



UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON NUCLEAR WASTE
WASHINGTON, DC 20555 - 0001

July 1, 2005

The Honorable Nils J. Diaz
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

SUBJECT: COMMENTS ON ICRP FOUNDATION DOCUMENTS – A FOLLOWUP TO THE
ACNW'S NOVEMBER 3, 2004 COMMENTS

Dear Chairman Diaz:

The ACNW has reviewed the five "Foundation Documents" offered by the International Commission on Radiological Protection (ICRP) in support of its 2005 Draft Recommendations. By this letter the ACNW reaffirms the recommendations in our November 3, 2004 letter and in the March 16, 2005 briefing to the Commission. Nothing in the Foundation Documents changes our earlier observations and recommendations.

As the ACNW stated, the Commission should consider deferring action on any of the Draft ICRP Recommendations until BEIR VII is published and available for review, and consider implementing changes in tissue weighting factors, radiation weighting factors, and more recent methods and models for assessment of internal dose. There is no urgent need to make these changes; they can be made when regulations are revised for other reasons.

The ACNW has several observations on the Foundation Documents:

1. As written the Foundation Document on the "Representative Individual" lacks clarity. Even though it usefully clarifies compliance with dose limits (constraints); the term "representative individual" is used in different senses in the document. The definitions and their applications need to be clarified. Examples could be used to convey the intent and use of the various dose assessment protocols and strategies discussed in the document.
2. Unless substantial clarifications are made to the definition and use of the "representative individual" concept, it offers little use when compared to the concepts of the "Average Member of a Critical Group" or the "Reasonable Maximally Exposed Individual" (RMEI).
3. Consistent with its November 3, 2004 letter, the ACNW recommends that the Commission defer consideration of the Foundation Documents regarding the "Biology" and "Dosimetry" until the BEIR VII Committee report is issued and available for review and comparison.

4. The ACNW believes that the additional guidance provided in the Foundation Document on "Optimization" would not substantially improve current ALARA programs, or protection of workers, the public, or the environment. The principle of stakeholder involvement discussed in the Optimization document is consistent with the Commission's current programs and activities as discussed in the agency's Strategic Plan and implementing documents.
5. Regarding the draft Foundation Document on "The Concept and Use of Reference Animals and Plants for the Purposes of Environmental Protection," the ACNW continues to hold the view expressed during our March 16, 2005 briefing to the Commission: that there has been no evidence to contradict the philosophy that by protecting humans the environment is protected. This Foundation Document tries to make the case that separate recommendations are needed or justified.

More detailed comments are given on the foundation documents in the Attachment.

Sincerely,

/RA/

Michael T. Ryan
Chairman

Attachment: Detailed comments on the
ICRP Foundation Documents

4. The ACNW believes that the additional guidance provided in the Foundation Document on "Optimization" would not substantially improve current ALARA programs, or protection of workers, the public, or the environment. The principle of stakeholder involvement discussed in the Optimization document is consistent with the Commission's current programs and activities as discussed in the agency's Strategic Plan and implementing documents.
5. Regarding the draft Foundation Document on "The Concept and Use of Reference Animals and Plants for the Purposes of Environmental Protection," the ACNW continues to hold the view expressed during our March 16, 2005 briefing to the Commission: that there has been no evidence to contradict the philosophy that by protecting humans the environment is protected. This Foundation Document tries to make the case that separate recommendations are needed or justified.

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Sincerely,

/RA/

Michael T. Ryan
Chairman

Attachment: Detailed comments on the
ICRP Foundation Documents

DOCUMENT NAME: C:\MyFiles\Checkout\Final ICRP letter final (July 1, 2005).wpd

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| OFFICE | ACNW | ACNW | ACNW | ACNW | ACNW |
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ATTACHMENT: DETAILED COMMENTS ON THE ICRP FOUNDATION DOCUMENTS

Foundation Document “Assessing Dose of the Representative Individual for the Purpose of Radiation Protection of the Public”

The document is very repetitive. Basic concepts, ideas, and approaches are repeated many times. Unfortunately, terms like “representative individual” are slightly different in each instance. The Abstract, Executive Summary, and Introduction all cover the same ground with different terminology.

The value of the document is derived from its focus on several principles:

1. Both nonstochastic (deterministic) and stochastic assessments have a place. The document offers comments on where each is best employed. The document should be more focused on this point. Clear examples should be given for each case and the limitations should be spelled out. A common criticism of nonstochastic analysis is that true risk can be missed. ICRP should offer a case to counter this assertion.
2. For nonstochastic assessments, doses below a limit (“constraint” in ICRP terminology) demonstrate compliance. This is a helpful statement.
3. For probabilistic risk assessment, the document suggests compliance with a dose limit: if the 95th percentile of the dose distribution is within a factor of 3, compliance is demonstrated. This needs clarification. Additionally, the ICRP should advise regulators on how to make the compliance algorithm clear. Examples would help to demonstrate these concepts.

