U.S. Nuclear Regulatory Commission Comments on the 2006 Draft Recommendations of the International Commission on Radiological Protection

The U.S. Nuclear Regulatory Commission (NRC) appreciates the opportunity to offer its views on the draft recommendations of the International Commission on Radiological Protection (ICRP), and we commend the openness and responsiveness of the ICRP in making drafts available for public comment. The most recent draft, posted on the Internet for public comment on June 7, 2006, represents a considerable evolution from the earlier draft on which the NRC commented in 2004. We look forward to interacting with the ICRP as these recommendations continue to evolve.

General Comments:

1. The ICRP has stated that these recommendations are intended to consolidate, simplify, and elaborate on the previous set of recommendations published in 1991 as ICRP Publication 60. However, the current draft does not appear to appreciably consolidate or simplify the recommendations. For example, the draft simply indicates that all of the previously published values should be considered as constraints. Furthermore, much of the material that elaborates and expands on previous recommendations, in fact, describes the current state of the system of radiological protection being implemented by many well-run radiation protection programs throughout the world. With the conclusion that there has not been any significant change in radiation risks, there is no compelling public health and safety argument to make any changes to the recommendations, or to national regulations that implement those recommendations.

2. The ICRP proposes changing the radiation weighting factors, tissue weighting factors, and nominal risk coefficients for cancer and hereditary disease. Of all of the material in the draft recommendations, these changes have the greatest potential for a major impact on regulations promulgated by national authorities. Yet, some of these changes may be premature. The cancer incidence data used by the Biology Working Group is largely based on data published in the early 1990s (Thompson et al., 1994; Preston et al., 1994) using Japanese A-bomb data and the DS86 dosimetry. A new dosimetry system has since been developed, but the "new analyses of the latest A-bomb cancer incidence data are expected soon (Preston et al., in preparation)" [see Annex A, lines 1647–1648]. Promulgating this series of tissue weighting factors and nominal risk coefficients may result in a system of radiological protection that is overly conservative. We believe that recommendations of the ICRP should be based upon published, peer-reviewed scientific information that reflects the current state of knowledge. Thus, we propose that the ICRP not adopt a new set of tissue weighting factors and nominal risk coefficients until the assessment of the A-bomb data is completed and published in a peer-reviewed journal for public scrutiny.

3. The ICRP notes that it intends its guidance and judgments to be flexible to allow for national and regional variations. From an NRC perspective, we have determined that our current occupational dose limit of 50 mSv (5 rem) per year is consistent with the recommendations of the ICRP, and we note that the actual outcome (as measured by occupational exposures reported to the NRC) meets the ICRP recommendations. We believe that the variations in protection of the most highly exposed individuals are best addressed by the use of source-related dose constraint (i.e., an administrative constraint) selected by the licensee and applied in conducting the licensee's required radiation protection program and process of optimization of protection.

4. The ICRP's attempt to clarify the meaning and use of dose constraint is an improvement over the previous draft, but further clarification is needed. The use of the phrase "provides a fundamental level of protection" clouds the relationship of constraints and dose limits. We believe a constraint is a value that helps to ensure the achievement of a fundamental level of protection in the process of optimization. However, from an individual's standpoint, it is the dose limit that provides the ultimate fundamental level of protection. The constraint, properly implemented in the context of a radiation protection program and a licensee's optimization of its activities, will contribute to ensuring that each individual is adequately protected. This is, in fact, how a well-run radiation protection program functions. Therefore, the dose constraint can be seen as a value, selected by the licensee, for use in the radiation protection program that the licensee employs to ensure compliance with the regulatory requirements, i.e., an administrative limit. The national authorities' role is to ensure that licensees establish appropriate values. Thus, we request that the ICRP further clarify how constraints function within a radiation protection program and the optimization of protection for a source to ensure that adequate protection for an individual is achieved.

5. As the draft recommendations have been developed, the ICRP continues to draw a connection between optimization of protection and the concept of a safety culture. This draft publication has not resolved the previous confusion between these two concepts. Optimization of radiation protection activities will not create a safety culture. Likewise, a safety culture may not result in optimized radiation protection activities. Although an effective safety culture will contribute to continuing efforts to optimize protection, they are not equivalent. The NRC believes that the underlying tenets of a safety culture and, in particular, the mindset of continually challenging the radiation protection activities to ensure that safety is being achieved, are also key components in the ongoing process of optimization. However, this relationship is not clearly articulated.

6. An apparent increased radiation sensitivity observed in females has been described in publications of the U.S. National Academy of Sciences in 1990 (BEIR V) and 2005 (BEIR VII) and by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR 2000). However, the ICRP does not recommend gender-specific data for the purposes of radiological protection, and continues to present gender-averaged tissue weighting factors and numerical risk estimates. Although the NRC agrees that the proposed approach provides adequate protection, we request that the ICRP clearly explain its rationale for this decision and how it accounts for gender differences in radiation sensitivity. Regulatory agencies, such as the NRC, will need to reference such a rationale and basis in developing any revised regulations.

7. The ICRP presents a number of recommendations related to small quantities of material, and the concepts of exemption and exclusion. As presently written, these recommendations are internally inconsistent, and could lead to misinterpretations. In particular, we believe that the present text inappropriately implies that exemption would only be appropriate when the individual dose is very low, when in fact, an exemption may be the logical regulatory solution even when individual doses are greater than the values given. Furthermore, the 10 μSv value, as currently presented, may be inappropriately considered as a boundary between significant and insignificant doses. We also disagree with the presumption that some international values, such as those for foodstuffs following an accident, are appropriate for generic exemption.

