Towards Greater Harmonization of the System of Radiological Protection - Views from the Global Nuclear Industry

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Abstract – The international system of radiological protection is currently under revision. At the governmental level, this is formally achieved through the revision of the IAEA Radiation Safety Standards. This process accounts for scientific developments on health risks from exposure to ionizing radiation as reported by UNSCEAR and by ICRP. In view of achieving a greater harmonization of the IAEA Global Safety Regime by integrating all safety fields, the novelty is that the revision needs to be driven in a top-down manner from the IAEA Safety Fundamentals (SF-1). This paper shows that IAEA BSS draft 1.0 was revised mainly using a bottom-up approach, from the new 2007 ICRP recommendations and upward. As this approach overwhelmed the benefits that come from the agreed top-down approach, BSS draft 1.0 contains many inconsistencies which do not lead to greater harmonization. This starts from the new ICRP approach on exposure situations, which cannot be common to all safety fields. Next, the new text on the Principles of Optimization and of Limitations is not fully consistent with SF-1. For planned exposure, dose constraint (DC) remains the No.1 issue as it cannot be clearly differentiated from limit or sub-limit. We see a continuously constructive role for DC only as a flexible tool that is part of Optimization. We noted that most of ICRP's guidance on emergency and existing exposure has not been integrated in BSS draft 1.0. The same applies to ICRP's guidance on non-human species. Behind this side step, there are considerable new and rather idealistic ICRP's concepts under development that pose issues. We advise caution before considering taking on board any of this new ICRP guidance. On the concepts of exclusion, exemption and clearance, we noted that BSS draft 1.0 departs from the current international consensus that led to IAEA Safety Standards (RS-G-1.7), thus requiring re-alignment.

KEYWORDS: harmonization, global safety regime, policies and standards, radiation safety, radiological protection, basic safety standards, industry, world challenge on energy-environment.

1. Harmonization of the IAEA[1] Global Safety Regime

Simply speaking, the harmonization of the IAEA Global Safety Regime aims at integrating the whole set of IAEA Safety Standards into a coherent and common system for the safe management of nuclear facilities and activities, as well as of sources of exposure to ionizing radiation. Why integrate safety? This need arose naturally from the increased development and implementation of quality management systems (QMS) which started in the late 1980s or early 1990s. Among others, a QMS facilitates conducting systematically the key standardized management tasks of quality management, namely: Plan, Do, Check and Act (PDCA). Nowadays, QMS is part of normal practice for a wide range of organizations and activities. For example, many organizations have obtained the ISO[2] certification on quality management (called ISO 9000) for QMS which govern all aspects of their activities. Others have also obtained the ISO 14001 certification on environmental management. The international recognition of a QMS, such as ISO, is often considered as a key asset.

As safety is paramount for nuclear facilities and activities, the application of QMS to safety matters is of particular relevance for nuclear-related organizations. This is particularly true for operators and regulators as they hold prime safety responsibilities. With many years of experience gained in QMS applied to safety in nuclear-related organizations, comprehensive QMS is currently the norm - the larger is the organization the more comprehensive is the QMS. The current level of integration of safety in nuclear organizations is easily noticeable at all management levels and in the workforce.

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[1] IAEA International Atomic Energy Agency of the United Nations

[2] ISO International Standard Organization

Another example of this integration is reflected in audit function of QMS. In fact, audits are no longer the affairs of a given safety field in isolation of management and of other activities. Instead, auditing is a key cross-discipline function. Typically, an audit is conducted by a team which includes an expert in the auditing process, a few experts of the given safety field which is been audited, and others. Today, the integrated management of safety is well entrenched in the nuclear community, both on the operator side and on the regulator side.

