RulemakingComments Resource

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U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Attention: Annette L. Vietti-Cook, Secretary

Dear Ms Vietti-Cook

http://www.regulations.gov Docket ID NRC-2015-0057

I am submitting the attached letter in support of the February 9, 2015 petition by Emeritus Professor Agustin Alonso from Spain on the foreseen revision of the NRC 10 CFR Part 20, *Standards for Radiation Protection Against Radiation* so that the US NRC radiation protection and nuclear safety policies and regulations are based on the Nuclear Safety Principles and Radiation Protection Requirements formally proposed by the International Atomic Energy Agency, developed with the participation of most countries, including the United States, and sponsored and endorsed by the most relevant scientific international institution. I am also proposing to base the revision on the basic fundamental safety principles of justification, optimization and limitation, as formulated by the said Agency, and avoiding any reference to ALARA , or to the LNT hypothesis.

As I not a United States citizen, I am no sure if I have the right to formulate the attached proposal. In any case, it has been a pleasure to suggest the use and value of international standards and I will appreciate any consideration from the NRC reviewers and experts.

Sincerely

Emeritus Professor Agustin Alonso
Madrid Polytechnic University

Madrid, August 30, 2015

Annette L. Vietti-Cook
Secretary, USNRC
Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Ms. Vietti-Cook:

1. PROPOSALS

NRC regulations have been used by many countries as valid examples in developing national regulations. The proposed revision of 10CFRPart20 will be of interest to those countries which have traditionally imported nuclear technology and practices from the United States. 10CFRPart20 has been a reference in the development of the Spanish radiation protection regulations and practices.

Article III.A.6 of the International Atomic Energy Agency Statute authorizes the Agency: "…to establish or adopt…standards of safety for protection of health and minimization of danger to life and property…" This has moved the IAEA to develop standards in consultation with the competent organs of the United Nations and with the specialized international agencies concerned. The IAEA Safety Standards Series now includes unified **Fundamental Safety Principles**, which represent an international consensus on what must constitute a high level of protection and safety.

From those Principles a set of specific **Requirements** have been developed to cover the different aspects of nuclear activities and practices. This set of documents pretend to be of universal interest and be of use to develop national regulations considering the national administrative organization and needs. Because of that, in this letter the following proposal is formulated: **The revision of 10CFRPart20 should consider the IAEA Basic Safety Principles and the corresponding Requirements on radiation protection.** To help on that issue, it is included a cursory analysis of such Principles and Requirements and how they can be introduced into national new or revised regulations.

As a related issue, there have been advances on understanding risk associated to low and low rate radiation doses, at least for certain low LET radiations and some radiation exposures, which may put into doubt the universal application of the Linear Non-threshold Hypothesis, LNT. Because such hypothesis is one of the major supporters of nuclear phobia, it is also proposed: **The revision of 10CFRPart10 should consider means to avoid the use of LNT through ALARA in regulating very low doses limits in situations of low radiation risk and a great expenditure by properly applying**

the IAEA radiation protection basic principles and requirements. The rational for the proposal is given.

2. THE IAEA FUNDAMENTAL SAFETY PRINCIPLES AND RADIATION PROTECTION REQUIREMENTS

To justify the proposal that the revision of 10CFRPart20 should consider the universality and the validity of the IAEA standards on radiation protection, a cursory description is included of the two most relevant IAEA publications: The Fundamental Safety Principles (1) and the Requirements on Radiation Protection (2). Both documents have been endorsed and jointly sponsored by the European Commission (EC), the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Labour Organization (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO), the United Nations Environment Programme (UNEP) and the World Health Organization (WHO).

2.1 The IAEA Fundamental Safety Principles

The IAEA Fundamental Safety Principles, as defined in document SF-1, were published in 2006 after close to ten years of work. The main value of the document is in the full integration of principles on nuclear safety, radiation protection, radioactive waste management and transportation of radioactive materials, originally regulated separately, and now considered as essential parts of the wide concept of nuclear safety. The fundamental safety objective of SF-1is (§ 2.1): "… to protect people and the environment from harmful effects of ionizing radiation." Under the condition that such objective: "… must be achieved without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks." SF-1 is based on ten Principles; three of them are specifically applicable to radiation protection activities:

Principle 4: **Justification of facilities and activities**

Facilities and activities that give rise to radiation risks must yield an overall benefit.

