for males and females have been the same, with the exceptions of female breast and gonads, and when considering the embryo/fetus. By referencing gender specifically, does ICRP now mean to imply that there are underlying risk differences that should be recognized based on gender? Are gender specific dose coefficients to be developed?

25. Page 28, paragraphs 70 - 73. The discussion on Exposure Distributions in Time and Space seem to ignore the fundamental mechanism in optimization, often referred to as sensitivity analysis. Basically, the report acknowledges the final steps in optimization as case-by-case in nature. The knowledge in making a valid decision on a case-by-case basis, is the fundamental understanding of the situation. Such an understanding may lead to dismissal of some of the matrix elements, so that the decision can be reduced to a more accessible one. The language of the optimizations process replaces what is traditionally called "scenarios" to "individual characteristics" and "exposure parameters." Although there may be value in the "disaggregation" approach, no advice is provided on how to aggregate the information to determine compliance to the dose constraint, whether it is a group, average or maximum dose. For example, one scenario may provide a larger group dose, but another may result in a larger mean dose. How does

one decide which is a better optimized scenario for compliance? From the text, there is an implication that social sensitivity or equity may play the role of the tie breaker, but when it comes down to the making of the decision, the report merely indicates that it is done on a case-by-case basis. The immediate criticism is the lack of uniformity and harmony between decisions and the basis on which they are made; this is a real issue which the report remains silent on.

26. Page 30, paragraphs 74 - 79. The ICRP report does not go into any detail regarding examples of how optimization is actually used in practice or how it should fit into the regulatory process. This comment is related to the prescriptiveness of requirements and/or guidance and their enforceability. Without detailed guidance, it is difficult for an applicant or licensee to implement the optimization requirements. It is also more difficult for the competent authority to ensure implementation of optimization requirements. This is a real issue that needs to be addressed in order for optimization efforts to be successful.

27. Page 30, paragraphs 74 - 79. We suggest adding text to this section regarding methods used to verify application of ALARA principles during operations. The text should also include specific examples of how optimization analyses have been used in various applications, e.g. waste disposal optimization use in decision-making to authorize operation of waste disposal facilities, or to determine the level of clean-up for decommissioning facilities. Another example use of optimization is to determine the need for additional mitigative measures to reduce the risks of severe accidents. Additionally, issues regarding the need for optimization and the level of complexity of optimization analyses based on the overall risk of the regulated activity should also be addressed.

28. Page 30, paragraph 79. 1st sentence: "optimization is more an obligation of means than of results." This is not intuitively clear. Optimization is a mechanism by which the "means" of the operation are associated with the "results" of the operation. This connection allows the modification of the means to achieve the preferred result.

29. Page 35, Annex A1, Chapter 1, second paragraph: Categorizing workers into groups A and B is a European practice and need not to be described here (it does not give any additional information for the optimisation purposes). This section gives some historical trends but doesn't give much guidance on how they were achieved. This text should describe how collective dose is the "currency" of ALARA planning, the vital role of Management (and worker) understanding and buy-in. Hazard characterization, dose projections, work planning, dose tracking, and lessons learned feedback are vital to successful optimization.

30. Page 36, Annex A1,Section 2, "Implementation of the process," what are the economic impacts of using new equipment and retraining of personnel in support the optimisation process? This issue should be addressed.

31. Page 37, Annex A1 2.1 The nuclear industry; 4th para. Using special zoned areas may reduce transit dose, but may make it more time consuming to get from one point to the other. The only efficiency is that the dose to workers is reduced. This argument is not clear from an ALARA perspective. Furthermore, concern over the itinerant and contractor workers having divided responsibility is one of adequate training and sanctions, in cases of intentional work practice violations.

32. Page 37, Annex A1, 2.1 The nuclear industry; 6th para; 2nd sentence. If the optimization is a disaggregated one, it is not clear how results can be compared, especially if the different matrices relate to different populations, genders, age groups, and other characteristics

33. Page 38, Annex A1, paragraph 2.2, "Medical uses," omits important considerations that are essential for ALARA, including:
    (1) the absence of the type of extensive organization and skill typically available in the nuclear industry
    (2) the indistinct line between the minimization of occupational exposure of medical staff in conducting diagnosis or therapy and the needs, as expressed by the practicing physician, of the medical procedures and the diagnostic information or therapeutic efficacy of the procedure
    (3) the final authority of the practicing physician in deciding and selecting the diagnostic or therapeutic conditions that lead to the occupational exposures.