The above evolution is also transcending into the IAEA Safety Standards. At the top tier level, the starting point is the IAEA Safety Fundamentals (called 'SF-1') which were published in 2006 [1]. In short, IAEA SF-1 outlines ten common safety principles for the management of all safety matters that are within IAEA's scope: i.e. nuclear safety, radiation safety, waste safety, decommissioning safety and transport safety. What is the main change? Before, each safety field had its own set of safety principles, thus representing a source of inconsistencies and disharmonization between the safety fields at all levels of the IAEA Safety Standards: from the top-tier standards – the Safety Principles, down to the sub-tier standards - Safety Requirements and Safety Guides. This genuinely contributed to sustain a proliferation of sub-tier safety documents which resulted in a set of IAEA Safety Standards that is difficult to manage. In 2007-2008, the international nuclear community of experts developed and reached an international consensus which aimed at remedying this widely recognized issue. This consensus concerns the overall integration of the IAEA Safety Standards in a top-down manner, starting from SF-1 which is the main driver of this integration. This is the "raison d'être" of the on-going revision of all IAEA Safety Standards. Among others, a new integrated long-term structure has been issued for the IAEA Safety Standards, together with a road map (issued on 23 May 2008) [2] which outlines relevant guidance and criteria for the development of Safety Requirements and Safety Guides. As stated on repeat occasions by the IAEA Commission on Safety Standards (CSS), the overall goal is to end-up with a manageable set of IAEA Safety Standards. The recent road map specifies that the complete set of IAEA Safety Standards should '*consist of a manageable number of publications each of them being as concise as possible and addressing the essence of the safety issues*.'

1.1 Other Key Dimensions

1.1.1 Global Challenge of Growing Energy Needs and Environmental/Public Health Issues

It is widely recognized that world-scale growing energy needs and environmental/public health issues are the key challenges of the current era and that the two are closely interconnected. Also, if abstraction is made of the long-term security of energy supply, 'Energy' is local but 'Environment' is global – simply meaning that local energy choices can impact negatively or positively on the planetary environment. With this in mind, opportunities for negotiating growing energy needs tend to be limited and sensitive due to their direct link to local development. In other words, often, energy needs are virtually not negotiable. This means that progress on the energy-environment challenge relies more on wise choice of energy supply which can best mitigate growing environmental and public health issues. (Radiological protection of the public is a sub-set of public health.) Another key point to emphasize is an increasing need for a better balance between countries that are facing more pressing challenges, and those countries that can afford further delays – e.g. at the more local level, delays can be associated with a weak energy growth forecast for the coming decade in a context of acceptable environmental and public health issues that are not expected to deteriorate greatly.

At the international level, with the increasing pressure on governments and industry from around the world to deliver on clean energy (CO2 free) and on environmental and public health, it is clear that an adequate international system of safety standards (such as those of the IAEA) can no longer be developed in isolation of this world challenge. One of the key reasons for this is that international safety standards impact on regulations which in turn bear implications on the ranking of the energy sources that can help progressing on this world challenge. In other words, it may lead to using more or less of a given energy source with the caveat that some energy sources may carry much broader negative environmental and public health implications. With the important role that the global expansion of nuclear energy can play in the world challenge on energy and environment, it is clear that

IAEA must pay more attention to the development of a truly sound - meaning integrated and balanced - IAEA Global Safety Regime. The required institutional support for this should start from a clearer policy on energy and environment at the United Nations (UN) level, together with a clearer mandate for the IAEA and for the other relevant UN organizations to implement this policy as appropriate throughout their institutional programs. The same is also valid for the OECD[3] and its Nuclear Energy Agency (NEA). There is a compelling case for IAEA and NEA to ramp-up efforts on the world challenges. In comparison, much less gain is expected from IAEA and NEA at the site-specific level.