Principle 5: **Optimization of protection**

Protection must be optimized to provide the highest level of safety that can reasonably be achieved.

Principle 6: **Limitation of risks to individuals**

Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.

Other principles do also apply to radiation protection, in particular:

Principle 9: **Emergency preparedness and response**

Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.

Principle 10: **Protective actions to reduce existing or unregulated radiation risks**

Protective actions to reduce existing or unregulated radiation risks must be justified and optimized.

2.2 The IAEA Requirements on Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

The IAEA Requirements on Radiation Protection and Safety includes up to 52 requirements divided into four chapters, one including requirements for protection and safety and three on exposure situations: planned, emergency and existing or unregulated radiation risks. The document includes four Schedules with the numerical limits for each one of the natural and artificial radionuclides to determine exemption and clearance; categories for sealed sources used in common practices; dose limits for planned exposure situations, and criteria for use in emergency preparedness and response. The following analysis identifies those requirements related to each one of the three fundamental radiation protection principles: justification, optimization and limitation

2.2.1 Requirements related to the principle of justification

Principle 4 is developed in Requirement 10**: Justification of practices**

The government or the regulatory body shall ensure that only justified practices are authorized.

It requires that (§ 3.16): "The government or the regulatory body, as appropriate, shall ensure that provision is made for the justification of any type of practice and for review of the justification, as necessary, and shall ensure that only justified practices are authorized." The document includes a list of practices deemed to be not justified.

Principle 4 is also considered in Requirement 37**: Justification of medical exposures**

Relevant parties shall ensure that medical exposures are justified.

Although dose limits do not apply to medical exposures, the document considers (§ 3.156) : "Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments." Such justification should weight the diagnostic or therapeutic benefits against the radiation detriment that the radiological procedure might cause, also considering alternatives that do not involve radiation exposure.

2.2.2 Requirements related to the principle of optimization

Principle 5 is developed in Requirement 11: **Optimization of protection and safety**

The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized.

The document makes the government or the regulatory body responsible for establishing and enforcing requirements for the optimization of protection, requiring the appropriate documentation and approving constraints on dose and on risk as appropriate. Registrants and licensees shall ensure that protection and safety is optimized and that all relevant factors are taken into account in a coherent way.

Principle 5 is also considered in Requirement 38**: Optimization of protection and safety (on medical practices)**

Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

The IAEA document is very strict on the application of the optimization principles in medical exposures. The document requires that medical radiological equipment and software should only be used (§ 3.162): "…if they conform to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization or to national standards adopted by the regulatory body." There are also specific procedures for radiological diagnostics and therapies, image guided interventions and the use of radiopharmaceuticals. Patient's dosimetry is performed (§ 3.168): "…by or under the supervision of a medical physicist, using calibrated dosimeters and following …accepted protocols…" There should also be diagnostic reference levels and a comprehensive programme of quality assurance for medical exposures and dose constraints.

There is also an optimization Requirement 39**: Pregnant or breast-feeding female patients**

Among other activities, it is required (§ 3. 176): "Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding."

2.2.3 Requirements related to the principle of limitation

Principle 6 is developed in Requirement 12**: Dose limits**

The government or the regulatory body shall establish dose limits for occupational exposure and public exposure, and registrants and licensees shall apply these limits.

The dose limits are established in Schedule III for occupational exposures and public exposures in planned exposure situations. The government or the regulatory body shall determine what additional restrictions may be required to be complied with by registrants and licensees and why to ensure that the dose limits specified in Schedule III are not exceeded. Registrants and licensees

shall ensure that the exposures of individuals (§ 3.28) "…due to the practices for which the registrants and licensees are authorized are restricted, so that neither the effective dose nor the equivalent dose to tissues or organs exceeds any relevant dose limit specified in Schedule III."

Dose limits do not apply to patient medical exposures.

