

World Nuclear Association Annual Symposium
7-9 September 2005 - London

WNA Views on the ICRP Proposed Profound Changes to the Current RP System and on Continuing to Build an International Consensus towards an Improved Proposal

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For several years, international policy on radiological protection has been under discussion with a view to a significant revision (recently delayed until 2006-2007). The focal point of this discussion has been an evolving draft proposal of the International Commission on Radiological Protection (ICRP). The ICRP's seminal role in its field is well known. Generally, ICRP recommendations are translated into the international and national standards that govern industry operations worldwide.

The current ICRP draft proposal, which is entitled: "2005 Recommendations of the International Commission on Radiological Protection", was presented in May 2004 at a key international conference called IRPA-11. This proposal emerged from two earlier forums jointly organized by ICRP and the Nuclear Energy Agency (NEA) of the Organization for Economic Co-operation and Development (OECD). Moreover, following IRPA-11, ICRP launched an open consultation on its draft proposal that ended in December 2004.

This openness in the development of the next ICRP recommendations has been widely appreciated by the international RP community and no doubt helped many parties further reflect on the current RP system and on its potential evolution. Further to this open consultation process, ICRP acknowledged the overall negative reaction its draft proposal provoked. The key reasons that seem to explain this negative reaction are that:

1. The ICRP proposal includes a number of 'Profound Changes' to the current RP system
2. The general context does not warrant such changes
3. The overall rationale of the ICRP proposal is insufficient in view of such changes

The most fundamental of these ‘Profound Changes’ (detailed herein in [Annex A](#)) are:

1. The introduction of maximum dose constraints that are given a primary, broader and stricter role than the current dose constraints (defined as part of the current optimization procedure) and even than the current dose limits. *Figure 1* herein illustrates the potential magnitude of this issue for ‘Practices’.
2. An RP system to be based on natural background radiation rather than on the well-developed health risk-based approach of the current RP system.
3. A series of subsequent steps, beyond the introduction of a broad policy on the RP of non-human species, are prematurely introduced as an integral part of the RP system when the current common position of the international community (IAEA meeting in Vienna, June 2004) is to first develop an international consensus on the need for such a new component to the RP system, and then, if necessary, to develop and define its form and content. This effort is to be carried out through an IAEA plan of activities (yet to be approved by the Member States) that will coordinate, the input from many parties over the next few years, including that from IAEA, UNSCEAR, ICRP and many others. It would therefore seem more appropriate that ICRP puts forward its developmental work on non-human species for deliberation as part of this IAEA process before considering including it as an integral part of the RP system.

Key factors that show that the general RP context does not warrant such ‘Profound Changes’ include:

- There is widespread recognition of the need for stability in regulatory systems - many international and national regulations have only fairly recently been brought into line with the current RP system.
- The current RP system is working well for ‘Practices’.
- ICRP’s new scientific evidence that indicates that the overall risk from ionizing radiation is slightly lower than originally thought (ICRP60), is further confirmation of the adequacy of the current RP system.

Our views are that the current RP system can and should be improved through consolidation and simplification with substantive changes being focused to correct specifically identified shortcomings or weaknesses. For a careful and smooth evolution of the current RP system, it is essential that any proposed changes do not unnecessarily disturb the current RP system for “Practices” (e.g. see *Figure 1*). The ICRP draft proposal should clearly identify shortcomings or weaknesses and explain how it specifically helps to address them. It is precisely this overall rationale that is currently insufficient.

In March 2005, ICRP asserted that many comments on its draft proposal “arise because the Foundation Documents (FDs) have not yet been put out for consultation”. The resulting expectation was that ICRP’s five draft FDs¹ would complement its draft proposal (including the overall rationale of the proposal). ICRP’s openness with regard to the consultation on these draft FDs is appreciated.

Our review of these draft FDs confirms that they fall short especially in terms of an overall rationale for the proposed changes. In other words, the FDs do not seem to clearly identify the shortcomings or weaknesses of the current RP system or explain how the proposed changes specifically help to address them. We believe that before considering moving forward, this step is essential in order to fully understand and carefully assess any substantive changes to the current RP system. Concerning the ‘Profound Changes’ highlighted herein (Annex A), the FDs do not seem to bring explanations that would allow us to modify our position.