1.1.2 The Need for Greater Flexibility as Part of the Global Expansion of Nuclear Energy

The above also points to a need for greater flexibility in the IAEA Safety Standards which is necessary in view of better supporting a rapid expansion of nuclear energy, especially in developing countries which are striving to fulfil significant energy needs in a context where the deterioration of the environment and human health is already challenging. This should not be confused with the need for maintaining high standards in safety. For example, during the construction and the ramp-up phase of a large-scale energy generation plant (not limited to the nuclear sector) a great deal of flexibility is required (e.g. as part of the licensing process) in view of thoroughly testing and reaching the design capacity without undue delays. Once this is achieved, in-depth improvement programs which aim for greater efficiency of all aspects, including safety, are thoroughly implemented. The earliest this can be safely achieved the better. As part of comprehensive regulatory regimes in countries with large nuclear energy programs – all of them have experienced a long period of quasi-stagnant nuclear energy developments, it is not unusual to find some built-in features in licensing process, which are not necessarily sufficiently flexible for a nuclear new build phase as part of an era of challenging energy growth. Notwithstanding the depth of knowledge and expertise gained in nuclear technologies by these countries, one needs to be cautious before directly extrapolating such features to the IAEA Global Safety Regime. What suits countries with well developed nuclear energy programs and a stagnant energy demand for the coming decade should not be confused with what suits energy striving countries that rely on nuclear energy developments to help meeting immediately challenging energy demands and environmental issues.

2. Evolution of the Radiation Safety System as Part of the IAEA Global Safety Regime

As for all safety fields, the currently valid IAEA policies and standards in radiation safety were developed and issued in the 1990s - i.e. the IAEA Basic Safety Standards in 1996 [3] which is commonly called the IAEA BBS, in a context whereby each safety field was developed separately from each other. The IAEA BSS 1996 resulted from the usual process followed by IAEA to develop safety standards. For radiation safety, this process is mainly handled by the IAEA Radiation Safety Standard Committee (RASSC) which consists of radiation safety experts who officially represent the IAEA's Member States as well as a few relevant international institutions (e.g. World Nuclear Association for the global nuclear industry). Among others, the IAEA Radiation Safety Standards account for scientific developments on health risks from exposure to ionizing radiation as reported by UNSCEAR[4] and for the recommendations of the ICRP[5] that cover both the radiological protection (RP) system's philosophy as well as the underpinning scientific developments. UNSCEAR, which is part of the United Nations (UN) and which regroups governmental expert representatives, makes decisions on relevant scientific developments. ICRP, being a Non-Governmental Organization (NGO) of international experts, makes recommendations. IAEA, which is also part of the UN, makes decisions on the Radiation Safety Standards. Another notable difference is the fact that the UNSCEAR and the ICRP documentation are written for RP experts, whereas the IAEA Safety Standards (including the BSS) are written in regulatory-style for users. The latter are written more clearly and more concisely because they can be used directly by regulators as a basis for tabling national regulations, and by operators for implementation. As part of the IAEA deliberations, governmental representatives also have the key responsibility of accounting for broader challenges beyond the

[3] OECD Organisation for Economic Co-Operation and Development
[4] UNSCEAR United Nations Scientific Committee on the Effects of Atomic Radiation
[5] ICRP International Commission on Radiological Protection

technical aspects of radiation safety such as regulatory stability and potential implications (e.g. socio-economic) associated with changes to current standards.

The IAEA BSS 1996 is largely based on UNSCEAR 1996 [4] and on the 1990 ICRP recommendations [5].

Why change the current IAEA BBS 1996? As mentioned earlier, the main driver is no doubt the overall integration of all IAEA Safety Standards in view of a greater harmonization of the IAEA Global Safety Regime. This is to be achieved in a top-down manner, starting from SF-1 – IAEA's Safety Fundamentals. A second reason for updating the IAEA BSS is to account for the new 2007 ICRP recommendations [6] which were published early in 2008, with the important caveat that full consistency with SF-1 must be preserved for obvious reasons. For further context, it is also worthwhile to emphasize the following key points:

1) In agreement with its Member States, IAEA stated that regulatory stability is paramount – in other words, 'change for change' would be unwelcome.

