

U.S. Department of Energy (DOE) Comments and Recommendations:

“Protection of Non-Human Species from Ionizing Radiation”
(ICRP Reference 02/305/02; Draft 2002-08-26)

To

International Commission on Radiological Protection
Task Group on Protection of the Environment

December 13, 2002

The U.S. Department of Energy (DOE) has been involved in the ongoing review and comment on “Protection of Non-Human Species from Ionizing Radiation” (herein after “Report”) as an official corresponding member to the International Commission on Radiological Protection’s (ICRP) Task Group on Protection of the Environment (herein after “Task Group”). This set of DOE comments and recommendations is offered in response to the ICRP’s decision to make the Report available for public consultation, and the ICRP’s request for comments on the Report by December 15, 2002. General impressions and comments on the Report are first summarized; detailed comments and recommendations follow. Note that any references identified in the comments below are already completely cited in the Report.

Consistent with suggestions made by several other corresponding members, we encourage the ICRP to prepare a comment tracking and resolution matrix that documents the disposition of all comments and recommendations received through this ICRP Report consultation process.

We appreciate the opportunity to comment on the Report and look forward to continuing our involvement in the Task Group and related ICRP meetings on this topic.

Summary Comments and Recommendations -

(1) The Report provides a good starting point for re-examining the ICRP’s 1997 policy statement that “if man is protected then other living things are also likely to be sufficiently protected.” The Report provides a useful background summary of the work that has taken place to date in this area by several international organizations and government agencies, to include DOE’s initiatives in this area. However, we believe that the Task Group’s recommendation to the ICRP Main Commission that the ICRP should proceed with a complex, comprehensive biota research and dosimetry development program is premature based on the current level of justification provided in the Report.

(2) The Task Group’s recommendation, with detailed specifics for its implementation, appears to have been conceived without sufficient analysis to justify its need. The proposed recommendation presumes that the case has been made that protecting man does not protect the environment. We agree that there may be certain environmental exposure scenarios for which explicit biota dose evaluations may help demonstrate to stakeholders and regulators that biota are protected from the potential effects of ionizing radiation. However, the Report, in both tone and content, appears out of balance regarding the overall potential for biota to be negatively impacted from the presence of anthropogenic sources of radiation in the environment. As such, it may give stakeholders, special interest groups, and the nuclear industry the impression that there is a bigger “problem” or “issue”

concerning radiation protection of the environment than actually exists. This is particularly so in light of the protection already afforded to the environment as a result of frameworks, practices, and regulatory standards in place for radiation protection of the public. More discussion should be added to the Report on the current level of protection already afforded to non-human species as a result of our protection system for man. The Report, based on a thoughtful analysis by the Task Group, should then emphasize those particular exposure scenarios or management decisions for which an explicit demonstration of radiation protection of biota may be helpful. From this assessment, the degree to which a comprehensive system (e.g., to include detailed dosimetric models) for biota protection is needed, versus the need for alternative approaches or perhaps application of currently available approaches within some consensus-based framework, can then be determined.

(3) Therefore, rather than placing such an immediate priority on the development of dosimetric models for biota, we believe that the ICRP's first priority should be to develop high-level umbrella policy and associated guidance on the topic of radiation protection of non-human species. The ICRP policy statement should be balanced, in that it: (a) clearly identifies those cases in which explicit demonstrations that non-human species are protected are warranted, and why they are warranted; and (b) should provide an indication that non-human species are already indirectly afforded a high degree of protection from our radiation protection system in place for humans.

(4) As a general observation, the Task Group does not appear to have addressed some of the stakeholder comments and recommendations that were provided in February 2002 at the Nuclear Energy Agency (NEA)/ICRP Forum on Radiological Protection of the Environment and summarized in the NEA Forum Summary Comments (as contained in the NEA Forum Proceedings). DOE participated in the NEA Forum and supports the NEA's role of facilitating the provision of stakeholder views and recommendations on this issue to the ICRP. Upon review of the NEA Forum Summary Comments, many of them do not appear to be addressed in the current draft of the Report. We suggest that, as part of the ICRP's consultation process on this Report, the NEA Forum Summary Comments be reviewed, and their disposition documented in a comment resolution matrix. Several NEA summary comments and findings from the NEA Forum are highlighted below for context as part of DOE's comments and recommendations.