    In many situations, speed may result in an increase in the occupational exposure of the medical staff but improve the benefits to the patient or increase the number of procedures that may be accomplished. The discussion in the draft is silent on how these may be resolved, even in principle.

34. Page 38, Annex A1, paragraph 2.3, "Industrial and research/education," fails to note that the major cause of radiological events in these settings is industrial accidents, the risks for which are relatively quite high. A frequent contributing factor to such events is that ALARA practices often conflict with work schedules. There are typically no management structures that would intervene to establish a balance, as is the case in the nuclear power industry. These considerations are important in defining what ALARA means in these industries, but the draft is silent on all of them.

35. Page 39, Annex A1. The log-normal scale of Figure 4 distorts the data presented. It makes the distribution of dose across the dose ranges appear more uniform than they are. It also exaggerates the apparent decrease in the number of individuals with an annual dose greater than 2.0 mSv. It is not clear whether reducing the number of individuals with annual doses greater than 2.0 mSv is a recommended goal of an ALARA/optimization program.

36. Page 39, Annex A1. The heading "Relative Weighting" at the bottom of the page does not seem to relate to the following text, which summarizes the preceding discussion about dose trends and then switches to a very vague discussion of matrix parameters that can be used in characterizing collective dose.

37. Page 41, Annex A1, paragraph 4, "The role of operators and authorities," add a discussion of the difficult problem of shifting dose to different populations in the process of implementing ALARA. For example, some measures may be used to reduce emissions from a facility, and hence public dose, but they result is an increased exposure to workers, such as exposures from holding tanks, and pipes, waste treatment, and waste disposal. Is such shifting appropriate? Should doses to the public and to workers be weighted differently?

38. Page 45, Annex A2, "Selection of Relevant Dose Constraints", second paragraph: It is unclear what "more realistic assumptions" means.

39. Page 45, Annex A2, "Selection of Relevant Dose Constraints," it might be useful to add a discussion of ICRP's view on what the approach would be if a facility is to be built in an area where constraints have already been apportioned amongst the existing facilities. Would such a facility be dis-allowed? Would the constraints on the existing facilities have to be adjusted to accommodate the new facility? How would the situation be treated in which facilities of very different technological sophistication are located within the same area? Should the facility with the less advanced technology, and therefore lower ability to restrict effluents, be given a higher constraint to compensate, or should it be shut down?

40. Page 46, Annex A2, 3: Example given in the second point of the list seems to be too complicated. Consideration of the half-lives of radionuclides and age range of the exposed population will make analyses too complicated in most all circumstances.

41. Page 46, Annex A2, 3. Distribution of Exposures; Relative Weighting: The recommendation to discount exposures beyond a few generations in calculating collective risk might be misinterpreted as saying that no action need be taken regarding any such doses. To clarify, add language to the paragraph on "relative weighting" in Section 3 of Appendix A2 similar to the following: "Although one should be wary of including exposures beyond a few generations in collective risk - cost optimizations, actions to limit such long-term potential exposures may be considered in the manner recommended in ICRP Publication 81."

42. Page 46, Annex A2, 3. Distribution of Exposures; Relative Weighting; second paragraph and Figure 7: This paragraph makes an important point about the usefulness of dose predictions at times far in the future and it is good to see a scientific guidance body presenting this opinion. However, the accompanying figure does not seem to really reflect the message in the text. The text mentions "a few generations." However, the weighting factor example in Figure 7 does not decrease until 1,000 years. This is much more than "a few" generations. Thus it is not clear what recommendation ICRP may be making.

43. Page 50, Annex A3. The Application of Optimization for Radon Exposure. It is not clear what optimization has to do with this. This annex is on air concentration reduction strategies, which are binary rather than optimization relevant. Either you mitigate it or you don't. Optimization would be whether the ventilation system is operated constantly or whether it is intermittently operated to stay just below the dose constraint level. Does one just seal a sufficient number of foundation cracks to meet the compliance limit?

Optimization fits into a frame work of radiation protection involving justification of the practice and the use of dose constraints. Many workplace environments are not regulated as practices under the ICRP regime. To apply optimization in this context is out of scope. The other alternative is to treat such situations as interventions, which would be impractical especially, if radon is an element of the production process (metals extraction from ore; fertilizer production). A number of structures would necessarily need to be grandfathered, such as statuary hall in the U.S. Capitol Building.