WNA therefore feels it important to first draw the attention of the international RP community to the WNA views about the ICRP draft proposal in the context of continuing to build an international consensus towards an improved draft proposal. In the next pages, these views are presented in the following categories:

- I. Areas that seem to be in line with the current international consensus
- II. Areas that seem to have evolved but need to progress further
- III. Areas that seem to depart from the current international consensus

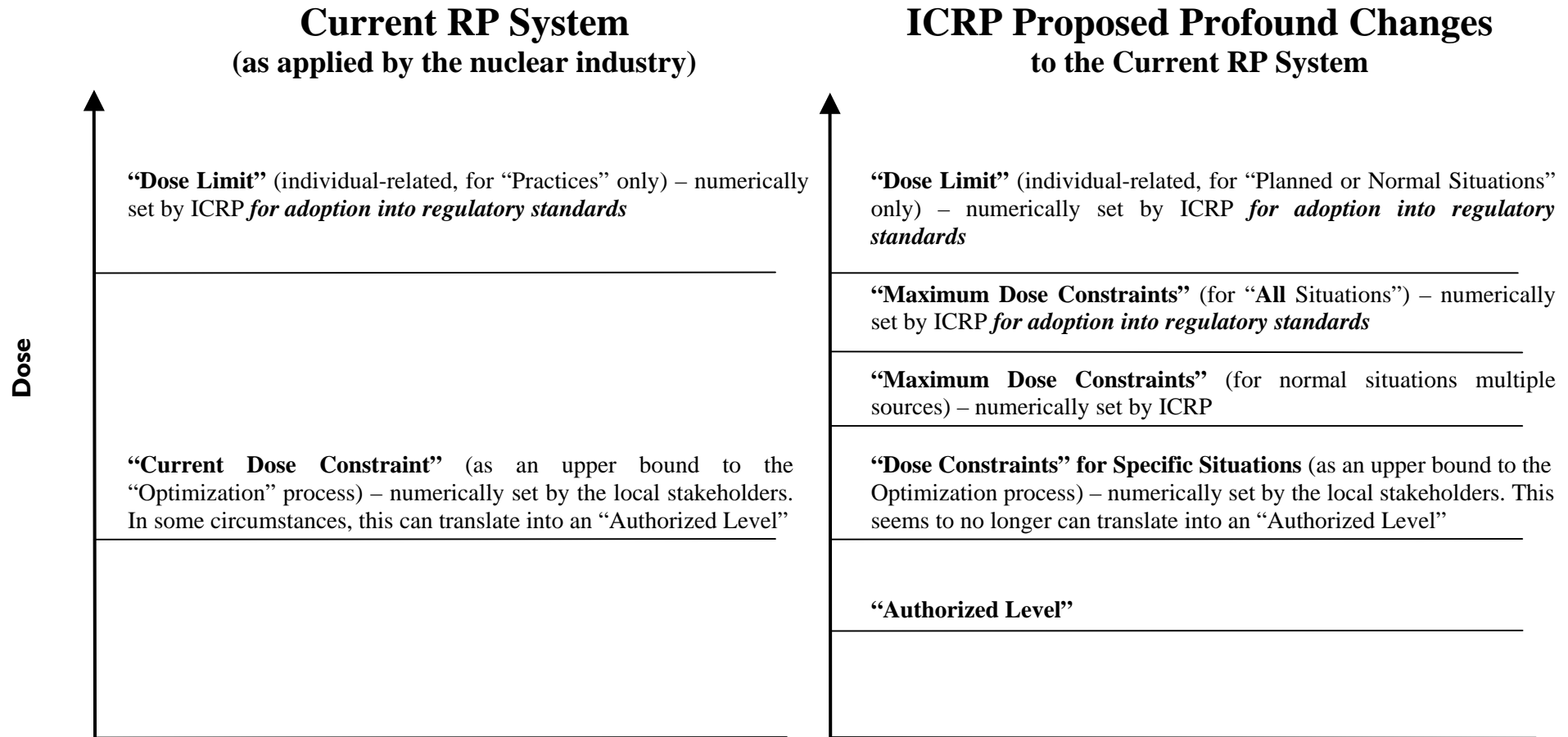
To complement our broad comments on the draft proposal, we also offer herein (Appendix E) a few specific comments on each of the FDs. Given the current Profound Changes in the draft proposal, we have not attempted to provide a comprehensive list of specific comments on the FDs. We feel it more appropriate to offer such more comprehensive specific comments at a later stage once the overall rationale of the ICRP proposal has been expressed more clearly. We hope that this overall rationale will help better understand the ‘Profound Changes’ that ICRP is proposing to the current RP system.