2) UNSCEAR's 2006 [7] most recent analysis reported that the general health risk factor for human exposure to ionizing radiation remains unchanged. No change is also anticipated in the new UNSCEAR report to be issued in 2008. ICRP 2007 reported a slightly lower general risk factor compared to before in ICRP 1991.

3) ICRP's Chairman confirmed on repeat occasions that the new ICRP recommendations do not trigger any practical change for the nuclear industry.

- In other words, current practices (e.g. normal operations and emergency response) in the nuclear industry and the related regulations are already adequate, thus maintaining stability in the practical implementation of the RP system.

- With its new recommendations, ICRP hopes that RP practices such as those in the nuclear industry would be extended to the medical sector and to the non-nuclear industry sector (e.g. offshore oil and gas production, mining, phosphate fertilizer production) as there are widely recognized RP shortcomings in these two sectors.

4) Based on an key OECD-NEA consultation meeting (Tokyo, December 2007) on the new ICRP recommendations which closely preceded their issuance, in essence, the main message from governmental RP representatives was that they were comfortable with the new recommendations at the generic level (e.g. RP approach based on exposure situations: planned, emergency and existing) but that they were less comfortable about the specifics that are necessary for a common understanding and application of many key concepts. The concept of Dose Constraint (DC) was the No.1 issue followed by the issue of Reference Levels (RL). At the time, the necessary ICRP guidance that could help in better understanding the more succinct views on emergency and existing exposures in the new ICRP recommendations was not published. The recommendations on RP of non-human species were not well understood and required more development.

5) In view of achieving greater harmonization among national regulations, a proper sequence must be followed. In the past, some developed countries based their national regulations on ICRP 1991 and others (e.g. developing countries) based them on the IAEA BSS 1996. Some countries have even directly incorporated the IAEA BSS 1996 into their national regulations. This time, a proper sequence is to first complete the revision of the IAEA BSS. In doing so, due care is required for integrated safety management; consistency with SF-1 and a top-down revision approach; clarifying the key RP concepts and their application; and accounting for broader challenges that governments are facing. This key responsibility of government representatives cannot be delegated to any third party. Once the revision of the IAEA BBS is appropriately completed, national regulations could be revised accordingly, thus achieving greater harmonization.

2.1 Key Inconsistency Issues of the IAEA BSS 2008 draft 1.0 (July 2008) [8]

The following information highlights some key inconsistency issues related to the IAEA BSS draft 1.0 which was published in July 2008. BSS draft 1.0 reflects the current stage of deliberations on the revision of the IAEA BSS 1996. BSS draft 1.0 should derive from IAEA SF-1 and should account for the new 2007 ICRP recommendations as long as they are fully consistent with SF-1.

i) Re-Writing the Principles of Optimization and Limitations? – IAEA draft BSS 1.0 attempts to re-write a great deal of text on these two principles which are already well described in SF-1. To achieve full consistency with SF-1, draft BSS 1.0 should instead textually incorporate Principle 5 (Optimization of protection) and Principle 6 (Limitation of risks to individuals) of IAEA SF-1. Selecting different wordings for covering these essential aspects of the RP system into draft BSS 1.0 is not advisable as this would augment the risk of inconsistencies between the different safety fields.

ii) Shifting the RP System's Approach from 'Practices and Intervention' to 'Exposure Situations: Planned, Emergency and Existing' – Concerning radiation safety alone, this change would likely not cause significant practical issues. However, at the IAEA level, the RP approach by exposure scenarios does not fit well with the need for greater harmonization of the safety fields. For example, it is obvious that an exposure situations approach would not be appropriate for nuclear safety, transport safety, waste safety and decommissioning safety. What is common to all safety fields is the fact that regulators and operators control equipment, sites, facilities, people and activities. An exposure situation is a less tangible concept which represents the outcome of a person exposed to a source. As such, it can only be controlled indirectly. For all these reasons, it is probably better to keep a common safety approach for all safety fields as it is the case in SF-1. (This integrated safety approach is more consistent with the current mode of functioning – and its expected evolution - of an increasing number of regulators and operators which are now managing safety in an integrated manner.) The idea (see the current IAEA road map for the revision of all IAEA Safety Standards) that a revised BSS based on exposure situations can subsequently (as a second step) serve as the basis for the future General Safety Requirements – which integrate all IAEA Thematic Safety Standards (for which, exposure is not a driving parameter) – is another clear example that witnesses the RP community's difficulties in fully understanding the concept of integrated safety management.

