ASSESSMENT OF AND COMMENTS ON THE 2005 INTERNATIONAL COMMISSION ON RADIOTHERAPEUTICAL PROTECTION RECOMMENDATIONS

In 2004, the International Commission on Radiological Protection (ICRP) issued its latest recommendations for comment. The recommendations have undergone comment and revision and the Health Physics Society (HPS) is pleased to have the opportunity to comment on the latest draft of the recommendations dated 05 June 2006.

The objectives of the new recommendations are to further clarify certain concepts and offer additional guidance for their proper use, summarize and bring together important points from publications since ICRP Publication 60 in 1991, and introduce some new terms and limits. Also included in these recommendations is an overview of radiation protection in the environment; this is an idea that was discussed in more detail in ICRP Publication 91 published in 2003.

General Statement
In general, the clarification of some concepts and the added guidance on the use of these concepts is well done. The addition of a glossary was very useful. However, the question remains as to the need and value of these recommendations and whether they are, in fact, new recommendations. There are very few changes recommended and the new sections generally end with the statement that information provided in previous reports is reaffirmed. In fact, ICRP recognizes this as shown in the following examples:

- “The Commission’s extensive review…has not indicated that any fundamental changes are needed to the system of radiation protection.” (Paragraph 12)
- “There is…more continuity than change in these revised recommendations…” (Paragraph 12)
- “Thus, the revised recommendations should not be interpreted as suggesting any changes to radiological protection regulations that are appropriately based on its previous Recommendations in ICRP 60 and subsequent policy guidelines.” (Paragraph 12)
- “The system of protection now recommended by the Commission is to be seen as a further clarification of the 1990 Recommendations.” (Paragraph 159)

Without a clear and substantiated explanation for the 2005 recommendations, the HPS is reluctant to support their publication.
Specific Thoughts and Comments

Individual Dose Restricted Values
In Paragraph 8, the document states that publications after and including ICRP 60 have over 30 different numerical values for restrictions on individual dose. While this leads the reader to believe that these new recommendations will review and consolidate this number of values, the new recommendations do not. When put in a table format (which would be a nice inclusion into a document that is reviewing fifteen of its publications since 1990), the new recommendations appear only to confirm all of the previously documented values.

If this document is published, we have the following suggestions:
- Include a table of the numerical values for restrictions for all publications after and including ICRP 60 with an indication whether the new recommendations change that value or have added new values.
- State at the front of the document (i.e. in paragraph 8) that while there are some 30+ numerical values throughout the various publications, all but [XX] remain unchanged.

Optimization
Paragraphs 13 and 192-197 discuss expansion of the use of optimization techniques to all controllable exposure situations as opposed to just medical scenarios. The HPS supports this expanded use as it is in keeping with the As Low As Reasonably Achievable principle.

Deterministic and Stochastic
Paragraph 29 introduces “tissue reactions” to be used interchangeably with “deterministic effects” and “cancer or hereditary effects” to be used interchangeably with “stochastic effects.” The reason given for this interchange is that “The generic terms, deterministic and stochastic effects, are not always familiar to those outside the field of radiological protection.” (Paragraph 49). The terms deterministic and stochastic have been used throughout numerous ICRP publications including those of NCRP, ANSI, IAEA and others, and in standards and regulatory documents.

While it is agreed that those outside the radiation protection arena may not understand the definition, it is not incumbent on ICRP to change terminology for that purpose. If documents are created to assist someone who wishes to understand radiation protection publication but is not in the field of or familiar with radiation protection, those then could include terminology that is less scientific. It also is not understood why only two radiological protection terms were chosen to define for better comprehension when it is well known that most of the terminology used in radiation protection is not well understood by those outside the field.

If this document is published, we have the following suggestions:
- Remove references to tissue reactions and cancer or hereditary effects and instead stay with deterministic and stochastic effects.
- If ICRP deems it necessary to make a change, then:
  - Switch to the use of one set of terms consistently rather than switching back and forth (tissue reactions and cancer or hereditary effects, or deterministic and stochastic effects); and
  - Give due consideration to modification of other radiation protection terminology that is not well understood.
Exposure Situations
Paragraphs 37, 162, and 185 introduce the situations where radiation exposure may occur as planned, emergency, and existing versus the previous “practices” and “interventions.” The Health Physics Society welcomes this clarification in light of how radiation protection has changed especially since 2001 with a significant emphasis on planning for events that may involve radiation dispersal. These distinctions are important with regard to the differences in the application of justification and optimization.

Radiological Practice in Medicine
Paragraph 40 provides no value. The discussion of the use of the term “practice” as it is used in medicine with no concrete concluding recommendation is not useful.

If this document is published, we have the following suggestions - either:
- Remove the paragraph in its entirety, or
- Recommend that the phrase “Radiological Protection in Medicine” be used instead of the generic term “practices” when describing a medical procedure(s) that uses radiation.

Use of LNT-Based Risk Model
(Paragraphs 55, 56, 58) With regard to the use of the LNT hypothesis, the Commission admits that uncertainties in health effects mechanisms exist that may not support LNT but that they are too great to judge their impact on the theory so they are dismissed. The commission does not acknowledge that human health effects data for exposures <0.1 Sv that use LNT also has at least as much uncertainty.