8. The NRC appreciates the observations provided to the ICRP with regard to the use of collective dose and calculation of health effects from very small doses. We also welcome the clarification that collective dose is mainly an instrument for optimization; i.e., for comparing radiological technologies and protection practices. In addition, we agree that collective dose should not be used as a tool for epidemiological risk assessment and is inappropriate for use in risk projections. The ICRP has also indicated that the linear, no threshold assumption combined with a judged value of a dose and dose rate effectiveness factor provides a prudent basis for the practical purposes of radiological protection (i.e., management of risks from low dose radiation exposure). However, these assumptions and judgments are not appropriate for calculating the hypothetical number of cases of cancer or heritable disease that might be associated with very small radiation doses. (See paragraph 57). The general statements contained in the draft recommendations are not likely to impact practical regulation and risk communication if additional guidance is not provided with regard to when these concepts actually are, and are not, appropriate. The ICRP should clearly articulate the boundary conditions within which the calculations are valid, as well as the dose ranges for which epidemiological and cellular or molecular data provide information on the health effects associated with radiation exposure.

9. The NRC continues to believe that the established system of protection has provided adequate protection of the environment. In the introduction to the draft recommendations, the ICRP states that Section 10, “Protection of the Environment,” describes a policy approach for radiological protection of non-human species. However, Section 10 does not, in fact, state a policy. Instead, Section 10 provides a brief description of ongoing work of the ICRP. No framework for protection or assessment of exposures and pathways is proposed, and no recommendations are provided. Consequently, the entire section, as presently constructed, should be removed from the draft publication, and stakeholders should be afforded the opportunity to comment as the assessment framework is developed.

10 The NRC believes that material related to specific implementation of radiation protection recommendations is generally more appropriate in documents published by the International Atomic Energy Agency, and national regulations. The discussion in Section 11, for the most part, replicates the work of other organizations and does not seem to be necessary or appropriate in the ICRP’s recommendations, and, therefore, should be deleted.

11. The draft recommendations require a thorough editorial review. There are numerous instances of incorrect spelling, incorrect usage of terms, references to publications that are not included in the reference lists, text and table numbers that do not agree, and references to documents that are yet to be drafted, being drafted, under review, or in press. If material is not publicly available at the time of publication, references to such material should be removed.

Specific Comments:

1. Page 3, Preface, 7th sentence:

   To enhance clarity, we recommend rewording "they have proved robust in the main" to "these assumptions and concepts remain robust."

2. Page 6, para. 8:

   A series of publications have provided additional guidance for the control of exposures from radiation sources since the issuance of ICRP Publication 60. These reports specify 30 different numerical values for restrictions on individual dose for various circumstances. The values are justified in many different ways. As a result, the ICRP should explain how the new recommendations simplify the system of radiological protection and clarify if any of the 30 numerical values have changed in the way they are used and how the justifications have been made consistent.

3. Page 8, para. 11, last bullet:

   We recommend deleting this bullet. A policy approach on radiological protection of non-human species is not necessary in this set of recommendations. See Specific Comment #98 for additional justification.

4. Page 11, para. 22:

   Although it is not the NRC's desire to establish gender-specific tissue weighting factors or nominal risk estimates because they would be inconsistent with U.S. legal statutes, the ICRP should explain its rationale for not making such a recommendation. We believe that a sound, consistent rationale exists, but it is not presented. BEIR III, BEIR V (Tables 4.2 – 4.4), BEIR VII (Table ES-1, page 15) and UNSCEAR 2000, Annex I (para. 359) specifically note that females are more sensitive than males to radiation exposure.

5. Page 12, para. 29:

   The term "tissue reactions" is slightly more intuitive than "non-stochastic" or "deterministic effects." However, if the ICRP's intent is to assist the public in understanding deterministic effects, the term "tissue reactions" is still too ambiguous to accurately convey the concept of injury from acute exposures to high doses of ionizing radiation. Conversely, if the adoption of "tissue reactions" is intended to clarify the concept for radiation protection practitioners, it is unnecessary, given that the term "deterministic" is already part of the professional vernacular.

6. Page 13, para. 30:

With regard to optimization of protection, the recommendations make reference to keeping exposures as low as reasonably achievable. While this is good, it maintains the perception that optimizing protection simply means reducing exposures. The earlier foundation document included a discussion of broadening the process of optimization to include consideration of all factors relevant to protection, including the generation of waste, potentials for accidents, etc. Such a broadening does not seem to be reflected in this definition and, in fact, is not readily apparent in the section on optimization (see, for example, Paragraph 194).

7. Page 15, Response to ICRP Yellow Text Box Question for Scope, Exclusion, and Exemption:

The treatment of justification is not adequate. Additional comments and requests for clarification and expansion are provided.

8. Page 16, para. 42:

The discussion of exemption lacks any reference to optimization.

9. Page 17, para. 43:

This section is unclear and should be revised. In particular, it is not clear whether the characterization of regulatory controls as "unfeasible or the societal efforts needed for its application would be disproportionate to the saving in detriment it would be considered to achieve" refers to what is called "excluded" or whether this refers to a mix of both "excluded" and "exempted."

10. Page 17, para. 45:

It is not clear why a practice or source that has been justified, and inherently safe (third item), and contributes an insignificant risk to any individual (first item), must also then be subjected to regulatory controls that are "optimized." Note also that the use of the term "optimized" here can be somewhat confusing, since it refers to optimizing programs, rather than optimizing dose, as used throughout the recommendations. Additional explanation should be provided.