iii) Planned Exposure Situation: Dose Constraint Remains the No.1 Issue

A flexible tool that is part of Optimization or a per source sub-limit? - Based on SF-1, the concept of dose constraint (DC) can only be one of the flexible tools of Optimization (see Principle 5 of SF-1). The latter covers a whole range of factors. Among others, it includes broad factors such as economic, social and environmental factors. It can also include other non-technical factors such as education, training and raising awareness. In other words, Optimization is achieved through a wide range of tools that cannot be limited to a dose level.

By applying Optimization with the necessary inherent flexibility, the nuclear industry has steadily achieved significant dose reduction over the last two decades. The concept of DC was subsequently created and introduced by ICRP as an attempt to match what was already implemented in practices. However, in doing so, ICRP made the concept of DC more rigid (i.e. restriction per source which is equivalent to a sub-limit to Optimization) - in comparison to the wide range of applications that were already place.

If any, what is the role of DC as a per source sub-limit? - In fact, this key issue directly derived from the 1st ICRP proposal (around 2002) which substituted dose limits (DL) by DC, thus making DC a more rigid concept analogous to a limit. By subsequently re-introducing DL while keeping the concept of DC in its proposals, DC *de facto* became analogous to a sub-limit: i.e. more restrictive than the dose limits. Based on Principle 5 of SF-1, it is quite clear that the concept of 'dose' alone is too simplistic for bounding or for restricting the Optimization in such a way.

As currently defined in BSS draft 1.0 and in ICRP 2007, DC cannot be clearly differentiated from the concept of limit or sub-limit. Such ambiguities cannot be appropriate in the context of international safety standards requirements (such as those of the IAEA) which by definition requires clearer (in regulatory-style) language for users. To illustrate this key issue, the reader is invited to closely examine the content (including the definitions) of BSS draft 1.0 about 'Dose limits' and 'DC and their application. In particular, we wonder how confusing wordings such as "restriction, upper bound, limit, etc." that are used in the definition and description of DC really differ from the concept of limit or sub-limit.

Why artificially fix DC per source when this differs from reality? - Moreover, as the concept of DC is fixed by source, we wonder if it reasonable to define 'source' '*as anything…*' (see BSS draft 1.0 definition) so that it can artificially fit in all cases? For example, the concept of DC per individual is often used in practices in the case of occupational exposure. What is the 'source' in this case: the physical source, the person's behaviour that results in doses, a combination of both, etc.? In reality, through good practice, DC can take various forms. For example, it can include dose targets, dose budgets and other dose-related forms that can be expressed in relation to different parameters such as a physical source, an individual, an activity, and a site or a facility. Flexibility should therefore be inherent to the concept of DC. There is no compelling case to make the concept of DC inflexible by fixing it 'per source'.

Invoking the notion of severe inequity as the main justification for the need for rigid DC? - We do not understand the justification given in BSS draft 1.0 (see art. 1.18). It seems awkward to invoke equity as the justification for rigid DCs in the RP system. Invoking '*severe inequitable outcomes'* is even more awkward. In fact, it is obviously too simplistic to claim that the notion of equity can be adequately dealt with simply by a dose level. Moreover, the logic seems reversed and incorrect: i.e. even more rigidity for public doses than for worker doses despite the fact that public doses are much lower than worker doses. Perhaps, equity can be invoked for the most exposed workers but it becomes meaningless for the less exposed workers and it becomes even more meaningless for public exposures. We are unaware of a practical case where equity would apply for public exposures.