(5) The Report comes across as presenting a single path forward in response to a perceived need for an immediate and comprehensive dosimetry, radiobiological research, and reference organism modeling initiative by the ICRP. In contrast, we believe that the Report would be more effective by presenting the ICRP Main Commission and its stakeholders with several potential ways for moving forward. These options might include qualitative approaches or use of operational practices that rely on optimization, ALARA, and pollution prevention principles, in addition to or in preference to the dosimetric and evaluation focus of the current Report. The NEA Forum Summary Comments highlight this point, stating that, for those scenarios where protection of man alone may not demonstrate protection of non-human species, "addressing these issues may not require an entire new ICRP recommendation based on a 'standard reference man' dosimetry approach for biota."

(6) The ICRP, in consultation with its stakeholders, should explore new ideas and approaches (e.g., to include a more performance-based approach) for demonstrating protection of non-human species over the current theme of evaluating the hazards of radiation through detailed dosimetric models.

(7) We are pleased that, compared to previous drafts, the current Report presents a much more inclusive and broader situational analysis of protection frameworks (and associated approaches, dose rate guidelines, and reference organism models) already under development or completed by other organizations and countries, including those developed by DOE.

(8) Relative to comment (7) above, the Report makes no mention that one workable option is to develop a framework along with supporting guidance for its implementation, without any ICRP development of standard reference organisms, as these and associated dosimetry models are already available or are under development (e.g., DOE's graded approach methodology employing reference organisms and derivation of screening values or "Biota Concentration Guides;" the Canadian Nuclear Safety Commission's (CNSC) tiered framework and application of screening protocols and reference organisms; the UK Environment Agency's reference organism approach; the Framework for the Assessment of the Environment (FASSET) which has a completion date of 2003). This option should be put forth in the Report.

(9) The ultimate framework for protection should be flexible such that users can select and bring into the framework those dose evaluation and modeling tools matched to the specific purpose and data quality objectives of their assessment. There are already many biota dose evaluation models and approaches under development or currently available that could be employed within a flexible, performance-based framework. It is noteworthy that this is the approach commonly applied in ecological risk assessments of non-radiological stressors. That is, there is no one single methodology or model that users must utilize. The user selects the analysis methods and models from among a variety of available approaches that meet the data quality objectives of their assessment. The important point here is that, regarding the development of a single, standardized ICRP approach, one size may not fit all. This point was raised several times at the NEA Forum (Sicily, Italy, February 2002) and at the Third International Symposium on Protection of the Environment from Ionizing Radiation (SPEIR3, Darwin, Australia, July 2002). As such, it needs to be a key guiding principle for the development of any ICRP framework.

(10) The ultimate framework should include provisions for screening (i.e., using radionuclide concentration levels in media that clearly are not harmful to the environment under bounding conditions) that can be employed along with more detailed organism dose modeling, ideally within a graded or tiered approach. Screening is valuable as a tool for demonstrating protection relative to recommended biota dose rate guidelines (e.g., as a compliance tool) and as a first step in ecological risk assessments of radiological impact. The benefits of screening are well described in IAEA Technical Document 1091 (July 1999); variations have already been successfully employed by DOE (DOE, 2002) and the CNSC. The availability of "graded screening models" was cited by Commissioner Paloma Sendin (Nuclear Regulatory Commission, CSN, Spain) at the NEA Forum in Sicily (February, 2002) as an important element of a framework to be developed for protection of the environment (refer to Commissioner Sendin's presentation slides, as distributed on CD by the NEA, which document this point). In DOE's NEA Forum presentation, we emphasized the need for and the value-added of a screening component within a tiered approach for evaluating radiation doses to biota. Mr. Ralph Anderson (Nuclear Energy Institute, USA), in his response to comments during his presentation at the NEA Forum, supported the application of screening approaches, stating that "screening is vital as a compliance tool." Finally, the [NEA Forum Summary Comments](#) state that the ICRP should "Acknowledge and encourage a phased or tiered approach to evaluating potential impacts to the environment, and to the amount of environmental monitoring that may be needed in support of the potential recommendations, to reduce the impact of the monitoring program on the environment." Hence, there is broad recognition that a screening component, preferably provided

within a tiered evaluation framework, would be a necessary element in any framework proposed and advanced by the ICRP.