11. Pages 17–18, para. 45 and 46:

The draft ICRP recommendations advocate the use of an annual dose of 10 μSv (1 mrem) as a principle to govern exemption of individual risk for manmade sources. However, the document does not explain the basis for establishing such a generic exemption dose, but does use this value to distinguish between "insignificant" and "significant" risks for the purpose of exemption from regulations. Typically, exemption is associated with a specific and well-known practice. This recommendation could have two significant undesired consequences. First, the public may perceive this value as establishing the boundary between "significant" and "insignificant" risks. In other words, some stakeholders may conclude that there should be regulatory control over sources

that may cause annual dose exposure exceeding 10 μSv (1 mrem), thereby causing unnecessary burden on regulators and the public. Second, this value could have significant impact on development of realistic guidelines or limits for clearance or release of solid materials and other safe practices. Therefore, we recommend either eliminating such a generic exemption value, or providing a range of dose (e.g., 10–100 μSv/y (1–10 mrem/y)), which should extend above 10 μSv/y (1 mrem/y). As stated in Paragraph 46, other factors besides dose could influence a decision regarding whether to grant an exemption in a particular situation, and a higher recommended exemption dose criterion would add flexibility to such decision-making. Regulatory authorities' activities and decisions may not be optimized with a 10 μSv/y (1 mrem/y) exemption dose. The ICRP should allow regulatory authorities to set exemption levels within the range of dose values.

12. Page 18, para. 47, line 6:

Delete "and in some foodstuffs" and references to FAO and WHO. The Codex guidelines are for use during the first year after a radiological accident, and the draft guidelines are reduced up to three orders of magnitude for long-term exposure. Also, the WHO guidelines for drinking water are up to five times higher than current U.S. drinking water standards. In addition, the FAO and WHO values are unacceptable as generic exemption criteria in the United States.

13. Page 20, para. 53, last sentence:

We recommend deleting this sentence. The ICRP should focus on information published in peer-reviewed journal, rather than commenting on topics that may be published at a future date.

14. Page 20, para. 55 and 56:

The discussion regarding the applicability of LNT should be revised. The phrases "low dose range under 100 mSv" (at Paragraph 55) and "below around 100 mSv (at Paragraph 56) are vague. The range of doses for which the LNT can be assumed to be valid needs to be clearly stated. Also, the term "low dose" can lead to confusion, since it is used in two different contexts in this section . Although 100 mSv is considered a low dose range in epidemiology, it is equal to 5 years of occupational exposure at the maximum exposure limit recommended by the ICRP and is definitely not considered low dose in terms of radiation protection, as implied by the last sentence of Paragraph 56. The ICRP should clearly indicate the exposure levels at which (1) valid scientific information exists (e.g., >100 mSv for epidemiology; >20 mGy for chromosome aberrations), (2) health effects are extrapolated, (3) nominal risk coefficients have utility, and (4) it is appropriate, for public health purposes, to calculate the hypothetical number of cancer cases or heritable disease. Also, it is arguable whether the LNT can be extrapolated below 100 mSv with any kind of confidence.

15. Page 21, para. 57, line 3:

Change “ambiguously” to “unambiguously”.

16. Page 21, para. 57, sentence 2:

Organizations such as the World Health Organization have used risk coefficients and collective radiation doses to predict cancer mortality 50–60 years into the future (ref. “Health Effects of the Chernobyl Accident and Special Health Care Programmes,” WHO, April 2006). The ICRP should specify a numerical threshold for the “very small radiation doses” below which should not be used to calculate the hypothetical number of cases of cancer or heritable disease.

17. Page 21, para. 57, line 10:

Change “contemporary” to “hypothetical”. The coefficients in Table 2 and Annex A relate to a hypothetical construct, rather than a contemporary human population.

18. Page 24, Table 2:

Retitle as “Detriment adjusted nominal risk coefficients for cancer and hereditary effects (10^{-2} Sv^{-1}) for low dose, low dose rate exposure to ionizing radiation”. The modification is needed to clarify that these risk coefficients are not applicable to single acute exposures to ionizing radiation, which might be associated with medical exposures or exposures associated with a terrorist device. The ICRP should also articulate the risk coefficients for acute, high dose rate exposures.

19. Page 24, Table 2:

Revise the nominal risk coefficients under the column Total, Present to read 5.7 and 4.2 for whole and adult populations, respectively. See Annex A, Table 4.4.

20. Page 25, para. 75:

The current international radiation safety standards are based on a cancer mortality risk coefficient of 0.00005 per mSv. The cancer mortality risk coefficient, based on the latest DS86 information is 4% per Sv (see Paragraph 73), and this value is overestimated by at least 8% if the DS02 information is used. In addition, as cancer treatment improves, the cancer mortality rate (and the cancer mortality risk coefficient) will continue to decrease. The ICRP should state the radiation risk coefficients for cancer morality and cancer incidence for their hypothetical population using the DS02 dosimetry and A-bomb data based on this dosimetry system. If the system of radiological protection is dose-based, this issue is unimportant. However, other public health hazards are managed on a risk-based system. If the ICRP’s recommendations become risk-based, this becomes important.

21. Page 26, para. 81:

The ICRP notes that in utero exposure should not be a specific protection case in prolonged exposure situations where the dose is well below 100 mSv. The ICRP should articulate why pregnant workers should declare their pregnancy and be restricted to an exposure limit of 1 mSv given the statement above.

22. Page 27, para. 87:

Revise the 100-mSv threshold for noncancer disease to 1 Sv. The radiotherapy data clearly demonstrate a threshold for noncancer disease of 1–2 Sv. Russian data provided by Ivanov for the Russian Federation liquidators is not controlled for confounding factors such as diet, smoking, alcohol consumption, or deteriorating economic and medical conditions. Similarly, the Japanese A-bomb survivor data are not as robust as the radiotherapy data and may also be subject to confounding.