In view of the upcoming ICRP deliberations, we hope that this information could be useful to a wide range of interested parties for the preparation of their own submissions to ICRP.

¹ The ICRP five draft FDs are:

- 1. “The Optimization of Radiological Protection – Broadening the Process”
- 2. “Assessing Dose of the Representative Individual for the Purpose of Radiation Protection of the Public”
- 3. “Biological and Epidemiological Information on Health Risks Attributable to Ionizing Radiation: A Summary of Judgements for the Purpose of Radiological Protection of Humans”
- 4. “Basis for Dosimetry Quantities Used in Radiological Protection”
- 5. “The Concept and Use of Reference Animals and Plants for the Purposes of Environmental Protection”

Figure I
RP System for ‘Practices’



Note – Complementary information to *Figure I* is included in Annex D

WNA Views on the ICRP Draft Proposal (and FDs) in the Context of Continuing to Build an International Consensus towards an Improved Draft Proposal

I - Areas that seem to be in line with the current international consensus

1. “There is no hurry” – in terms of significant work that lies ahead for the development and completion of a suitable proposal for the next recommendations.
2. The overall intent to consolidate and simplify the current RP system with a view to making it easier to understand and comprehend.
3. The indications that the proposal “will consolidate and replace all the numerical advice included in and developed” since ICRP60 “(stand-alone document)”.

II - Areas that seem to have evolved but need to progress further

1. The draft proposal shows progress in terms of the consolidation of information into a main stand-alone document. ICRP should consider further consolidating this information. Key suggestions for the main stand-alone document are:
 - Significantly expand (preferably at the beginning) the rationale that identifies the specific shortcomings or weaknesses of the current RP system and explain how the proposal specifically helps to address them, without unnecessarily disturbing the rest of the current RP system.
 - Significantly expand (preferably at the beginning) the core information about the ICRP itself (its mission, role, aim, scope, etc., including its relationships with other key international organisations) so that a non-familiar reader can have a broader view and understanding of ICRP and of its recommendations. This would be of great value to a broad range of stakeholders.
 - Group all policies together along with the key numerical values of protection (i.e. dose limits). Simply stating that some or all post-ICRP60 policies continue to be valid does not really address the current concern about consolidation, simplification and clarity and in fact appears to be in contradiction to this objective. A stand-alone document explaining which values hold would be better.
 - Simplify the number of key numerical values of protection. At the international level, numerical dose limits should be kept whereas numerical maximum dose constraints should not as the latter cannot possibly be integrated without raising important issues about the current RP system. (Though, the current concept of dose constraints should be kept.) Annex B herein further elaborates on this issue.
 - The supporting scientific information (such as the radiation weighting factors) could be integrated into separate more detailed documentation. This would facilitate updating this data without triggering a review of the main document.
2. It is well recognized that the RP system for 'Intervention' is causing some difficulties. Further ICRP guidance in this respect would be most welcome

provided that it does not perturb the RP system for “Practices”. Some progress has been made but further guidance is needed. For example, guidance on the specific context for using higher values than the current dose limits for the public is needed. The role and content of dose constraints in the context of ‘Intervention’ are unclear and warrant further explanations.

Extremely low doses – ICRP should consider recommending more clearly, for sound policy making, a practical dose level (which would theoretically bear some tiny risks) from which protection should be systematically applied – and in turn prevent applying the RP system where it is unlikely to produce any substantive RP benefit. ICRP should consider incorporating this practical dose level in its guidance on estimating risk from ionising radiation and on the scope of application for “Collective Dose”.

Such a practical dose level is key for the overall coherence of the current RP system and is currently notably missing. It would also serve to better introduce the concepts of “Exclusion” and “Exemption”. These latter concepts are welcome but ICRP should consider further alignment with the international consensus reached by the IAEA (2004) ([Annex C](#)).