(11) The potential second priority would then be to provide recommendations on acceptable effects endpoints and dose rate guidelines (or acceptable ranges of guidelines) for protection of biota. Virtually all evaluation methods are based on the calculation of a dose to biota, which is then related to or compared with dose rate guidelines or a unit of measure/threshold (e.g., radionuclide concentrations in environmental media) that is determined to be protective of biota. Consensus-based effects levels and dose rate guidelines (whether for broad groupings of biota types, for individual taxa, or expressed in terms of environmental media concentrations, or as increments of background) will be needed for the implementation of any framework that contains as an element the estimation of doses to biota. The dose rate guidelines recommended by the NCRP (in 1991) and IAEA (in 1992) for protection of populations (using reproduction as the critical endpoint of concern) have generally been well received, validated, and implemented by a number of countries and organizations. As a starting point these dose rate guidelines, along with additional data available from recent studies (e.g., through the FASSET effects database) and from other countries (e.g., Canada through the CNSC efforts) could be re-evaluated. Up-front discussions and agreements regarding the data quality objectives for inclusion and interpretation of available data (and the planned approach to be taken, such as generation of No Observed Adverse Effects Levels, NOAELs) would need to be carefully and thoroughly discussed and agreed upon prior to this effort.

The critical and key issue here is that, without the validation and/or re-affirmation of the currently applied NCRP and IAEA dose rate guidelines, or the development of consensus-based ancillary or alternative dose rate guidelines (or “benchmarks,” “consideration levels,” or some other acceptable terminology), risk assessors, regulators, and nuclear facility operators will be faced with many different and contradictory protection guidelines for biota that will complicate decision-making, particularly when working with stakeholders.

(12) The standard and accepted practice regarding demonstrations of protection of the environment (i.e., non-human species) from stressors or agents (e.g., chemicals) is at the population level. As such, the development of acceptable dose rate guidelines (or environmental media concentrations corresponding to acceptable dose rates) should be based on population-relevant attributes (e.g., effects on reproduction; mortality; morbidity). They should not be based on effects that, while observed at the individual or sub-individual level (e.g., cytogenetic effects), have no relevance to protection of populations or cannot be quantified in terms of their impact to populations.

As another example of the difficulty and misapplication of effects observed at the sub-individual level, consider the point made by Dr. Norman Gentner, chairperson of UNSCEAR, at the NEA Forum in Sicily (February, 2002) and as quoted from his presentation abstract: “A special caution is urged if data on radiation-induced mutations *per se* are utilized as part of environmental assessments, as the average rate of radiation-induced mutation applicable in the context of environmental risk assessment is likely to be much lower than assumed from studies of induced mutation in non-essential genes, which is usually what is involved. Findings from the UNSCEAR 2001 Report (‘Heredity Effects of Radiation’) illustrate this point.”

(13) The ICRP development of a standardized set of reference organisms and related dosimetric models (if determined by the ICRP Main Commission to be needed) should carry a much lower priority of activity than the development of a revised policy statement and the development of

acceptable effects endpoints and dose rate guidelines for protecting populations of non-human species.

(14) The Report should present the ICRP Main Commission with some insights as to which specific elements or options should be pursued first. As currently written, the Report seems to suggest that a comprehensive development program should be initiated, with all elements being equal in importance. A staged approach, with provisions for stakeholder involvement and feedback at each stage, would improve the likelihood of success and subsequent buy-in of any ICRP-developed approach and its individual components. The NEA could continue to facilitate this process for the ICRP. This staged approach and stakeholder support will facilitate and accelerate implementation which will move ICRP recommendations into use more quickly.