23. Page 34. Equation 4.4:

$D_{T,R}$ [mean absorbed dose from radiation (R) in a tissue or organ (T)] is not defined in the text.

24. Page 35, Table 4:

The UNSCEAR 2000 report (Paragraph 77) specifically notes that there are statistically significant effects of radiation for cancers of the stomach, colon, liver, lung, breast, ovary, bladder, and thyroid, as well as non-melanoma skin cancer. However, statistically significant risks were not seen in either incidence or mortality for cancer of the rectum, gall bladder, pancreas, larynx, uterine cervix, uterine corpus, prostate gland, kidney, or renal pelvis, or for lymphoma or multiple myeloma. Other draft United Nations materials reiterate the current UNSCEAR assessment that there are some cancer sites for which there is little evidence for an association with radiation (e.g. pancreatic cancer, cutaneous melanoma, prostate cancer, non-Hodgkin's lymphoma, Hodgkin's disease, multiple myeloma), and others where excess risks have only been seen following very high dose (radiotherapeutic) exposures (e.g. cancers of the small intestine, rectum, uterus, kidney). BEIR VII (Figure 6.3) also indicates that there is no statistical increase in rectum, pancreas, uterus, and prostate cancer mortality, and no evidence of association was observed for lymphoma or multiple myeloma incidence (page 151). Based on this information, the ICRP should justify why the remainder tissues (e.g., gall bladder, kidney, pancreas, prostate, small intestine, uterine cervix, and lymphatic nodes) should not be removed from Table 4. Inclusion of these tissues implies that there is a low dose risk of cancer incidence for these tissues and, thus, individuals who are exposed to low doses of ionizing radiation should be considered for compensation if they develop cancer at these sites.

25. Page 36, para. 118:

The ICRP should clarify, from an operational and practical standpoint, why it is useful to determine one value of effective dose for both genders. The tissue weighting factor for breast increased almost threefold — an increase due exclusively to female radiation exposure. Given the rationale in Specific Comment #4 (above), the ICRP should clarify how it deals with gender difference in radiation sensitivity.

26. Page 36, para. 118:

The discussion is very confusing and introduces unnecessary complexity into internal dosimetry. It is not clear that when determining the effective dose for an individual, more accurate results are obtained by averaging in the dose to the pertinent tissues the individual would have received if they were the opposite gender, before applying the gender-averaged tissue weighting factors (as indicated in Equation 4.5).

27. Page 36, para. 120:

Equation 4.6 is unnecessarily complex. The equivalent dose for the remainder tissues can be summed over all 14 tissues, independent of gender. It only needs to be noted that the doses are determined with the appropriate gender-specific phantom, and that the dose to the uterus/cervix for a male is numerically zero, as is the dose to the prostate for a female.

28. Page 38, para. 128, last sentence:

Revise to state, “For infants and children, the dose is evaluated to a commitment period of 70 years.” The current text implies that the commitment period could be less than 70 years.

29. Page 39, para. 131, line 6:

Reference to Equation 1.9 should read 4.9.

30. Page 39, para. 133:

For clarity, the ICRP should explain what is excluded from “most situations,” or the second sentence should read, “The effective dose, E, can be estimated in cases of relatively uniform occupational exposure from operational quantities using the following formula.”

31. Page 42, para. 146, sentence :

Revise to state, “In the case of low individual dose which are small fractions of the radiation dose received from natural sources and may involve wide geographical areas and/or long time scales, the use of collective dose for risk estimates is not a reasonable procedure and should not be used in the decision making process and combines several sources of uncertainty.”

32. Page 42, para. 148:

The ICRP should clarify what “limiting conditions” it believes need to be set.

33. Page 44, para. 159:

The second sentence should be clarified by adding the phrase “… in the process of optimization.” The constraint sets the boundary of acceptable values for optimization of protection. The draft should be clarified to avoid any perception that a constraint exists outside of the optimization process. In this regard, the last sentence of the paragraph would seem to be incorrect.

34. Page 45, para. 162:

Revise the second sentence of the second bullet to read, “Emergency situations may arise from practices *or the malicious use of radioactive material*.” This change is necessary because the description of *emergency situations* is incomplete. Text should be added to encompass the theft and malicious use of radioactive material (e.g., a radiological dispersal device).

35. Page 46, para. 168, sentences 2 and 3:

We recommend deleting these sentences. Exposure of the fetus of a pregnant radiation worker should not be considered a public exposure. In Paragraph 81, the ICRP states, “in utero exposure should not be a specific protection case in prolonged exposure situations where the dose is well below 100 mSv.” To support this position, the ICRP cites a number of judgments first expressed in Publication 82.

36. Page 47, para. 170 and 171:

An occupationally exposed person is one who receives radiation exposure as a result of his or her work, but the worker “in controlled areas” is classified as such because of his location. This means that anyone in a controlled area is an occupationally exposed worker. Further, the implication seems to be that a worker not in a controlled area should be subject to public dose constraints for optimization, and subject to the public dose limit for their individual exposure. These definitions should be clarified.

37. Page 47, para. 174:

The last sentence introduces a conceptual problem and confusion. A constraint is a value applied in optimization, and is to be used prospectively. Therefore, it should not then be a value against which a planned exposure situation is judged. This type of language causes the continued confusion between a limit and a constraint. The last sentence could be modified to state, “Therefore, an individual dose from a single source in planned situations should be assessed using the results of an appropriately constrained optimization.”

38. Page 48, Section 5.5:

This section purports to address exposure of women. However, it actually deals with the mechanisms for protecting the embryo or fetus, and should be retitled.