The Commission should acknowledge in their recommendations, if they continue to support the use of LNT, that the extrapolation of risk from large radiation doses to small radiation doses may not be valid. The Commission might also consider the following as it pertains to background information on LNT provided in the recommendations:
- “The Health Physics Society recommends that assessments of radiogenic health risks be limited to dose estimates near and above 0.1 Sv. Below this level, only [actual] dose is credible and statements of associated risk are more speculative than credible.” Health Physics Society Position Statement on Risk Assessment. 1995
- There is substantial scientific evidence that this model (LNT) is an oversimplification. It can be rejected for a number of specific cancers, such as bone cancer and chronic lymphocytic leukemia, and heritable genetic damage has not been observed in human studies.” Health Physics Society Position Statement on Radiation Risk in Perspective. 2004
- “…the question of the shape of the dose response relationship up to 20 mGy (2 rad) remains…” BEIR VII. 2006
- “…there is insufficient scientific evidence to support the use of the Linear No Threshold Hypothesis in the projection of the health effects of low-level radiation.” ANS Position Statement. 2001
Exclusion and Exemption
The Health Physics Society supports the concepts of exclusion and exemption as clarified in Paragraph 42, and agrees with the assessment in Paragraph 41 explaining why these categories are needed. Specifically, with respect to Paragraph 45, the use of ionizing radiation for security screening of persons should be exempt from certain controls and requirements with the criterion that the effective dose delivered is less than approximately 0.1 µSv.

Calculation of Risk at Low Doses and Use of Collective Dose
The Health Physics Society strongly agrees with Commission statements in Paragraph 57 that it is not appropriate to calculate the number of health effects at low doses and Paragraphs 146 & 147 on appropriate use of collective dose. In light of continued misuse, these positions should be highlighted in Commission summary statements if these recommendations are published. In addition, the Health Physics Society believes the scientific validity and reasonableness of assumptions regarding the estimation of cancer and genetic risk from radiation exposure only allows the risk estimates to be extrapolated out for a period in the order of several generations. The basis for this is that today’s limited knowledge of radiation risk mechanisms results in the necessity of knowing the lifestyles and underlying cancer and genetic experience of the population for which the risk is being estimated, and it is unreasonable to think these can be known beyond a few generations. Of course, this limitation may be changed as our knowledge of the radiation risk mechanisms improves.

Hereditary Effects
(Paragraphs 65-75) BEIR VII data also bears out that the risk of hereditary effects is quite low because there is no consistent scientific information suggesting otherwise. The Health Physics Society supports the lowering of the risk estimate.

Tissue Weighting Factors
(Paragraphs 113-120) There are new tissue weighting factors and a new calculation method for remainder tissues. The new weighting factors are based on updated tissue biological effect information – the most obvious change is that for the gonads due to the lowering of the risk for hereditary effects. With regard to susceptibility to thyroid cancer, Paragraph 113 includes a statement that the thyroid weighting factor is now 0.04 to account for the increased sensitivity of the thyroid in children.

The Health Physics Society suggests that in a few cases where the gender or age-related risks of radiation differ significantly, that the Commission include separate weighting factors. Two examples using BEIR VII data are thyroid cancer (an ERR for children <10 years old of 9.5/Sv and an ERR for adults of approximately 1/Sv) and female breast cancer (an ERR for women <35 years old of 13/Sv and an ERR for other men/women of 1-2/Sv).

The Health Physics Society would support the use of separate weighting factors when a population’s risk of a radiation-induced biological effect is significantly different than that of the average population.

Representative Individual
Paragraph 175 introduces the phrase “representative individual” to be used in place of “critical group.” It still is not clear why this change was necessary and how, operationally, representative individual should be used. It is our understanding that a report soon to be released (Publication 101) will explain this concept in more detail.
**Pregnant Worker**
Paragraph 177 states that the working conditions of a pregnant worker, after declaration, should be such that it is unlikely the fetus would receive an additional 1 mSv. This is the same constraint suggested in Publication 75, but differs from Publication 60 which suggests a constraint of 2 mSv.

While it is unlikely that the fetus of most occupationally exposed pregnant workers would receive an additional 1 mSv, the decrease from 2 mSv to 1 mSv is not supported. Information in Paragraphs 76-80 of the new recommendations in addition to new information provided in BEIR VII do not bear out any lessening of the constraint. Decreasing this constraint is not scientifically founded and could, if organizations adopt the recommendation as a policy, unnecessarily restrict the work that can be performed by interventional radiology and cardiology residents, and individuals who work in nuclear pharmacies.

The Health Physics Society does not support the decrease in additional fetal dose of a declared pregnant worker from 2 mSv (Publication 60) to 1 mSv (Publications 75 and 2005 New).

**Exposure of Pregnant Patients**
Paragraph 263 has a statement that doses below 100 mGy to the developing organism (embryo/fetus) should not be considered a reason for terminating a pregnancy.

While it is understood by HPS that ICRP is not suggesting that termination should, automatically, be considered above 100 mGy, we have strong concerns that this is what may be perceived leading to practitioners drawing a hard line when to terminate a pregnancy due to radiation exposure. Too often, radiation dose numbers to be used as guidelines are taken as rule because little other information exists.

The HPS recommends that this paragraph either be written more broadly with no dose number or omitted in its entirety.

**The Protection of the Environment**
(Paragraphs 351-357) The Commission should consider whether there is any evidence to show that, at current human protection levels, there is a possibility that some part of the environment would likely to be harmed. This might be a better way of looking at this matter before a specific approach is recommended. In short, the proposed approach is premature especially with regard to the statement that the Commission “believes that it is necessary to consider a wider range of environmental situations, irrespective of any human connection with them.” There appears to be no rationale supporting this.