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"