39. Page 48, para. 177 and 178:

The recommendation that the dose to declared pregnant workers should not exceed 1 mSv appears unjustified and contradictory to the discussion concerning the radiation effects in the embryo and fetus in Section 3.2.4 and Publication 82. The ICRP should explain its rationale for the suggested recommendation, given the other statements in the draft publication.

40. Page 49, Figure 2:

The terminology in Figure 2 should be revised to be consistent with the definitions of exposure types included in Paragraph 162.

41. Page 50, para. 184:

Replace “most highly exposed individual’ with “representative individual”.

42. Page 50, para. 184:

The construction of the first sentence implies that a constraint could be used retrospectively to assess compliance, although this would be incorrect. We suggest modifying this sentence to state, “A dose constraint, therefore, ensures a fundamental level of protection will be achieved in a source-related assessment and optimization.” The last sentence again introduces confusion regarding the role of a constraint. The phrase “compliance with…” implies that the constraint is used in a retrospective manner, as if it were a limit. However, other portions of the recommendations clearly state that a constraint is a prospective tool, used in optimization, to establish the controls on a source.

43. Page 50, Response to ICRP Yellow Box Question for Justification:

The treatment of justification now appears to be generally adequate, subject to the specific comments provided for particular paragraphs.

44. Page 50, para. 185:

The discussion of the “principle of optimization” would have been the expected location for a succinct description of the “broader” view of optimization laid out in the foundation document, to explicitly consider prevention of accidents, generation of waste, and other attributes important to protection beyond doses to individuals.

45. Page 50, para. 185:

This section states that dose constraints are designed to prevent inequities in the optimization of protection. However, the ICRP states elsewhere that constraints serve the main function of protecting individuals against the possible effects of multiple sources of exposure. If this is the inequity to which this section refers, then some discussion should be provided to clarify these connections.

46. Page 51, para. 190:

Wording that appears elsewhere in this document, to the effect that radiation protection considerations serve as an input to the broader decision process, are equally applicable here for justification.

47. Page 51, para. 191, line 4:

To enhance clarity, revise this line to state, “although that justification lies more often with the medical practitioner than with the regulatory authority.”

48. Page 52, Response to ICRP Yellow Text Box Question for Optimization:

The treatment is not adequate. Confusion remains in various portions of the text with regard to the relationship between optimization and constraints, and between the use of constraints and the application of limits. In addition, the text does not mention certain concepts that were described as “broadening” the process. For example, the text offers no discussion of “stakeholders,” although this is a significant aspect of the foundation document presentation.

49. Page 52, para. 192:

To avoid the perception that constraints are a principle, the first sentence should be modified to state, “The principle of optimization of protection using constraints is….”

50. Page 52, para. 193:

This paragraph should be modified to reflect its historical context, since the next paragraph talks about broadening the process.

51. Page 52, para. 194:

From the foundation document, it was apparent that the “broadening” related to both involvement of stakeholders and ensuring individual equity, and the more explicit inclusion of other contributors to protection, such as waste disposal and accident prevention. However, the latter items are not included here.

52. Page 52, para. 194:

Confusion remains between optimization and safety culture. Optimization will not result in a safety culture, and a safety culture may not result in optimized activities. What is true, is that the tenets of a safety culture and, in particular, the mindset of continually challenging to ensure that safety is being achieved, are also key in the ongoing process of optimization. This relationship is not clearly articulated and, as written, this paragraph could be misinterpreted.

53. Page 52, para 196:

The dot-points seem to imply an order of consideration. If so, the point about considering the avoidance of accidents and other potential exposures for planned situations should be moved earlier in the sequence, before selection of the best option. The same dot-point should also reference waste disposal and other factors that may impact the level of protection provided.

54. Page 53, Response to ICRP Yellow Text Box Question for Dose Constraint:

The treatment of dose constraint is not adequate. Additional comments and requests for clarification and expansion are provided.

55. Page 53, para. 198:

Replace “most highly exposed individual” with “representative individual”.

56. Page 53, para. 198:

The phrase “The most fundamental level of protection is the source-related restriction called a dose constraint…” is confusing and misleading. The constraint is not “the fundamental level of protection,” particularly since bands of values are recommended, and values can be quite different depending upon the circumstances. What is true, is that “…a fundamental level of protection is provided by applying a source-related restriction called a constraint in the process of optimization.” Thus, the first sentence could be revised to state, “The dose constraint, or risk constraint for potential exposures (see Section 8), is used in the process of optimization to ensure adequate protection of individuals from a source of exposure.” The third sentence should also be revised to state, “They are used to ensure that an adequate level of protection is provided….”

57. Page 54, para. 200:

The third sentence should be amended to state, “Such constraints will always be less than *or equal to* the pertinent dose limit.” In addition, because the last sentence is awkward and repetitive, it should be reworded to state, “During planning of the operation, optimization of protection will establish a level of dose below the constraint.”

58. Page 54, para. 201:

We suggest stating, “It will usually be appropriate for dose constraints to be fixed at a local level, considering national requirements and the Commission’s guidance.”

59. Page 54, para. 202:

We suggest deleting the statement that “Epidemiological studies have shown a statistically significant excess of cancer deaths in populations exposed to doses in excess of around 100 mSv.” This statement implies a “dividing line,” when, in fact, there may not be one. The value of 100 mSv has significance only because it indicates the power limit of the statistical tests used to detect significant excess deaths. It would be better to state that for exposures above approximately 100 mSv, the risks for stochastic effects, as well as the occurrence of deterministic effects, are deemed to be unacceptable under most circumstances.