III - Areas that seem to depart from the current international consensus

The ‘Profound Changes’ addressed earlier herein depart from the current international consensus:

1. The introduction of maximum dose constraints: see *Figure 1*

We suggest keeping the current concept of dose constraints intact without introducing the concept of maximum dose constraints – which unnecessarily introduce multi-layers of dose constraints.

2. The RP system is based on natural background radiation rather than on the well developed health risk-based approach of the current RP system

We suggest keeping the current health-risk approach for the basis of the RP system while allowing natural background radiation to be used as a useful comparator and for practical context.

3. A series of subsequent steps, beyond a broad policy on the RP of non-human species, are prematurely introduced as an integral part of the RP system

For the time being, we suggest keeping the on-going ICRP developmental work outside of the scope of the draft proposal and of the FDs and ensuring that it is an integral part of the IAEA joint international effort (IAEA plan of activities, June 2004, Vienna, yet to be approved by the Member States). Once it is internationally road-tested and understood, the ICRP model on Reference Animals and Plants (definition and dosimetry) together with the similar developmental work of other key organizations, may eventually prove to be a key component in the development and definition of an RP system for non-human species.

Other subsequent steps (e.g., a common approach, assessment of effects, derived consideration levels, etc.) on the potential use of this model that are proposed by the ICRP are even more premature at this stage. For such steps, the consensus of the RP community is that any consideration should proceed with great deliberation at the IAEA level – before reaching the stage of an adequate assessment framework that complements current tools commonly used to demonstrate protection of the environment.

4. Other “Profound Changes”

- Practices and Intervention

We suggest that the concepts of “Practices” and “Intervention” should be re-integrated as per the current RP system. Further developing the guidance on the concept of “Intervention” would be an improvement. The role and content of dose constraints in the context of ‘Intervention’ are unclear and warrant further explanations.

- Optimisation or ALARA

We suggest that the “Optimisation” Principle or As Low As Reasonable Achievable (ALARA, taking into account social and economic factors) should be kept as per the current RP system. Removing the new concept of maximum dose constraints should help to achieve this. It should be borne in mind that both quantitative aspects and qualitative aspects (the latter include “safety culture” and “stakeholder involvement”) are integral parts of ALARA. This is already accounted for in the IAEA Basic Safety Standards (BSS). We therefore see no need to introduce a distinction between Optimisation and ALARA.

Best Available Technology (BAT), not entailing excessive costs, should be part of Optimisation with considerations for health-driven standards. This would be more consistent with the “Optimisation” Principle or ALARA and with the fundamental aim of the draft proposal which includes “the balancing of risks and benefits”.

We are concerned about the implication of the ICRP proposal that ALARA may be an endless downward process; e.g. continue optimising exposures until all parties involved are in agreement as a way to move forward, BAT without considerations for health risk, and 0.01 mSv/y as the minimum dose constraint which implies applying ALARA somehow blindly at even lower doses! This clearly shows that the concept of a practical dose level mentioned earlier (page 6 – item 3) is key for the overall coherence of the current RP system and is currently notably missing.

ANNEX A

ICRP Proposed ‘Profound Changes’ to the Current RP System

The highlights of our comments on the ICRP proposed ‘Profound Changes’ to the current RP system are presented below. For further detail on these comments and on other aspects of the draft proposal, please refer to our earlier letter to ICRP dated December 23, 2004.

1. The introduction of maximum dose constraints – See *Figures 1*

By ‘Profound Changes’ to ‘Practices’, we mean moving from the current RP system (as applied by the nuclear industry) consisting of:

- “Justification”,
- “Optimization” - with “Dose Constraint” which can, in some circumstances, translate into an “Authorized Level”
- “Limitation” (“Dose Limit”);

to the proposed RP system for “Planned or Normal Situations” consisting of:

- *Dose limit,*
- *Maximum Dose Constraints (for All Situations) that are given a primary, broader and stricter role than the Current Dose Constraints (defined as part of the current optimization procedure) and even than the Current Dose Limit,*
- *Maximum Dose Constraints (for normal situations multiple sources)*
- *Expanded “Optimization” - with Dose Constraints (for Specific Situations - as an upper bound to the Optimization process),*
- *“Authorized Level”.*

How could an RP system that includes dose limit, maximum dose constraints (two layers), dose constraints for specific situations (defined as upper bound to the optimization procedure) and authorized levels work better in practice? What are the differences between dose limit, maximum dose constraints, dose constraints for specific situations, and authorized level? How would this be simpler and easier to understand and comprehend? How could an RP system that makes dose limit secondary to more stringent maximum dose constraints be consistent with one of the main outcomes of the ICRP/NEA forum in April 2003 (Lanzarote, Spain) namely to “keep dose limit”? This implied that dose limit should remain the most stringent level of protection and that the concept of current dose constraints should stay intact as part of the optimization.