When both limits and optimization are legally required, is there a need for extra more stringent legal instruments like DC at the international level and why? - We do not see a compelling case for adding stringency to Optimization by defining the concept of DC as an extra rigid instrument to restrict Optimization. In contrast, we see a continuously constructive role for DC as a flexible tool that is part of Optimization. DC and its application must be defined and described accordingly in BSS draft 1.0.

The risk of amplifying the imbalance in public RP policies - The IAEA should be particularly cautious about the introduction of any legal instrument (such as rigid DC) that is more stringent that the current public dose limit of 1 mSv/y. This is because of the key concern of amplifying the current imbalance in RP policies for the control of various types of public exposure to ionizing radiation. It should be emphasized that the public health rationale to justify why comparable levels of exposure are heavily controlled in some sectors (like in the nuclear industry) and are overlooked in some other sectors (like the medical sector and air transport sector) remains poor. For example, common public exposures such as a single chest x-rays or a passenger aboard of a one-way transatlantic air flight are comparable to the level of exposure received over the entire year by the most exposed residents living the nearest of large-scale nuclear sites! Such gap in RP policies could have been more understandable in the former context of a public dose limit of 5 mSv/y whereby many common public exposures could be more easily ignored. However, this gap becomes problematic with the current public dose limit of 1 mSv/y. The rationale for controlling these exposures more fairly or not goes beyond the RP community. In comparison, the usual justifications (voluntary exposure or benefit from the exposure, etc.) put forward by the RP community to explain this gap fall short.

iv) Emergency and Existing Exposure Situations: ICRP Rushing In Idealistic Changes – We noted that many of the new 2007 ICRP recommendations on these two topics have not been integrated into BSS draft 1.0. We therefore offer below some views on the ICRP Task Group 2008 draft report on emergency exposure ('*Application of the Commission's Recommendations for the Protection of*

People in Emergency Exposure Situations') [9] put-up for open consultation until early August 2008. As the ICRP Task Group 2008 draft report on existing exposure ('*Application of the Commission's Recommendations to the Protection of Individuals Living in Long Term Contaminated Territories after a Nuclear Accident or a Radiation Emergency*') [10] has just been issued in view of an upcoming OECD-NEA expert review meeting in early October, we have not yet commented on it.

Rushing in the ICRP development process - We emphasize that the ICRP process for developing new guidance on the important topic of emergency seems a little rushed – and we hope that the IAEA process will not become a hostage of this shortcoming. This rush occurred despite the fact that the document includes considerable new and rather idealistic concepts which do not necessarily match the reality well. Also, a lot of the guidance was rather off-target as it mainly aims at conditions that precede or follow the emergency itself. In other words, ICRP overlooked the 'during the emergency' situation which is the central topic. There was a consensus around these key findings at an expert review meeting of OECD-NEA in May 2008.

ICRP introduction of extra complexity and rigidity - We emphasize that although it is very easy to see the level of complexity (operational and else) and rigidity that this ICRP report [9] introduces about RP for Emergency, it is much more difficult to see (if not impossible) how it also '*provides a significant amount of increased flexibility…* (as claimed in the ICRP draft report). The report generally introduces and favours further complexity and rigidity around the concept of reference levels and of their numerical values. Like the concept of dose constraint (DC) for planned exposure, the concept of reference levels (RL) now introduced by ICRP for emergency exposure - as a mean to restrict Optimization (which is a flexible broader concept by definition) - is a key example of extra rigidity. The concept of Reference Levels cannot be clearly differentiated from the concept of a sub-limit. We also emphasize that by associating '*severe injuries*' with 100 mSv, ICRP is unnecessarily contributing to further ratcheting down the RP approach, whether or not this was intentional. Of course, such higher doses are extremely rare and they would most likely result only from a significant accident but it is a different matter and even incorrect to directly associate them to severe injuries. In fact, scientific health data suggests that the actual range for severe injuries is rather closer to 1,000 mSv. For such a judgment call on the scope of 'severe injuries', it would be key (and unavoidable) to fully rely on the expertise of the medical profession. Both the extra complexity and rigidity are not welcome and contradict the current need for more simplicity and flexibility that governments and industry are seeking for the integrated management of safety (i.e. harmonization of the Global Safety Regime).