60. Page 54, para. 203:

It is difficult to understand how all of the values in the Commission’s previous publications can be regarded as constraints. Those values were developed from a variety of backgrounds, and some were provided as a line where no action was needed. This clearly conflicts with the definition of a constraint as a level where action is almost always warranted, and below which optimization is to be conducted.

61. Page 55, para. 205 and 206:

There is no clear rationale for providing bands of constraints, rather than upper limits of those constraints. In view of the requirement to optimize, the utility of the bands should be clarified. The bands do not consolidate or simplify the recommendations.

62. Page 56, para. 210 and 211:

Change and demote the responsibility of setting administrative dose constraints from national authorities to licensees or users of radiation/radioactive material. The ICRP recommends that national authorities be involved in setting dose constraints for licensees or practitioners. However, this would result in constraints becoming de facto regulatory limits. Implementation of this recommendation by the NRC would result in lower occupational and public dose limits (constraints) than those currently established in ICRP Publication 60 and Title 10, Part 20, of the *Code of Federal Regulations* (10 CFR Part 20). We strongly suggest that administrative constraints should be used on a case-by-case basis by regulatory authorities, and encouraged for use by licensees in most cases.

63. Page, 58, para. 217:

Considerable problems arise from the statement that a constraint should be established at 0.1 mSv for planned, unverified discharges into the environment. Since levels of 0.01 mSv are seen as not requiring any action (exempt), it is unclear regarding what remains for optimization. The existing statement implies a generic finding that the detriment associated with 0.1 mSv is sufficient to require some degree of expenditure of resources. This is incorrect. Furthermore, this statement is inconsistent with the ICRP's own recommendations regarding existing naturally occurring exposures.

64. Page 59, para. 219:

The ICRP should state its basis for the maximum recommended constraint for existing situations. In addition, the ICRP should clarify how a dose constraint that is five times the maximum occupational dose limit is acceptable for a member of the public under a non-emergency situation.

65. Page 58, para. 221, sentence 3:

To enhance clarity, we recommend revising this sentence to state, "Optimization is a continuous decision-making process, always questioning…."

66. Pages 58–59, para. 223 and 224:

These statements are inconsistent and seem to blur the selection of a constraint with the outcome of optimization. A "level of ambition" is not consistent with the earlier definition of a constraint as the level at which action is almost always certain to be necessary (as shown in Paragraph 224). As written, the process of setting constraints and then optimizing becomes confused and circular. Clarification is needed.

67. Page 59, para. 225:

The last sentence should refer to "Section 2," rather than Section 10, which involves protection of the environment.

68. Page 59, para. 226:

While it may be true that the result of optimization is a dose that is below the exclusion criteria, this is mere coincidence and not relevant. Unless the result of the optimization is that no further controls need to be applied and, thus, the source exempted, there is no reason to draw a relationship between the concepts. The last sentence introduces confusion and should be deleted.

69. Page 60, para. 231:

In paragraph 147, the ICRP specifically cautioned against computing cancer deaths based on collective doses involving trivial exposures to large populations. However, in Paragraph 231, the ICRP is assigning greater weight to moderate and high doses. This wording implies that some weight is given to low doses, which would establish a position different from the previously stated position.

70. Page 61, Table 5:

Note that this table is misnumbered, as are all the subsequent tables. For consistency with the statements in Paragraph 219, “existing exposure situations” should be added to the “20 to 100 mSv” band.

71. Page 62, para. 235:

Use of the phrase “tolerable exposure” implies a value judgment with which many stakeholders will not agree. We understand the phrase to mean that the exposure is within the bounds of the dose limits, but has not been subjected to optimization. Since an exposure is either acceptable or unacceptable, we recommend deleting this phrase.

72. Page 63, Table 6:

Note that this table is misnumbered. Also, Footnote 3 to Table 6 indicates that the skin dose subject to the dose limit is to be averaged over 1 square centimeter. However, experience has shown that this method is unnecessarily restrictive for the extremely non-uniform exposures from point sources (commonly referred to as “hot particles”) on or near the surface of the skin. Averaging over 10 square centimeters allows for the much higher localized doses that result from hot particles, while maintaining a sufficient margin to ensure that no tissue reactions result. See NCRP Report 130 for the supporting technical basis.

73. Page 65, para. 251, sentence 2:

This sentence should be revised to state, “The optimisation of protection in patient exposures does not necessarily mean the reduction of doses to the patient, but does not necessarily exclude it either.” For example, computed tomography imaging for pediatric cases requires a different setup than that used for adults. In this instance, optimization of protection for the pediatric patient does mean a reduction of dose, although it maintains the same image quality.

74. Page 67, para 261:

The ICRP should clarify which diagnostic procedures (particularly nuclear medicine procedures involving 131-iodine) increase the risk of damage to the fetus.

75. Page 67, para. 263:

In Paragraph 21, the ICRP states that its advice is aimed "principally at the regulatory authorities and operators that have responsibility for establishing protection standards, as well as their specialist advisors." However, as drafted, Paragraph 263 implies that pregnancies should be terminated for abdominal exposures above 100 mGy. A discussion regarding the termination of pregnancy is beyond the scope of this document, and should be held on a case-by-case basis between a competent medical practitioner and the patient. The ICRP should not propose any numerical value that could be the basis for terminating a pregnancy. Thus, this paragraph should be deleted.

76. Page 67, para. 264:

Delete this paragraph in its entirety.

77. Page 67, para. 265:

Delete this paragraph in its entirety. The material is repeated, verbatim, in the following paragraph.