An “action plan” or a set of generalized tasks, timelines, and deliverables would be beneficial. This information would provide the ICRP Main Commission and its stakeholders with a better understanding and perspective of the general scope, resources, and timeframe that such an undertaking would require. This information would then help the Main Commission decide what level of activity the ICRP should pursue, which activities to concentrate on first, and which activities are most appropriate for the ICRP to pursue relative to the missions of other organizations (e.g., UNSCEAR; IAEA).

(15) A key initial activity that should be put forward in the Report as part of a recommended path forward is to first evaluate the strengths and areas of consistency/commonality for each of the methods already available or under development (as mentioned in comments 6 and 7). The results of this evaluation would provide the basis for the development of a potential ICRP reference organism approach that would stand a better chance of receiving buy-in, should it be needed or requested by the ICRP Main Commission.

(16) The NEA Forum Summary Comments include the point that “a program to validate the statements of the existing ICRP recommendations may be a more prudent strategy for the radiological protection of the environment and in any case is a necessary first step in determining if a ‘standard reference man’ approach should subsequently be developed for biota.” Perhaps the ICRP Task Group and/or a selected set of countries already possessing biota dose evaluation methods could conduct this validation exercise. For example, using available effluent release data and data from routine environmental surveillance programs, biota dose evaluation methods and models now available (e.g., DOE’s graded approach technical standard; Canada’s tiered approach; the UK Environment’s R&D Publication 128) and developed using ecologically-based exposure pathways could be used to evaluate the relative range of doses to biota that would be expected from the operation of commercial nuclear facilities, from other nuclear practices, or from sites with residual radioactive contamination. This could provide a relative baseline for deciding to what degree an explicit protection system for biota is needed, and for determining what environmental exposure scenarios and radionuclides warrant attention. Regardless of the analysis approach taken, some type of qualitative or semi-quantitative analysis is needed to help focus the need for an explicit radiological protection system for the environment.

(17) Relative to (16) above, it is very important to consider and estimate (at least qualitatively) the costs that could be incurred relative to the expected degree of increased protection of non-human species that is to be gained from implementation of an explicit protection system for biota as recommended in the Report.

(18) The Report suggests that the conceptual framework for protection of the environment could feed into the next set of recommendations regarding the ICRP’s recommendations for the

protection of humans (associated with its “recommendations for the 21st century”). This is apparent by the proposed use of bands of consideration or derived consideration levels for biota, similar in concept to that proposed by the ICRP for humans. Care should be taken not to pattern the approach for biota (e.g., applying a bands of consideration approach) solely for its ability to integrate with or be consistent with the ICRP’s recommendations for the 21st century. This would allow for consideration of approaches that may be more appropriate for non-human species.

Specific Comments and Recommendations –

(1) Section par. (1), section 1.1: The aims spelled out here indicate ICRP can contribute by developing a protection policy. Yet a protection policy or suggested policy statement for consideration is never explicitly presented in the Report. The thrust of the Report is on the development of a comprehensive dosimetric approach. It is recommended that a high-level umbrella policy statement be developed from which the assessment path forward can then be developed to meet the needs of the policy statement.

(2) Section par. (1), section 1.1: third bullet: Recommend changing the beginning of this to “proposing concepts and a possible framework...” AND changing the end to include: “...and ethical-philosophical principles, and drawing upon information and lessons learned from past and ongoing approaches for evaluating radiation impacts to biota.”

(3) Section par. (1), section 1.1: Recommend adding another bullet that states: “Considering progress and recommendations put forth to date on this subject through meetings and fora sponsored by international scientific organizations.”

(4) Section par. (7), section 1.2: There is no consideration or discussion of the use of optimization, ALARA, or pollution prevention practices and how these could be applied to protection of non-human species. This should be discussed in the current Report. Otherwise, one of the stated aims of the Report (integration with the overall protection system for man) cannot be achieved. The statement, “The Commission will address justification and optimization in its recommendations for the start of the 21st century, and will then have to decide how protection of other species will affect these concepts” does not address how the system for non-human species as proposed in the Report could be integrated with the system for man.