Editorial comments:

1. Paragraph (1), line 3, change "reasonably possible" to "reasonably achievable" because the word "possible" connotes more extreme measures than "achievable," and may be misunderstood.

2. Paragraph (7), line 4, change "Sections" to "Section."

3. Paragraph 14. Delete the word "concrete."

4. Paragraph (22) "As it is presumed ..." should be "As there is presumed ..."

5. Paragraph 29. Optimization helps to identify those operating parameters, which result in a successful.... In some cases, optimization is perfunctory.

6. Paragraph 42. The last sentence has more to do with justification, not optimization.

7. Paragraph (63) At the end of the next-to-last sentence, delete the "dose" from "group dose doses"

8. Paragraph (76) In the second line, delete "that" before "both"

9. Annex 1 Introduction; 3rd para; 1st sentence. Delete "lasting." Unclear implications.

10. Annex A1; 2.1 The Nuclear Industry; last paragraph; second line: "describe" should be "described"

11. Annex 1 2.3 Medical Uses. Delete "post graduate;" could be misinterpreted.

12. Annex A1; 4. The role of operators and authorities; second paragraph; third sentence: "In many countries registries dose operated ..." should be something like "In many countries dose registries are operated ..."

13. Annex A1; 5. Conclusions; end of third sentence: There should be commas after "international" and "regional"

14. Annex A2; Selection of Relevant Dose Constraints; second paragraph; last sentence: Delete "of the" from "... from each of the identified licensed facility ..."; or replace "facility" with "facilities"

15. Annex A2; Relative Weighting; second paragraph and Figure 7: Descriptive text refers to Figure 4, but figure caption indicates Figure 7.

16. Annex A3; 1) Introduction; first paragraph; first sentence; parenthetical expression: delete the "s" on "meters"

17. Annex A3; 1) Introduction; second paragraph; third sentence: Remove the word "but" after "well known"

18. Annex A3; 3) b) Measurements of concentration levels; second paragraph; fifth sentence: The parenthetical expression is set off by both commas and parentheses. Either the commas or the parentheses should be removed.

19. Annex A3; 3) c) Implementation of protective actions; fourth paragraph; second sentence: The sentence begins with "There." It seems like the word should be "This."

20. Annex A3; 3) c) Implementation of protective actions; fourth paragraph; last sentence: Should "aeration" be "ventilation"?

21. Annex A3; 3) c) Implementation of protective actions; fifth paragraph; second sentence: Remove "s" from "Constructions"

Basis for Dosimetric Quantities Used
in Radiological Protection
Task Group of ICRP Committee 2

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-2, Basis for Dosimetric Quantities Used in Radiological Protection. The opportunity to submit and review other stakeholder comments on Commission documents is greatly appreciated. The foundation document recommends several changes, which include adopting new radiation weighting factors for protons and neutrons and new tissue weighting factors used in the calculation of effective dose (formerly referred to dose equivalent).

General Comment:

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. Page 4 No rationale was provided for changing the term deterministic effects to "tissue reactions". The original terminology should be retained unless an explanation is provided.

2. Page 6 The LNT is defined twice (in paragraph 2 and 3). LNT is redefined again on page 11. Delete these redundant definitions.

3. Page 6 The last sentences of paragraphs 1 and 2 under the section 2.1 appear redundant. Recommend that these be deleted and the issue of the assumed LNT be addressed in a separate paragraph. The dose range of LNT applicability should be clarified; the term "for radiological protection purposes," is not clear (i.e., occupational, public, and environmental protection?)

4. Page 6 The task group should consider, or at least acknowledge, the information on noncancer effects described by the Radiation Effects Research Foundation at its web site www.rerf.org.jp/top/healthe.htm for a discussion of the dose response relationships between excess relative risk versus dose for cardiovascular disease.

5. Page 8 The sentence starting at the bottom of the page, which refers to the "protection of other biological organisms," seems out of place in this paragraph. The issue should be addressed in a separate paragraph, possibly at the end of the section.

6. Page 9 The text should emphasize that the N used in equation 3.1, and supporting text, is not the same variable as the N use in equation 2.1.