Major drawbacks to the document are:

The “representative individual,” as presented in the document, is discussed in contradictory ways. Paragraph 23 states:

Therefore, for the purpose of protection of the public, it is necessary to characterize an individual, either hypothetical or specific, who receives the highest dose which can be used for determining compliance with the dose constraint. This individual is defined as the representative individual.

How can a representative individual get the “highest dose?”

Paragraph (S9) uses a slightly different definition:

The representative individual is the hypothetical individual receiving a dose that is representative of the most highly exposed individuals in the population.

This definition implies that the representative individual is a member (perhaps the average, median, or mode) of the most highly exposed group. This qualitative definition is subject to interpretation and is not consistent with paragraph 23.

Paragraphs 67 and 68 imply that the representative individual possessed “mean” characteristics regarding habits that are not “outside the range of day-to-day life.” This is not easily reconciled with the individual who receives “the highest dose.” ICRP needs to clarify the definition and guidance.

Temporal uncertainty and variability seem not to have been considered. It appears that the approaches to dose calculations address only uncertainty and variability in spatial data. This report seems to indicate that once determined (for a specific point in time), the parameters used to model pathways of exposure and calculated dose are fixed throughout the entire life span of the exposed individual. The dose calculations need to consider temporal uncertainty and variability over time. Both are known to be important.

Foundation Document “Biological and Epidemiological Information on Health Risks Attributable to Ionising Radiation: A Summary of Judgements for the Purposes of Radiological Protection of Humans”

1. This Foundation Document suggests small adjustments to “detriment adjusted nominal probability coefficients for cancer.” These small adjustments do not substantially change previous cancer risk values. In addition, additional analyses are expected in the Biological Effects of Ionizing Radiation Committee of the National Academy of Science Report (BEIR VII), expected later this year. The ACNW continues to believe that the Commission should consider deferring action on any of the draft ICRP recommendations until the BEIR VII Report is published and available for review.
2. A related finding is reported: “For cancer and hereditary disease at low doses/dose rates the use of a simple proportionate relationship between increments of dose and increased risk is a scientifically plausible assumption.” This conclusion further supports taking no action until the BEIR VII report is published. ICRP recommends no large changes in risk factors.
3. The Foundation Document states: “Knowledge of the roles of induced genomic instability, bystander cell signaling and adaptive response in the genesis of radiation-induced health effects is insufficiently well developed for radiological protection purposes; in many circumstances these cellular processes will be incorporated in epidemiological measures of risk.” The ACNW believes that this statement is a fair assessment of the state of knowledge of these issues at this time though new information is reported regularly. The ACNW will keep informed of newer studies and report to the Commission as appropriate.
4. The document states: “Proposed changes in radiation weighting factors for protons and neutrons are noted; these judgements are fully developed in the ICRP Committee 2 Foundation Document, Basis for dosimetric quantities used in radiological protection (FD-C-2)”. This additional report provides substantive detail. The Foundation Document on “Biological and Epidemiological Information...” states that: “New radiation detriment values and tissue weighting factors have been proposed; the most significant changes from ICRP 60 relate to breast, gonads and treatment of remainder tissues.” ACNW’s comments on FD-C-2 are provided separately below.

Foundation Document “Draft for Discussion International Commission on Radiological Protection Committee 2 Basis for Dosimetric Quantities Used In Radiological Protection”

The two principal recommendations in this report are to change the radiation weighting factors for protons and neutrons and change the tissue weighting factors used to calculate the effective dose (formerly referred to as dose equivalent).

For protons, the ICRP recommends that the weighting factor be lowered from 5 (the value recommended in ICRP Publication 60¹) to 2. Currently, in 10 CFR 20.1004, Table 1004(B).1, Quality Factors and Absorbed Dose Equivalencies, a quality factor of 10 is given for high energy protons. Consistent with our letter of November 3, 2004, the ACNW believes that the Commission should consider updating this quality factor, but that the update can be done by issuing regulatory guidance or at a time when the regulations are revised for other reasons. The ICRP has developed a method to calculate the quality factor for neutrons as a function of neutron energies. Three equations for three different energy ranges are recommended in Equation 4.7:

$$w_R = \begin{cases} 2.5 + 18.2e^{-[\ln(E_n)]^2/6} & , E_n < 1 \text{ MeV} \\ 5.0 + 17.0e^{-[\ln(2E_n)]^2/6} & , 1 \text{ MeV} \leq E_n \leq 50 \text{ MeV} \\ 2.5 + 3.25e^{-[\ln(0.04E_n)]^2/6} & , E_n < 50 \text{ MeV} \end{cases} \quad (4.7)$$