2.3 Specific requirements on emergency exposure situations

Radiation protection is of particular interest in emergency exposure situations. The need for emergency preparedness and response is considered in Principle 9 and fully considered in the IAEA document.

Public exposure is considered in Requirement 44**: Preparedness and response for an emergency**

The government shall ensure that protection strategies are developed, justified and optimized at the planning stage, and that emergency response is undertaken by their timely implementation.

The requirement puts emphasis on the need to justify and optimize strategies to protect the public at the planning stage and ensure that such strategies are timely and properly implemented (§ 4.7): "…based on the hazard assessment, for avoiding deterministic effects and reducing the likelihood of stochastic effects due to public exposure." The Annex to the document provides a set of generic criteria for use in the protection strategy that are compatible with reference levels within a range of 20–100 mSv. Schedule IV includes dose levels required to be used as generic criteria for preventing severe deterministic effects.

Exposure of emergency workers is considered in Requirement 45**: Arrangements for controlling the exposure of emergency workers**

The government shall establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers.

The programme for emergency workers does not contemplate justification and optimization process, it goes directly to dose limitation (§ 4.15): "Response organizations and employers shall ensure that no emergency worker is subject to an exposure in an emergency in excess of 50 mSv…" That value could be overcome to save life, prevent severe deterministic effects, avoid development of catastrophic conditions; or to avert a large collective dose. Under such exceptional circumstances (§ 4.16): "…response organizations and employers shall make all reasonable efforts to keep doses to emergency workers below the values set out in Schedule IV". It adds (§ 4.16) such limits are justified: "…only when the expected benefits to others would clearly outweigh the risks to the emergency workers", a clear reference to the justification principle.

2.4 Specific requirements on existing exposure situations

Existing exposure situations are considered in Principle 10. They derive from a): Past activities that do not comply with current standard and recovery from a radiological emergency after an

emergency has been declared to be ended. b) Exposure due to commodities that incorporate radionuclides deriving from residual radioactive material. c) Exposure due to natural sources and cosmic radiation.

Public exposure from existing exposure situations are considered in Requirement 48**: Justification for protective actions and optimization of protection and safety**

The government and the regulatory body or other relevant authority shall ensure that remedial actions and protective actions are justified and that protection and safety is optimized.

In this particular requirement the three radiation protection basis principles are addressed.

Paragraph 5.7 establishes that: "The government and the regulatory body or other relevant authority shall ensure that the protection strategy for the management of existing exposure situations… is commensurate with the radiation risks associated with the existing exposure situation; and that remedial actions or protective actions are expected to yield sufficient benefits to outweigh the detriments associated with taking them, …". This paragraph includes a clear reference to the justification principle.

Paragraph 5.8 establishes that. "The regulatory body or other relevant authority and other parties responsible for remedial actions or protective actions shall ensure that the form, scale and duration of such actions are optimized." The optimization process should be based on a reference level expressed "…as an annual effective dose to the representative person in the range of 1–20 mSv or other corresponding quantity."

Paragraph 5.9 establishes that: "The regulatory body or other relevant authority shall periodically review the reference levels to ensure that they remain appropriate in the light of the prevailing circumstances. Reference levels belong to the limitation principle.

3. 10CFRPart20—STANDARDS FOR PROTECTION AGAINST RADIATION

10CFRPart20 is not specifically constructed on the three radiation protection principles discussed in the IAEA Requirements document. The justification principle is not directly mentioned; the optimization principle is introduced through the ALARA principle, itself based on the LNT approach; most of 10CFRPart20 is based on the limitation principle. A few examples taken from 10CFRPart20 are included to show how to avoid the term ALARA and be close to the IAEA radiation protection principles: justification, optimization and limitation.

3.1 § 20.1003 Definitions: ALARA

10CFRPart20 § 20.1003 includes: "*ALARA* (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of

technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest."