78. Page 67, Section 6.4:

The section (including its subsections) does not actually provide any material related to optimization. Although it describes the appropriate constraints that might be applied, this only sets the boundary for optimization, and no discussion is provided regarding what optimization might entail in such cases. U.S. materials licencees are required to provide some instructions to family and caregivers when patients are released from the licensee's control. These instructions describe ways to reduce exposure, minimize contamination, handle waste products, and so forth, and are valuable contributors in optimizing the exposure of a caregiver. Much of what can be done to reduce exposure rests on the actions of the individual caregiver. Consequently, optimization is dependent upon providing information to these individuals and, if the patient is within the licensee's control, some monitoring and ongoing guidance. Failure to adhere to this instruction may result in substantial exposure to family members and caregivers.

79. Page 67, para 266, last sentence:

In keeping with the ICRP's desire that the constraint discussed in this paragraph should not be used too rigidly, we recommend deleting "young children and infants, as well as". NRC regulations permit children and infants to exceed 1 mSv, provided that guidance is provided to the children and their parents/guardians (ref. 10 CFR 35.75).

80. Page 68, Section 6.4.1:

Other than the statement in the last sentence of Paragraph 267, it is not clear what value this section adds. The section does not actually talk about optimization. Furthermore, because it is not clear how there is any linkage from caregivers to volunteers, this subsection does not seem to logically fit within the section on caregivers. Either additional guidance should be provided, or this section should be deleted.

81. Page 68, para. 269:

The paragraph should be deleted. It does not discuss optimization of patient caregivers, and this issue could be discussed elsewhere. Moreover, national authorities should not be involved in setting constraints for medical exposures to screen for preexisting medical conditions. Furthermore, there may be a number of cases (e.g., security screening) where a so-called medico-legal exposure should not be considered to be medical exposure at all. The NRC currently uses small fractions of the public exposure dose limits as constraints and guidelines in justifying, setting up, and using such systems.

82. Page 69, para. 275, line 2:

Delete “infants, young children and”. See the rationale in Specific Comment #77.

83. Page 69, para. 276, sentence 2:

This sentence should be revised to state, “The public dose limits and dose constraints for other individuals should be considered when authorizing the release of patients containing unsealed byproduct material or implants containing byproduct material. Medical practitioners should provide the released individual, or the individual’s parent or guardian, with instructions on actions recommended to maintain doses to other individuals as low as reasonable achievable if the total effective dose to any other individual is likely to exceed 1 mSv.” This recommendation is consistent with NRC regulations and the ICRP’s desire not to prescribe constraints that are unduly rigid.

84. Page 53, Response to ICRP Yellow Text Box Question for Natural Sources of Radiation:

The values in the ICRP’s previous publications on natural sources were characterized as action levels below which no further action was needed. However, the ICRP is now introducing all of those values as constraints, for which action is almost always needed, and for which optimization must then be applied to further reduce the exposures. Conceptually, these are completely different, and the ICRP has not adequately explained the need for a change in approach.

85. Page 70, para. 279:

Conversion of the ICRP’s action levels to constraints is a de facto reduction in exposures that are considered to be acceptable, even though the risks of radiation have not changed significantly. This requires additional explanation or justification by the ICRP.

86. Page 71, para. 286, sentences 3 and 4:

Sentence 3 is incomplete. (More what?) Also, it is unclear whether the reference to "this source" in the last sentence refers to thorium and uranium ingestion.

87. Page 72, para. 289:

The second sentence seems to require taking actions on existing facilities. This is not consistent with optimization. A risk-informed approach should be allowed, and the second sentence should be revised to state, "Steps may be needed to bring…."

88. Page 73, para. 294:

The last sentence contains an incorrect reference. Section 10 describes protection of the environment.

89. Page 76, para. 308:

The use of the terms "detriment" and "detriments" in this paragraph is not consistent with the usage in Section 3.2.3.

90. Page 77, Section 8.2:

Although we agree with the statements in this section, no specific guidance is provided on how to enhance radiation safety and security. Thus, the entire section should be either deleted or enhanced to provide recommendations regarding the types of considerations that a source user might pursue.

91. Page 77, para. 311:

Recommend adding a new sentence at the end of the paragraph, "In addition, the Code of Conduct on the Safety and Security of Radioactive Sources (2004) establishes basic principles applicable to the security of radioactive sources."

92. Page 78, para. 318, sentence 3:

The ICRP should clarify whether the generic risk constraint and radioactive waste constraint are annual or lifetime values. Further, the risk constraints are not the equivalent of the dose limits or maximum constraints, and there is no reason for the risk constraints to be more restrictive. Thus, this paragraph would benefit from the range of probabilities in a year from which risk constraints may be selected as presented in Table 1 on page 13 of ICRP Publication 64, "Protection from Potential Exposure: A Conceptual Framework." These probabilities should be reproduced here for completeness.

93. Page 78, para. 320 and 321:

The guidance on optimization for potential exposures is rather sparse and not well-developed. We suggest that the ICRP either provide more extensive guidance, or add a statement that this area is beyond the scope of these recommendations.

Optimization of protection is not a matter of safety culture. Although an effective safety culture will contribute to continuing efforts to optimize protection, they are not equivalent. Furthermore, the linkage is even more difficult to understand when dealing with potential exposures. One tool for achieving protection is recognizing the precursors of an accident. Procedures, engineering controls, and so forth are other tools for achieving protection.

94. Page 79, para. 323:

The last sentence seems out of place, and would be better located as the last sentence of Paragraph 322 if it is to be retained.

95. Page 79, para. 324:

Revise the first sentence to state, "There has been increasing concern internationally about the deliberate dispersion of nuclear and radioactive material to cause panic and chaos, and this has raised the awareness regarding the security of radioactive material."