Emergency Response as part of integrated safety management - It is also difficult to see how such detailed level of guidance for RP alone (in isolation of the rest) is appropriately balanced and proportionate relative to all aspects (not just RP and radiation exposures) and the multiple dimensions that must be dealt with as part of Emergency Preparedness, Response and Management. A much better approach for useful practical guidance on Emergency is to develop it in a top down manner as part of a common approach for the management of all safety aspects (including RP) with proportionate efforts on each of these aspects. For example, integrated safety management must be capable of adequately dealing with simultaneous events such as a fire, an explosion, a nuclear criticality event, etc. …and an emergency exposure situation.

ICRP triggering significant practical changes or not - We therefore wonder what the ICRP now practically means by the following statements in the draft report: '*...However, the advice contained in these new recommendations has important implications for emergency preparedness and response.'* If the latter is true and that the draft report has been developed accordingly, it would be incompatible with the repeated commitment by the ICRP Chairman that the new ICRP commendations do not trigger any practical changes.

v) RP of Non-Human Species – As for emergency and existing exposure situations, we noted that the ICRP guidance on RP of non-human species in the new 2007 ICRP recommendations and in two ICRP reports in 2003 [11] and in 2008 [12] have not been integrated into BSS draft 1.0. We therefore

offer below some views on this ICRP documentation. For our more complete views on this topic, please see the related WNA paper in 2008 [13] as part of IRPA12's proceedings.

Although the new ICRP recommendations contain broad wordings on RP of the environment and on non-human species, they offer little in terms of an assessment framework and of a compelling case for such assessments. In fact, RP of the environment remains narrowly covered through the new concept of reference animals and plants. This new concept, pushed forward by ICRP 2003 and 2008 as a new policy tool, falls short of playing any role of significance in 'real' environmental protection (including its demonstration). To illustrate this, it is easy to imagine that for the protection of the marine environment (e.g. fish health and public health related to fish consumption), radiation effects on animals and plants are not even part of the prevailing factors that are widely known to adversely impact the environment: e.g. overfishing, oil spills, climate change, chemical releases, etc.

Moreover, there is a strikingly imbalanced and huge gap throughout this ICRP documentation between a wish to stimulate scientific developments in the narrow field of radiation effects on animals and plants and the act of demonstrating compliance which requires matured and well established scientific knowledge and expertise. In fact, this report confuses the scope of existing environmental protection regulations (e.g. regulations on endangered species and biodiversity) with the narrow topic of radiation effects on animals and plants. As the latter is rather trivial, it is clear that such a narrow demonstration would add little to a 'real' demonstration of environmental protection that account for the prevailing factors that do impact on the environment. We emphasize that an independent expert overview conducted by SENES Consultants [14] '*has confirmed that both people and nature have been adequately protected from radioactive releases from all kinds of nuclear sites, old and new*.

vi) Exclusion, Exemption and Clearance that Departs from the Current International Consensus – On such an important topic with a wide range of implications worldwide, we are surprised to note that the IAEA BSS draft 1.0 departs from the current international consensus (in the form of standards) reached by IAEA in 2004 (commonly called IAEA RS-G-1.7) [15] after more than ten years of difficult negotiations between the Member States. In particular, we note the omission of the provisions that made this important consensus applicable to larger quantities of radioactive materials. It is widely known that the latter was a key basis of this consensus, as otherwise the standards would only apply to small quantities of radioactive materials, thus considerably reducing the scope of RS-G-1.7. IAEA BSS drat 1.0 requires re-alignment.