From the definition it comes that the purpose of ALARA is to reduce radiation doses to the minimum possible by using mainly economic reasons, while the IAEA justification principle is a comparison between the social and individual benefits and detriments from a given radiological practice. A practice should be considered ethically justified if benefits overcome detriments. 10CFRPart20 ALARA does not cover the essence of the optimization principle, the aim of which is to develop a sound radiation protection management, not only to ensure compliance with the dose limits, but to do it in well-established and optimized manner in accordance with the IAEA applicable requirements.

It is therefore proposed to introduce in 10CFRPart20 the concepts of justification and optimization as defined in the IAEA Requirements document and remove in 10CFRPart20 any mention to ALARA.

3.2 § 20.1101 Radiation protection programs, ALARA:

10CFRPart20 § 20.1101 include that:

"(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)."

Paragraph b) miss the point that radiation protection programmes should be based on requirements from the regulator; that such programmes have to be prepared by the licensee and approved by the regulator; put in practice by the licensee and supervised and enforced by the regulator, and that relevant radiation protection programmes should be based on the three IAEA basic principles: justification, optimization and limitation.

3.3 § 20.1402 Radiological criteria for unrestricted use, ALARA

10CFRPart20 § 20.1402 add that:

"A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal."

The reference to ALARA in this case is similar to a justification. In fact, a dose of 0.25 mSv/y is so small (about 1/10 of the average natural dose) that the radiation risks are negligible in comparison

with the transportation accidents. In this case the application of the justification principle will clearly prove there should not be any problem to increase the reference level several times.

3.4 § 20.1403 Criteria for license termination under restricted conditions, ALARA

10CFRPart20 § 20.1403 establish that:

"A site will be considered acceptable for license termination under restricted conditions if:

"(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of § 20.1402 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal"

The reference to ALARA has the same meaning that in **§ 20.1402**. The proper application of the IAEA justification principle will serve to prove that the dose limit of 0.25 mSv/y may be unnecessarily low.

3.5 § 20.1601 Control of access to high radiation areas, ALARA

10CFRPart20 § 20.1601 consider that:

"(f) Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this part and to operate within the ALARA provisions of the licensee's radiation protection program."

The term… *within ALARA provisions* could be substitute with advantages by…*within the radiation protection principles*.

3.6 § 20.2002 Method for obtaining approval of proposed disposal procedures, ALARA

10CFRPart20 § 20.1601 estates that:

"A licensee or applicant for a license may apply to the Commission for approval of proposed procedures, not otherwise authorized in the regulations in this chapter, to dispose of licensed material generated in the licensee's activities. Each application shall include:

"(d) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this part."

The expression ….*doses are maintained ALARA*…. Could be substituted with advantages by ….*radiation protection management is based on the justification and optimization principles*…

4. AVOIDANCE OF THE LINEAR NON-THRESHOLD APPROACH

The IAEA document includes a valuable list of definitions. The definition of ALARA is not included in the list, while the definition of LNT, although it is not used in the text, is included as quoted below:

"linear–no threshold (LNT) hypothesis

The hypothesis that the risk of stochastic effects is directly proportional to the dose for all levels of dose and dose rate below those levels at which deterministic effects occur.

> i This means that any non-zero dose implies a non-zero risk of stochastic effects.
>
> ii This is the working hypothesis on which the IAEA's safety standards are based. It is not proven — indeed it is probably not provable — for low doses and dose rates, but it is considered the most radiobiologically defensible assumption on which to base safety standards."

Although not specifically written, 10CFRPart 20 is also based on the LNT hypothesis, the document does not include the definition of LNT, but its application comes through the many references to ALARA, for which 10CFRPart20 includes the definition included before (**3.1 § 20.1003 Definitions: ALARA)**.

The LNT hypothesis was reinforced from the **precautionary principle** (lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures) formulated in the Rio Declaration as an outcome of the United Nations Conference on Environment and Development (1992). Its maintenance in radiation protection regulation comes from the uncertainties associated in estimating the risks of low radiation doses. It was soon found that below some 100 mSv radiation generates stochastic damage causing cancer, cardiovascular diseases and cataracts, although its probability was considered proportional to the dose received. The hypothesis has created a strong well known controversy among experts and scientific organizations.