Concerning ‘Intervention’, the role and content of dose constraints are unclear and warrant further explanations. It would also be useful to further explain the relation between action levels and dose constraints in the context of ‘Intervention’.

2. The RP system is based on natural background radiation rather than on the well developed health risk-based approach of the current RP system

We recognise that a reference to natural background (including radon!) and to its inherent variability is a useful comparator and gives practical context for appreciating the appropriateness of protection actions. We believe that it is important to retain this.

However, assessment of dose limits must continue to be guided by the question of whether a significant health risk is posed. For example, linking the public dose limit to health risk evidence is extremely important even if this may involve accounting for some kind of a safety factor.

Current ICRP discussions seem to indicate that some connection is to be drawn between the world average natural background, which becomes 1 mSv/y if the contribution from radon is excluded, and the allowable public dose limit. The fact that this “without radon” level is roughly the same as the current public dose limit of 1 mSv/y is purely coincidental and has no scientific significance regarding the question of the adequacy of the public dose limit.

Moreover, it is important to keep the system flexible in view of potential future health risk evidence that may trigger changes to the key values of protection (e.g., dose limits). Irrespective of background, lower values may become appropriate should the risk from radiation be higher and vice-versa. The health risk assessment approach is fit for both human and non-human species. The case for moving away from a risk-based RP system to a RP system based on natural background radiation is not compelling.

3. A series of subsequent steps, beyond a broad policy on the RP of non-human species, are prematurely introduced as an integral part of the RP system

There is a wide agreement that the current RP system has in practice provided appropriate standards of environmental protection, but also wide acknowledgement that the system needs to be further developed for completeness in order to fill a conceptual gap (i.e., exposure of non-human species where human exposure is not the predominant concern) and to address some specific outstanding situations.

The IAEA, ICRP and UNSCEAR all have an important leadership role in ensuring a clear direction for future work and the co-ordination of activities to develop and implement a sound international framework for environmental RP. In exercising this leadership, the three organisations should collaborate on a joint “road map”. This effort is to be carried out through an IAEA plan of activities ((June 2004, IAEA Technical Meeting, Vienna, yet to be approved by the Member States) that will coordinate, the input from many parties over the next few years, including that from IAEA, UNSCEAR, ICRP and many others. It would therefore seem more appropriate that ICRP puts forward its developmental work for deliberation as part of this IAEA process before considering including it as an integral part of the RP system.

For the time being, we therefore suggest keeping the on-going ICRP developmental work outside of the scope of the draft proposal and of the FDs and ensuring that it is an integral part of the IAEA joint international effort. Once it is internationally road-tested and understood, the ICRP model on Reference Animals and Plants (definition and dosimetry) together with the similar developmental work of other key organizations, may eventually prove to be a key component in the development and definition of an RP system for non-human species. Other subsequent steps (e.g., a common approach, assessment of effects, derived consideration levels, etc.) on the potential use of this model that are proposed by the ICRP are even more premature at this stage. For such steps, the consensus of the RP community is that any

consideration should proceed with great deliberation at the IAEA level – before reaching the stage of an adequate assessment framework that complements current tools commonly used to demonstrate protection of the environment.

For a more complete WNA position on the radiological protection of the environment/non-human species, please refer to our earlier letter to IAEA, UNSCEAR and ICRP dated February 2, 2003.

4. Other ‘Profound Changes’

“Practices” and “Intervention”

- The key concepts of “Practices” and “Intervention” are replaced by the new concepts (not yet defined) of “normal operations” or “planned activities”, “accident or emergency situations”, and “controllable existing situations”; thus eliminating the important distinction between “Practices” and “Intervention”. It should be borne in mind that the well advanced international consensus on the “Principles of Nuclear, Radiation, Radioactive Waste and Transport Safety – DS298 – Safety Fundamentals” at the IAEA level, embraces the key concepts of “Practices” and “Intervention”.