(5) Section par. (54), section 2.2: Recommend that the second (and last) sentence be re-written. Currently the discussion of the standard ecological risk assessment paradigm (problem formulation; risk assessment; risk management) is simply stated and then mentioned as: “their application can vary at a national level.” The entire concept of applying the ecological risk assessment framework (typically used for chemicals) as a framework for evaluating radiation as a stressor needs more attention and discussion here. We believe that the ecological risk assessment framework is general in nature and could be used for the evaluation of radiation, but not without some modification and provision of additional guidance. There are some noteworthy technical and implementation issues concerning the evaluation of radiation that require further consideration and elaboration. Some issues for radiation are the same as for chemicals, but some are unique to radionuclides. The paper by Jones et. al. (Principles and Issues in Radiological Ecological Risk Assessment; Journal of Environmental Radioactivity, 2002, In Press) explains these issues in more detail. This section of the Report requires more discussion of the unique considerations related to the application of the ecological risk assessment framework in evaluating radiation impacts. The development of a generalized, performance-based framework that can then be used by a variety of different users (employing the evaluation or assessment

methodology of their choice) and associated guidance should be considered a higher priority than the development of specific standardized dosimetric models, which is the current emphasis of the Report.

(6) Section par. (74), section 3.0: Given the discussion of the precautions and wide range of uncertainty in our ability, based on the current state of science, to determine the relevance of impacts at the sub-individual level (e.g., cytogenetic effects) to effects on individuals, and the relevance of impacts on individuals (and their numbers impacted) to populations, along with the uncertainties associated with the presence of other environmental stressors, it is not clear how the scheme proposed in Table 5.1 (application of Derived Consideration Levels) can be implemented on a technically sound basis. The use of the Derived Consideration Level approach, as shown, without some guidelines as to when and where each Level and Aspect of Concern are valid will be very problematical, in that stakeholders working with the users and regulators in a “problem formulation phase” of an assessment will naturally request protection to the most limiting endpoint or consideration level, which, as proposed, would be DNA effects. The concept of Derived Consideration Levels and the bands of concern as proposed will need serious debate and revision prior to any movement forward.

(7) Table 5.1: The following changes for “Aspects of Concern” relative to each of the Derived Consideration Levels are recommended: Level 5: change to “remedial action considered;” Level 4: change “concern” to “action;” Level 3: change “concern” to “action;” Level 2: change to “none;” Level 1: change to “none.”

(8) General comment regarding section 3.0: The entire section raises concerns by: (a) focusing on the effects at the sub-individual level (i.e., genetic effects) when this is an area for which the uncertainties on its relevance to protection of individuals, and populations is very large; and (b) not giving a more thorough situational analysis of the current state of science and degree of acceptability for the dose rate guidelines (e.g., 1 to 10 mGy/d) previously suggested in findings of the NCRP and IAEA. The following points need to be considered:

Regarding (a): There is no discussion of deterministic vs stochastic effects and the relative role of each in radiation effects to biota. The 1996 UNSCEAR report concluded that as long as the dose was kept below the criteria derived from dose-response relationships for reproductive effects, stochastic effects should not be significant at a population level. It is not known whether stochastic effects could cause harm in an individual organism (e.g., induction of a tumor that would result in premature death of an individual compared with the normal lifespan), and there are difficulties with interpreting the available data. First, the data on scorable cytogenetic effects appear to be considerably limited compared with the data on early mortality and reproductive effects. Second, although the available data in mammals and arthropods appear to indicate that scorable cytogenetic effects can be observed at dose rates roughly 100 times lower than the lowest dose rates causing early mortality and roughly 10 times lower than the lowest dose rates causing reproductive effects, it is difficult to interpret the significance of these effects in regard to harm to an individual organism (e.g., induction of tumors). For example, effects on DNA in humans who live in areas of unusually high natural background are easily observed, but increased incidence of cancers has not yet been observed in these populations.