The International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the National Council on Radiation Protection and Measurements (NCRP), and the National Research Council Committee on the Biological Effects of Ionizing Radiation (BEIR), among others, have endorsed and maintain the use of the LNT model. However, other institutions, notably the French Academy of Sciences, and many experts have rejected the LNT hypothesis at low doses. This disagreement is of concern and highlights the need for more research on the health risks at low radiation doses. The recently

created European Multidisciplinary European Low Dose Initiative (MELODI) is a relevant example in that direction.

The strict application of the LNT hypothesis has created significant economic implications in the cleanup of old nuclear development centers and installations, in the conduct of radiological emergencies and recovery activities afterwards (apparent in the management of the Fukushima Daiichi evacuation and recovery), in dismantling nuclear power plants and fuel cycle installations, in the management of low activity radioactive waste, and in the rapid increase in radiation-based medical procedures, among other examples.

Most significant, the intentionally wrong use of the LNT by antinuclear organizations has created a deep social nuclear phobia which is hurting the normal development and use of the many possible nuclear practices, mainly nuclear power. One of the most damaging activities is related to supposedly radiation damage lawsuits. For example, the Plant Director, the Plant Manager and the Radiation Protection Head of one of the nuclear power plants in Spain, together with two Resident Inspectors of the Spanish regulatory organization are undergoing a court accusation presented by several antinuclear associations that may bring to the incarceration of some of the people accused. During an outage operation some hot particles were inadvertently released to the environment. Once detected, the site was clean of hot particles and a costly operation was initiated to check that nobody-plant personnel, contractors and visitors- were contaminated or could have received radiation doses from the release. No anomalies were found. The Regulatory Organization accused the Licensee of operation misconduct and fined it in accordance with the law. Nevertheless, the antinuclear organizations accused the above cited persons of criminal misconduct in a still ongoing court process. The accusers hired a university professor of biology who in his formal declaration is using the LNT hypothesis to defend that a single cobalt-60 photon is sufficient to engender a cancer. Under such criteria it will be extremely difficult for the judge to come to a just sentence.

Despite the remarkable research efforts conducted since the early fifties and the numerous epidemiological studies it has not been proved with certainty and for all exposure situations the relations between low radiation doses and the carcinogenic or other human health effects. It is also not fully accepted the hormesis effects of low radiation doses claimed by relevant scientist and scientific institutions. In any case, it will not be possible to expect that the LNT dilemma will be clarified in a short time. Because its social implications, the primary interest in radiation protection regulations should be the exposure at low doses; as it is not possible to regulate correctly under uncertainties, the regulators have to overcome the situation by considering the consequences of their decisions, taking into account all opinions and being open to future research results. Reaching a regulatory equilibrium is a need, as there will be disadvantages in both underprotection and overprotection. The overprotection of current regulations has clearly proven the disadvantages of creating a nuclear phobia and increasing costs.

For the reasons above it is proposed: **That the revision of 10CFRPart20 is based on the three IAEA basic principles of justification, optimization and limitation avoiding any reference to**

ALARA. It should also be considered that it is negligible the risk associated to radiation doses up to a few times natural radiation, i.e. from 15 to 25 mSv/y.

Thank you for your attention and consideration.

Sincerely,

A. Alonso

Prof. Agustin Alonso

Relevant Curriculum Vitae

Emeritus Professor of Nuclear Engineering at the Madrid Polytechnic University (Spain)
Former Commissioner of the Spanish Nuclear Regulatory Council (Consejo de Seguridad Nuclear)
Founder and long term Member of the NEA/OECD Committee on the Safety of Nuclear Installations (CSNI) (A time Vice President of the Committee)
Founder and long term Member of the NEA/OECD Committee on Nuclear Regulatory Activities (CNRA)
Short term Member of the IAEA Commission on Safety Standards (CSS)
Long Term Member of the IAEA International Nuclear Safety Group (INSAG)

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REFERENCES

1. IAEA, *Fundamental Safety Principles*, IAEA Safety Standards: Safety Fundamentals Nº SF-1, IAEA, Vienna (2006)
2. IAEA, *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*, General Safety Requirements Nº GSR Part 3, IAEA, Vienna (2014)