Optimization

- By definition, maximum dose constraints are substantially different from the current dose constraints. This would imply corresponding changes to “Optimization”.
- Indicating that Best Available Technology (BAT) and “Optimization” complement each other, can possibly substantially modify the essence of the “Optimization” Principle. BAT not entailing excessive costs, should be part of Optimization with considerations for health-driven standards. This would be more consistent with the “Optimization” and with the fundamental aim of the proposal which includes: “the balancing of risks and benefits”.

ANNEX B

The Key Issue of Simplifying the Number of Numerical Values of Protection

Whereas there is a strong international consensus for integrating the current dose limits in a consolidated main document, numerical maximum dose constraints which would be more stringent than the current dose limits cannot be possibly integrated without disturbing the current RP system. Other key fundamental scientific values (such as the radiation weighting factors) can be integrated in separate ICRP documentation.

We recognize that industry and many others may not have reacted when such more stringent numerical dose constraints were published, but it should also be recognized that the ICRP process for dealing with these values has not been subject to the same level of openness and international discussions/debates that ICRP60 and the current ICRP draft proposal were subject to. Anyhow, the fact remains that the proposed basis for these values appears weak and that these values have still not benefited from a real debate. Should this be relevant, applying the new ICRP MUM (Meet Understand and Modify) approach would be most welcome here.

With this in mind, prudence and concern with regard to continuing to build a solid international consensus suggest that the case for having numerical maximum dose constraints in parallel to the current dose limits, thus interfering with the optimization process (accounting for social and economic factors), stakeholder involvement, and ultimately compliance matters, is not compelling. One cannot preclude that it may not be possible to define such values at the international level.

ANNEX C

Practical Dose Level for Making Sound Policy Making at Low Doses, Collective Doses, and Exclusion, Exemption and Clearance Levels

Practical dose level for sound policy making at low doses – Defining a dose level from which protection should be systematically applied – and in turn preventing the application of the RP system where it is unlikely to produce any substantive benefit – is a necessity for sound policy making. Based on Optimization and its essential aim of achieving a reasonable balance of risks and benefits, it is clear that down to very low and extremely low doses, such a practical dose level has an important role to play even if it would bear some tiny theoretical risks. ICRP should consider incorporating this practical dose level in its guidance on estimating risk from ionizing radiation and on the scope of application for “Collective Dose”.

We recognize that the context of the ICRP CI Task Group draft report may not be the suitable place to address this. However, the matter of adopting such a dose level on the basis of a reasonable balance between scientific and non-scientific issues should be seriously considered by the ICRP (at the upper level – e.g. Committee 4 or the Main Commission itself).

Collective doses – We welcome the ICRP effort in limiting the scope of collective dose. As such, we recognize the value of disaggregating the collective dose results, provided that this procedure also includes a dose level as mentioned above.

Exclusion and exemption levels – Similarly, we would welcome the concept of concentration levels from which protection should be systematically ensured. As part of optimization, provisions for higher concentration levels in the context of exemption and clearance levels would represent an improvement. This is another practical area where balancing beneficial actions giving rise to radiation exposure and the detriments of radiation exposure are particularly important. Further guidance would be welcome here. We would also welcome further alignment with the international consensus reached by the IAEA in 2004 on the key topic of exclusion, exemption and clearance levels.

ANNEX D

Figure 2
RP System for ‘Practices’

Key Features of the Current RP System:

- **“Justification”, “Optimization” and “Limitation”**
 - Well implemented into the regulatory context
- ***“Dose Constraint” as the upper bound of the “Optimization” process***
 - Well implemented into the regulatory context
 - “Dose Constraint” is numerically set by the local stakeholders
 - “Dose Constraint” for “Practices” can, in some circumstances, be translated into an “Authorized Level”
- ***Context of Application for “Practices”***
 - Well implemented into the regulatory context

Key Features of the Proposed RP System:

- ***“Dose Limit”, “Maximum Dose Constraints” and “Expanded Optimization”***
 - “Maximum Dose Constraints” (for all situations and for normal situations multiple sources) can interfere with “Dose Limit” and “Optimization”, thus it can in turn interfere with compliance matters and the “Current Dose Constraint” set by the local stakeholders
 - How “Dose Limit” and “Maximum Dose Constraints” can co-exist?
- ***“Dose Constraints for Specific Situations and “Authorized Level”***
 - Do the “Current Dose Constraints” remain unchanged – e.g. as the upper bound of the optimization process? What is meant by “Authorized level”?
- ***Context of Application for “Planned or Normal Situations”***
 - Do the fundamental concepts of “Practices” and “Intervention” (and their differences) remain unchanged?
 - Do “Planned or Normal Situations” are the same than “Practices”

Note: “Optimization” inherently accounts for social and economic factors.

ANNEX E

A Few Specific Comments on the ICRP Foundation Documents (These comments complement those already mentioned earlier herein)

1. *The Optimization of Radiological Protection – Broadening the Process*

- We are unsure about what is meant by “Broadening the Process”. If we have understood correctly, the report seems mainly to be about concepts of stakeholder involvement and of the quality of dialogue in the context of optimization.
- The document gives the impression that optimization or ALARA is currently at the stage of cost-benefit (technical) analysis rather than at the stakeholder involvement and dialogue stage, and in turn, promotes an apparent shift towards the latter. It also puts a disproportionate emphasis on subjective matters as if there were no rationale other than the dialogue itself (and its various elements such as opinions, consensus, etc.).

This view seems overly simplistic and far from the practical realities where stakeholder involvement and dialogue is already well implemented as part of ALARA (safety culture component). In doing so, it also tends to give the overall impression that stakeholder involvement and dialogue is much more complex than what is actually being done in practice. We also note the absence of any sense of hierarchy - which is normally expected in any responsible stakeholder process. We wonder what is the intended aim and objective of such a report in terms of practical guidance?

- Radiological protection can be viewed as consisting of three key components:
 - 1 - Design (e.g. defense in depth, etc.),
 - 2 - Management System (policies, work procedure, monitoring, etc.), and
 - 3 - People.

Safety culture relates to the latter item. For a Foundation Document on optimization or ALARA, it is striking to note that the first two essential components of radiological protection (Design and Management System) have been clearly overlooked. Without these two key components, the current principle of optimization or ALARA would be largely degraded. These two essential components (Design and Management System) of radiological protection should be fully re-integrated and well developed into this document on optimization or ALARA.

- Adding a definition of optimization and dose constraint would be helpful. Concerning dose constraint, we agree that:
 - It is set by the local stakeholders as an upper bound of the optimization process,

- It does not relate to regulatory matters unless otherwise specified by the local stakeholders. For example, in some circumstances, a dose constraint can translate into an authorized level.

We are not sure we understand the ICRP rationale for stating that:

“Quantified values of constraints are recommended by the Commission, which apply to all situations. They help in deciding which value to choose in a specific situation.”

It should be borne in mind that any numerical dose constraint set, at the international level, by ICRP at a lower value than the current dose limits, would interfere with the optimization process (accounting for social and economic factors), stakeholder involvement and dialogue, and ultimately with compliance matters. We would question the coherence of such numerical values.

- *Figure 1* is unclear and requires further explanations.
- This document does not seem to address ‘Intervention’, and in particular the role and content of dose constraints and its relation to action level.
- Given the ‘Profound Changes’ mentioned earlier, the disproportionate emphasis put on stakeholder involvement and dialogue, and the other issues just mentioned, we would like to better understand what is meant by: “The description of optimization is an evolution and consolidation, but not a fundamental change.”

2. **Assessing Dose of the Representative Individual for the Purpose of Radiation Protection of the Public**

- The overall direction in this document seems appropriate: definition of the representative individual, use of existing conditions as a starter to assess doses; and use of a sensitivity analysis as a complement.

3. **“Biological and Epidemiological Information on Health Risks Attributable to Ionizing Radiation: A Summary of Judgements for the Purpose of Radiological Protection of Humans”**

- Please refer to our earlier letter to ICRP dated March 24, 2005 (ICRP C1 TG Report).