96. Page 79, para. 327, lines 5 and 6:

Psychological issues should be clarified. We suggest revising "with psychological issues, such as distress, misattribution and fear of illness" to "with psychological issues, such as post-traumatic stress, the anxiety of future illness, and the misattribution of radiation exposure as the cause of any illness…." We also suggest deleting the references to a "starting point" in the second sentence, and clearly stating that typical medical precautions are generally adequate to protect the medical staff from the radiological hazards expected from an contaminated individual. In addition, this paragraph should include a statement that emergency planning for radiological attack events should include procedures for performing surveys and radiological triage of the injured persons for the purpose of protecting medical responders, and ensuring that needed medical assistance is not withheld because of misplaced fear of the exposure situation.

97. Page 80, para. 328:

This paragraph does not clearly distinguish that rescue operations should be regarded as emergency situations, rather than planned situations. As with any type of emergency situation, there may be reasons for higher constraints during the initial response, where the situation is not well-known and controlled (for example, rescue actions, life-saving, and activities to control the source of exposure). In the first sentence, we recommend changing "internationally accepted" to "nationally adopted." We also recommend deleting the last sentence. It is discriminatory to exclude female workers from employment as first responders because of their potential pregnancy or nursing status. In addition, Section 3.2.4 clearly states that there are no adverse effects below 100 mSv that should necessitate creating a special exposure case.

98. Page 80, Section 8.6:

Although this information is interesting, it is not clear how it contributes, in any way, to the substance of the recommendations. We recommend deleting Paragraphs 331

and 332. Alternatively, if Paragraph 332 is retained, we recommend deleting the third bullet because an abandoned cobalt therapy head was an orphan source, rather than an accident in radiotherapy. In addition, Paragraph 333 could be placed within the discussion of medical exposures.

99. Page 82, para. 338:

Although the conceptual approach of constrained optimization equally applies to emergency situations, the concept is clouded by the relationship of any so-called constraint with the protective action level or guide that is typically employed in planning for emergencies. Paragraph 348 states that these "PAG's" are the result of the constrained optimization, and not the constraint. The real intent of this paragraph seems to be that the purpose of a constraint in emergencies is to avoid tissue reactions. In Lines 11 and 12, delete "approaching that which would cause tissue reactions," The recommended level of dose that necessitates some kind of intervention, 100 mSv, is not a value that causes deterministic effects. Retaining this language would argue for a significantly higher level of dose before mandatory intervention would be needed.

100. Page 83, para. 339:

Add the following after the first sentence, "In ICRP *Publication 96*, additional recommendations were provided for protecting people against radiation exposure in the event of a radiological attack."

101. Page 84, para. 344, last sentence:

To enhance clarity, we recommend rewording this sentence to state, "The sum of the residual doses from all pathways after implementation of protective actions should be reviewed on a periodic basis."

102. Page 85, para. 350:

Revise to state, "It is important that decision makers involve the public in the decision-making process and inform the public of all aspects of their decisions, otherwise the public may be misled and the radiological protection efforts may be mistrusted."

103. Pages 86–87, Section 10:

Section 10 should be deleted, although the following relevant points could be retained in one or two paragraphs and added to Section 1.2 following Paragraph 22:

- There is no evidence that the current approach for environmental control does not provide adequate protection for the environment.
- There is no framework for consistent assessment of doses in the environment.
- Although the ICRP has identified a series of reference animals and plants for consideration in a system of environmental protection, the endpoints to assessing injury attributable to radiation exposure (e.g., chromosome aberrations, infertility, species extinction, etc.) have not been developed or agreed upon.

- Work continues to develop a framework for assessing and demonstrating environmental protection (and to acquire the necessary supporting data), but has not reached a stage of maturity to support any recommendations.
- Therefore, it is premature to propose a policy statement on protection of the environment until there is international consensus on the assessment framework.
- Finally, it is premature to conclude that any changes might be necessary in the ICRP system of source-related protection to ensure the continued protection of the environment.

104. Pages 88–94, Section 11:

This section should be deleted. The lengthy discussion of infrastructures, responsibilities, delegations of authority, provision of external expertise, occupational health services, and so forth, duplicate materials found in the IAEA and national regulations. They are not part of the basic recommendations needed for radiation protection.

105. Page 88, para. 361:

Revise first sentence to state, “Members of the public are often stakeholders when the development of decisions concerning radiological issues are to be taken, or have a legitimate interest in forming such decisions and reviewing information on how they were reached.”

106. Page 89, Section 11.1.1:

This subsection contains some useful statements regarding the role of the Commission’s recommendations in the broader context of providing protection. These paragraphs could usefully be retained elsewhere in the document (perhaps in Section 5, “The System of Radiological Protection of Humans”).

107. Page 92, para. 382:

Revise the second sentence to state, “These plans, by operating organizations and the regulatory authority, should be subject to periodic review.”

108. Page 93, para. 386:

Most material licensees do not have an occupational health service or any medical practitioners supervising the health of radiation workers. Some have radiation safety officers (or similarly designated individuals), who are responsible for radiation safety and instruction. Paragraphs 386–388 should be rewritten and additional information provided with the small business licensee in mind.

109. Page 94, para. 392:

Revise the third sentence to state, “ Verification procedures should include a review of quality assurance programmes, as well as inspection and enforcement programmes.” In addition, the next-to-last sentence states that inspection is a form of sampling. Although

true, this section should be expanded to note that proper inspection may also cover areas that cannot be viewed as sampling, such as verifying that proper procedures are in place for a variety of important functions, and that those procedures are being formally and periodically reviewed to ensure that they accurately reflect the current operating environment.

110. Page 95, Glossary of Key Terms and Concepts:

The glossary and text should be reviewed to ensure the inclusion of all key terms. A number are absent (e.g., intervention levels, constraint, etc.).