7. Page 13 Section 3.2 should also address extreme cases of non-homogeneous dose distributions from external exposures (i.e., partial body irradiations). The advisability of using the average dose to an organ that is only partially exposed (i.e., bone marrow, when only the upper legs are exposed), should be addressed. Local doses could exceed the threshold for tissue damage without exceeding the dose limit if the average dose is always used.

8. Page 18 Text at the top of the page implies that determining the dose to the lens of the eye in mixed beta, gamma fields, requires two dosimeters (calibrated to Hp(10) and Hp(.07) respectively). A single operational quantity should be specified for the protection of the eye.

9. Page 25 For clarification revise second sentence to read “Radionuclide emitting neutrons are not frequently encountered in operational radiological protection situations and their internal dose contribution to effective dose is generally low.”

10. Page 28 Equation 4.7 is not correctly expressed as a continuous function. The neutron energy variable, E_n, must be adjusted in each of the last two expressions in order for the function as a whole to remain continuous. Also, the inequality in the last expression is reversed. We suggest the following correction;

$$w_R = \begin{cases} 2.5 + 18.2e^{-\left[\ln(E_n)\right]^2/6}, & E_n \le 1MeV \\ 5.0 + 17.0e^{-\left[\ln(2(E_n-1))\right]^2/6}, & 1MeV < E_n \le 50MeV \\ 2.5 + 3.25e^{-\left[\ln(0.04(E_n-50))\right]^2/6}, & E_n > 50MeV \end{cases}$$

11. Page 32 Rephrase line four, paragraph 1 to “lifetime risk for cancer incidence for a composite population. The detriment is modeled as a function ...” There are seven groups of individuals that represent a single composite population.

12. Page 32 Delete kidney from the second to last sentence. The kidney is now considered a remainder tissue.

13. Page 35 The term "airborne activity density" in the 2nd paragraph should be revised to read "airborne activity concentration."

14. Page 35 The forth paragraph should also point out that since much of the activity inhaled is cleared through the digestive track, it is sometimes difficult to resolve the intake into $I_{j,inh}$, and $I_{j,ing}$.

15. Page 36 Equations (5.5) and (5.6) appear incomplete. Equation (5.5) has no term e(τ).

16. Page 37 The basis for the dosimetric quantity "annual effective dose" should be more clearly defined in section 5.3 and added to the glossary. The terms $E(T_X)$, $e_{j,k}(T_X)$, $e_{j,ing}(T_X)$, and $e_{j,inh}(T_X)$ in equation 5.8 do not contain the variable τ, which connotes committed effective dose, but the definition of the variables $e_{j,ing}(T_X)$, and $e_{j,inh}(Tx)$ eight lines below equation 5.8 do include τ. As a result, it is not clear how ICRP intends to define the dose quantity "annual effective dose." It could mean the effective dose, e, delivered during one year of exposure, or it could mean the committed effective dose, e(τ), for 50 or 70 years following the year of exposure.

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.

The Concept and Use of Reference
Animals and Plants for the Purposes
of Environmental Protection
Task Group of ICRP Main Commission

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 Foundation Document "The Concept and Use of Reference Animals and Plants for the Purposes of Environmental Protection". The opportunity to submit and review other stakeholder comments on Commission documents is greatly appreciated.

General Comment:

1. The U.S. Nuclear Regulatory Commission (NRC) continues to have significant concerns regarding the need and value of developing a separate radiation protection system for the protection of the environment.

2. Throughout the draft publication the need for additional information and data is highlighted. Significant additional research and model development, including gathering effects data for most species at low environmentally significant dose rates, will be required to bolster the scientific basis. The number of uncertainties associated with the use of a reference flora and fauna, given the wide range of species and exposure pathways, is very great. As such, the document is a statement of a research program, not a foundation for making policy recommendations.

   Given that this will take some time to develop, it seem premature for the ICRP to start development of a system before the scientific basis has been adequately formed. However, the ICRP's publication as a Foundation Document, and the inclusion of the material in the draft recommendations available last year implies that certain positions and conclusions have already been reached. The NRC staff does not agree, and recommends that ICRP clearly separate any program for examining the scientific issues with protection of flora and fauna from statements that could be read as recommendations of policy.