3. Summary Conclusions

The above shows that IAEA BSS draft 1.0 was revised mainly using a bottom-up approach, from the new 2007 ICRP recommendations and upward. This approach overwhelmed the benefits that come from the agreed top-down approach (including ensuring consistency with IAEA SF-1) that should drive the revision of all IAEA Safety Standards. This top-down route of integrating all safety fields was chosen to achieve greater harmonization of the IAEA Global Safety Regime. The main task of integrating safety standards being not really compatible with a bottom-up approach, it is evident that the new 2007 ICRP recommendations (with a restricted scope to radiation safety) cannot alone be used as the basis of the IAEA Radiation Safety Standards. Possibly, the concept of integrated safety management was not sufficiently well understood by the RP community during the BSS revision.

As a result, the IAEA BSS draft 1.0 contains many inconsistencies which do <u>not</u> lead to greater harmonization of the IAEA Global Safety Regime. This starts from the new ICRP approach on exposure situations which cannot be common to all safety fields. Next, the new text on the Principles of Optimization and of Limitations is not fully consistent with SF-1. Instead of this text re-write, for consistency, it would be better to simply incorporate the relevant text of SF-1. For planned exposure, dose constraint (DC), which is also inconsistent with SF-1, remains the No.1 issue as it cannot be clearly differentiated from limit or sub-limit. We see a continuously constructive role for DC <u>only</u> as a <u>flexible tool that is part of Optimization</u>. We do not see a role for DC as any form of limit or sub-limit, or as any extra legal instrument that is more stringent or rigid than the dose limit? As shown earlier,

invoking the notion of '*severe inequitable outcomes'* as the main reason to justify the need for such DC is awkward - especially in the case of public exposure.

IAEA should be particularly cautious about the introduction of any legal instrument (such as rigid DC) that is more stringent that the current public dose limit of 1 mSv/y. This is because of the key concern of amplifying the current imbalance in RP policies for the control of various types of public exposure to ionizing radiation. It should be emphasized that the public health rationale to justify why comparable levels of exposure are heavily controlled in some sectors (like in the nuclear industry) and are overlooked in some other sectors (like the medical sector and air transport sector) remains poor. The rationale for controlling these exposures more fairly or not goes beyond the RP community. In comparison, the usual justifications (voluntary exposure or benefit from the exposure, etc.) put forward by the RP community to explain this gap fall short.

We noted that most of the ICRP guidance on emergency and existing exposure situations has not been integrated in BSS draft 1.0. We emphasize that the ICRP process for developing this guidance is rushed and that the guidance includes a considerable amount of new and rather idealistic concepts which do not match well the reality. We advise caution before considering taking on board any of this new ICRP guidance. The same applies to the ICRP guidance on RP of non-human species, though in this case, a lot of the on-going effort is at rather early stages of scientific development, including their stimulation. In other words, it is far from the stage of matured and well established scientific knowledge and expertise that any regulatory regime requires. This is a vital component when it comes to demonstrating compliance with requirements.

On the key concepts of exclusion, exemption and clearance, we are surprised to note that BSS draft 1.0 departs from the current international consensus that led to the IAEA Safety Standards, RS-G-1.7. In particular, we noted the omission of the provisions that made this important consensus applicable to larger quantities of radioactive materials, thus considerably reducing the scope of RS-G-1.7. IAEA BSS draft 1.0 requires re-alignment.

In view of achieving greater harmonization of the IAEA Global Safety Regime and among national regulations, a proper sequence must be followed. This time, a proper sequence is to first complete the revision of the IAEA BSS. In doing so, due care is required for integrated safety management; consistency with SF-1 and a top-down revision approach; clarifying the key RP concepts and their applications; and accounting for broader challenges that governments are facing. This key responsibility of government representatives cannot be delegated to any third party. Once the revision of the IAEA BBS is appropriately completed, national regulations could be revised accordingly, thus achieving greater harmonization.

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