4. **“Basis for Dosimetry Quantities Used in Radiological Protection”**

- Equivalent dose would now be called ‘radiation weighted dose’. This change does not seem compelling. Also, it might be more appropriate that these kinds of changes be led by organizations that are specialized in measuring units such as ICRU.
- More emphasis would be put on Annual Limit of Intakes (ALI) and on Derived Air Concentrations. This change is welcome.
- For ‘remainder’ tissues, $w(T)$ is divided equally between the 15 specified tissues leading to additivity in effective dose. This change is welcome.

- In equation 5.1 on page 34, the activity reduces with time and it is conventional to express dN/dt as negative
- Non-stochastic effects (ICRP26) were renamed deterministic effects in ICRP60. They would now be called tissue reactions. This repeated changing of names causes confusion. The same comment applies to the change of equivalent dose to 'radiation weighted dose'. These changes do not seem compelling.

5. “The Concept and Use of Reference Animals and Plants for the Purposes of Environmental Protection”

- As with the draft proposal, this document prematurely advocates, in various ways, that the need for integrating a non-human component to the current RP system already exists. We believe that it is precisely these kinds of important issue that remain to be put forward and deliberated with the international RP community as part of the IAEA plan of activities on the radiation protection of the environment.
- Concerning the various links to regulatory matters, the document is unclear and warrants further explanation. For example, paragraph 6 gives the impression that regulatory requirements that are directly aimed at the protection of wildlife and natural habitats already exist whereas paragraph 27 gives the impression that they are anticipated. It is also not clear if this refers to the international regulatory context or to another regulatory context.

Although broad requirements for the protection of wildlife and natural habitats and for the protection of endangered species do exist at the international level, their translation to the very specific domain of the effects of ionization radiation on animals and plants would seem exaggerated and perhaps even inappropriate if considered in isolation of the many other factors (environmental releases from all industries, including the impact of climate change, agriculture, urban development, etc.) that impact on the overall well-being of animals and plants. One cannot exclude, a priori, the possibility that the impact of low doses of ionizing radiation may not even play a part in the prevailing factors.

- We welcome the introduction of a policy that revolves around the radiological protection of animals and plants at the population level (or a higher organizational level). In this respect, paragraphs 246 and 247 of the draft proposal are key.

We welcome the early development of a framework for assessing radiation effects in non-human species – with the expectation that such a system would primarily aim at establishing the links (robust scientific foundations) between effects at the individual level and the corresponding effects at the species level in terms of frequency of effects that are relevant to this latter level. However, as this early development is less about the policy itself than about how to implement the policy, we are not convinced that the ICRP proposal or a Foundation Document is a suitable place to address this matter at this time. Alternatively, putting this ICRP developmental work forward as an input for deliberation at the IAEA plan of activities would be welcome.

We emphasize that the need/case for ICRP to focus at the individual level appears weak, and we therefore seek further clarification and explanation. Most current regulatory regimes aim directly or indirectly at the protection of animals and plants at the species level. Even efforts to protect individual rare or endangered animals and plants are aimed at protecting the remaining population of a species. We ask this: How, on a practical level, could the current widespread legal and

regulatory structure possibly be adapted to a new protection policy and assessment framework not designed for the protection of species or populations?

The technical difficulties and challenges for the development of the assessment framework (e.g. linking dose-response at the individual level and population effects level) should not be the driver of the ICRP policy on non-human species. Para. 247 of the draft proposal is key in this respect.

- Concerning subsequent steps (e.g. a framework, a common approach/system, new standards, any related control matters, derived consideration levels etc.) that go clearly beyond the introduction of a policy, we firmly believe that this is premature and should not be included in the ICRP proposal or in a Foundation Document. It would raise confusion and be misleading. We believe that it is also the kind of important issue that remain to be put forward and deliberated with the international RP community as part of the IAEA plan of activities on the radiation protection of the environment.
- The adequacy of the derived consideration levels approach remains to be demonstrated. We believe that a health risk assessment-based approach with guidance values of protection would be better and more consistent with the current approach used for humans (see also Annex A – item 2). One cannot exclude, a priori, that the derived consideration levels, which are based on a simple reference to natural background radiation, could translate into poor indicators of the real potential harm to the health of non-human species.
- Please refer to our earlier letters to ICRP dated December 23, 2004 and to IAEA, UNSCEAR and ICRP dated February 2, 2003. The latter offers a more complete WNA position on the radiological protection of the environment/non-human species.