3. The draft publication lists several reasons for further developing the ICRP framework including: (1) demands upon regulators to comply with the requirements of legislation directly aimed at the protection of wildlife and natural habitats; (2) the need to make environmental impact assessments; and (3) the need to harmonize approaches to industrial regulation. Having such a framework would not significantly benefit NRC activities. Our regulatory framework, regulations and guidance are sufficient to prepare environment impact assessments, and demonstrate, if appropriate, that the environment is adequately protected with appropriate mitigation strategies to manage potential environmental harm. Thus, the proposals could result in no added benefit while being difficult to implement.

4. The draft recognizes that the approach discussed in the report cannot reflect the full range of biological diversity, or provide a general assessment of the effects of radiation on the environment as a whole. A safety case that the current system of regulations

(i.e., if humans are protected, then so is the environment) is an unacceptable method or has weaknesses has not been demonstrated. To the contrary, the empirical evidence demonstrates that the environment is being adequately protected by the current system of radiation protection. This fact is recognized in paragraph (6) of the draft publication ("Thus it is probably true that the human habitat has been afforded a fairly high level of protection through the application of the current system of protection.). The potential burden to regulators and industry associated with developing and implementing such a new system is not balanced by the any increased protection to non-human species.

Specific Comments:

1. Paragraph 8. The paragraph states, "The question of whether one should protect individuals or populations from harmful effects of radiation in any particular circumstance, however, is not an issue of direct concern to the Commission." This approach appears inconsistent with the ICRP's aim to safeguard the environment by reducing the frequency of effects likely to cause early mortality or reduced reproductive success to levels where they would have a negligible impact on conservation of species, maintenance of bio-diversity, or the health and status of natural habitats or communities. The draft publication also notes that a large number of animals and plants are already afforded protection at the level of the individual and that it would be inappropriate to provide advice that could not be used in such legal context. While the NRC recognizes that there are appreciable scientific difficulties in estimating the impact on communities of species and the ecosystem based on impacts of individual species, the NRC believes that affording every individual the same level of protection as threatened and endangered species is problematic. Such an approach could significantly restrict the beneficial uses of radioactive materials. Furthermore, harm to threatened and endangered species is largely achieved by protection of critical habitat rather than by restricting discharges of pollutants.

2. Paragraph 13. The NRC disagrees with the approach of comparing derived consideration levels (dose rates) for reference animals and plants to normal natural background dose rates of the reference organisms. Natural background for humans varies by location around the world because of many factors including local geology and elevation. Natural background will vary even more significantly among other species. For example, terrestrial mammals will have vastly different natural backgrounds then fish or even earthworms. Add to this the variability of natural background globally, the approach proposed by the ICRP will make practical evaluation exceedingly complex or potentially meaningless.

3. Paragraph 13. The text implies that levels of exposure at or above background are of concern. Our understanding of the available data is that exposure rates up to several orders of magnitude above background have not posed concerns of the types stated in the objectives.

4. Paragraph 14. The phrase "reducing the frequency of effects..." implies that there currently are effects, yet other portions of the report indicate that such effects are not existent. The task group should clearly articulate the objective(s) of the document (i.e., minimize, limit, prevent the occurrence of an effect).

5. Paragraph 15. This paragraph states that the ICRP intends to develop this environmental protection system so there is commonality in its basic approach to dosimetric modeling used for human protection. The draft further suggests that reference dose per unit internal and external exposure values would be developed. Again, this is an added complexity that is not needed to address an issue that should be adequately and quickly resolved with a "screening" calculation. It is difficult to understand the need for, or utility of a gastrointestinal or lung model that would be developed for reference animals and plants.

6. Paragraph 20. This paragraph states that the relevant effects considered are early mortality, morbidity, reduced reproductive success, or some form of observable cytogenetic damage, irrespective of whether or not they arose from stochastic or non-stochastic dose effect relationships. Defining "early" mortality may be difficult for species given natural variation and complex ecosystem interactions among species. It is also unclear how early mortality or morbidity of certain individuals, or individual species, would effect the overall health of the environment.

7. Paragraph 27. It is not clear why the candidate types in the first and second bullets are different. The lists in both bullets should be the same.

8. Paragraph 32. It is not clear in the last sentence whether the "Family" level or "Super Family" level "...has therefore been suggested as being the most suitable." From later discussion, it appears that the Family level was chosen.

9. Paragraph 51. By including the various stages of development, the original set of 12 reference plants and animals seems to be expanded by 3 or 4 times. Thus the reference system is much more complex than seemingly first described.