| Neutron energy (MeV) (thermal)..... | Quality factor (Q) 10 CFR 20.1004 (B) 2 | Values Calculated from New ICRP Methods | Ratio of ICRP Recommended Value to Current 10 CFR 20.1104 |
|-------------------------------------|---|---|---|
| 2.50E-08 | 2 | 2.5 | 1.25 |
| 1.00E-07 | 2 | 2.5 | 1.25 |
| 1.00E-06 | 2 | 2.5 | 1.25 |
| 1.00E-05 | 2 | 2.5 | 1.25 |
| 1.00E-04 | 2 | 2.5 | 1.25 |
| 1.00E-03 | 2 | 2.5 | 1.25 |
| 1.00E-02 | 2.5 | 3.0 | 1.21 |
| 1.00E-01 | 7.5 | 10.0 | 1.34 |
| 5.00E-01 | 11 | 19.3 | 1.75 |
| 1 | 11 | 22.0 | 2.00 |
| 2.5 | 9 | 19.8 | 2.20 |

The table above shows that the current quality factors for neutrons differ from those using the ICRP’s recommended formulas by factors ranging from 1.21 to 2.20. These factors are not substantially different and given the uncertainties in determining neutron spectra in practical

¹ ICRP. 1990 Recommendations of the ICRP. ICRP Publication 60. *Ann of the ICRP*, 21(1-3). Pergamon Press, Oxford (1991).

radiation protection situations, these factors may often be comparable to the errors associated with such measurements. Consistent with its letter of November 3, 2004, the ACNW believes that the Commission should consider incorporating this method of calculating neutron quality factors, but that the update can be done through regulatory guidance or at a time when the regulations are revised for other reasons.

This Foundation Document, along with the Foundation Document on Biological and Epidemiological Information, also suggests changes to tissue weighting factors:

“In the proposals for the new Recommendations the W_T for remainder (0.12) is divided equally between the 15 specified tissues given in Table 2, i.e. approximately 0.008 each. This value is smaller than the least value assigned to any of the named tissues (0.01). In practice this gives the arithmetic average of the doses to these 15 tissues. Since the formulation of remainder is the same in every case the system preserves additivity in effective doses which is a considerable advantage in practical radiation protection.”

This change clarifies how to calculate dose to other organs not specifically assigned weighting factors.

In changing these weighting factors, to be consistent it would be necessary to recalculate the existing Annual Limits on Intake and Derived Air Concentrations used in current regulations.

“The Optimisation of Radiological Protection - Broadening the Process,” Report by the ICRP Committee 4 Task Group on Optimisation of Protection

The ACNW observed in its letter of November 3, 2004, that

“current ICRP recommendations[are] sufficient regarding “optimization.” The Committee questions whether the draft ICRP recommendations are really improvements. ALARA as practiced in the U.S. provides a framework for accomplishing much of what the ICRP says about “optimization.” ALARA is well understood and ALARA programs identify both dose reduction opportunities and other safety issues. The draft ICRP recommendations would unnecessarily complicate existing ALARA principles and applications with new terminology or dimensions.”

The ACNW believes the additional guidance provided in this Foundation Document would not substantially improve current ALARA programs or protection of workers, the public, and the environment.

Additionally, this Foundation Document provides ICRP’s views on the “role of the stakeholder.” The ACNW believes that the Commission has developed significant initiatives to involve stakeholders in the regulatory process as described in the Strategic Plan and implementing documents and programs, particularly with regard to “openness” [reference: NRC’s Strategic Plan: FY 2000 - FY 2005, NUREG-1614, Vol. 2, part 1].

Foundation Document: “The Concept and Use of Reference Animals and Plants for the Purposes of Environmental Protection”

The ACNW believes that the ICRP has failed to make a case for overturning the principle that has guided radiation protection practice for more than 50 years. This principle states that protecting humans also protects the environment. The ICRP says in paragraph (6):

The Commission [ICRP] still believes that this judgement is likely to be correct in general terms, because the steps taken to protect the public, by reference to dose limits for them, have resulted in strict controls and limitations on the quantities of radionuclides deliberately introduced into the environment.”

The ACNW believes that the ICRP has not provided any evidence to contradict this long-standing principle.

Further, it seems clear that the ICRP’s guidance is driven by other concerns. As the ICRP states:

However, there are now other demands upon regulators, in particular the need to comply with the requirements of legislation directly aimed at the protection of wildlife and natural habitats; the need to make environmental impact assessments with respect to the environment generally; and the need to harmonise approaches to industrial regulation, bearing in mind that releases of chemicals from other industries are often based upon their potential impact upon both humans and wildlife.

The ACNW believes that this ICRP recommendation goes far beyond radiation protection issues and is more relevant to strategies for national policy on radiation protection. It is telling that in the last quote the ICRP cites “chemicals from other industries” as an example but does not explain why radioactive materials should be included with chemicals. The justification for this linkage is not clear and in any case is not developed or substantiated in the text.