Regarding (b): The 10 mGy/d dose rate guideline for protection of aquatic organisms and terrestrial plants, and 1 mGy/d for protection of terrestrial animals, have generally been well-received and applied by several countries and organizations, and remain scientifically sound for implementation. Yet the discussion of these dose rate guidelines, if any, has a negative rather than balanced tone and presentation. For example:

- In 1995, DOE held a workshop consisting of international technical experts who reviewed, validated, and re-affirmed the technical merits of applying these dose rate guidelines (Barnhouse, 1995).
- Recently, the UK Environment Agency reviewed the literature supporting these dose rate guidelines originally suggested by NCRP (in 1991) and IAEA (in 1992) and found that the data, coupled with “more recent studies provide further evidence that these values remain appropriate” (Coppelstone et.al., 2001).
- Consider also that in 1996 UNSCEAR summarized and reviewed information on the responses to acute and chronic radiation in plants and animals, both as individuals and as populations. Their conclusions were consistent with the findings of the NCRP and IAEA concerning the effects data and these recommended dose rate guidelines. In 2002, at the NEA Forum in Sicily (February 2002), the chairperson of UNSCEAR reported that, regarding UNSCEAR’s 1996 report, “The assessment by UNSCEAR provided dose-rate criteria: as an example, for natural plant and animal communities, a dose-rate of 0.1 mGy/h to a small proportion of individuals was deemed unlikely to have any detrimental effect at the population level. This and related dose-rate criteria remain defensible” (from: UNSCEAR abstract and presentation slides as contained in the NEA Forum CD distributed by NEA).
- In 2002, the Advisory Committee on Radiation Protection (ACRP), which was charged with providing advice to the Canadian Nuclear Safety Commission (CNSC) regarding approaches needed for the radiological protection of the environment, provided recommendations concerning appropriate dose rate criteria for protection of biota. The ACRP recommended that the generic dose rate criterion for protecting biota should be in the range of 1 – 10 mGy/d (CNSC, 2002).
- Therefore, given that many reviews and re-reviews of the available dose effects data have all resulted in the finding that these dose rate guidelines remain technically acceptable and generally appropriate, it seems that significantly different interpretations of the existing data, coupled with new data that would significantly contradict these findings, would be needed if the international community were to move away from these current recommendations. The Report should provide a more balanced presentation regarding past and recent technical reviews, acceptance, and current use of these dose rate guidelines, along with any needed qualifiers, based on our current scientific knowledge and understanding of radiation effects on biota, considering the references and points made above.

(9) Section par. (101), section 5.1: As written, the paragraph starts out with “A number of obvious questions have arisen around the dose-limit standard approaches...” Keeping in mind that all of the approaches presented in section 5.1 also have a number of “obvious questions” about them, we recommend either deleting the use of the terms in the first paragraph regarding the dose standard approach, or add to each of the other examples the terms “a number of obvious questions have arisen” at the introduction of each. Our recommendation is to change the first paragraph sentence to: “The implementation of a dose-limit standard approach requires consideration of the following:....” And then continue with: “by what agreed methodologies...,” etc. It also should be noted that many of the same questions posed regarding the dose limit standard approach can also be posed for the approach described in sections 102 and 103.

(10) Section par. (101), section 5.1: Related to (9) above, as a clarification to DOE's application of a "dose-limit" approach, it is important to clarify that, as stated in DOE's technical standard for evaluating doses to biota (DOE, 2002), section 1.2.2.4, "The biota dose limits specified in this technical standard are based on the current state of science and knowledge regarding effects of ionizing radiation on plants and animals. They should not be interpreted as a 'bright line' that, if exceeded, would trigger a mandatory regulatory or remedial action. Rather, they should be interpreted and applied more as 'Dose Rate Guidelines' that provide an indication that populations of plants and animals could be impacted from exposure to ionizing radiation and that further investigation and action is likely necessary." As such, the following sentence, "USDOE's dose limits are not applied as a 'bright line' such that their exceedance would require a mandatory regulatory or remedial action, but rather as Dose Rate Guidelines that if exceeded, provide an indication that further investigation and action is likely necessary," should be inserted immediately prior to the sentence beginning with, "A graded approach for evaluating radiation dose has been..."

(11) Section par. (101), section 5.1: the USDOE reference of "(US DOE, 2000)" should be changed to (US DOE, 2002)."

(12) REFERENCES section: For the "USDOE 2002" reference: delete the extra period after "USA"