Restructuring Nuclear Regulations

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Nuclear regulations are a subset of social regulations (laws to control activities that may negatively impact the environment, health, and safety) that concern control of ionizing radiation from radiation-producing equipment and from radioactive materials. The impressive safety record among nuclear technologies is due, in no small part, to the work of radiation safety professionals and to a protection system that has kept pace with the rapid technologic advancements in electric power generation, engineering, and medicine. The price of success, however, has led to a regulatory organization and philosophy characterized by complexity, confusion, public fear, and increasing economic costs. Over the past 20 years, regulatory costs in the nuclear sector have increased more than 250% in constant 1995 U.S. dollars. Costs of regulatory compliance can be reduced sharply, particularly when health and environmental benefits of risk reduction are questionable. Three key regulatory areas should be closely examined and modified to improve regulatory effectiveness and efficiency: *a*) radiation protection should be changed from a risk-based to dose-based system; *b*) the U.S. government should adopt the modern metric system (International System of Units), and radiation quantities and units should be simplified to facilitate international communication and public understanding; and *c*) a single, independent office is needed to coordinate nuclear regulations established by U.S. federal agencies and departments. *Key words:* dose, economic costs, nuclear regulations, radiation quantities, regulatory framework, risk. *Environ Health Perspect* 111:13–17 (2003). [Online 7 November 2002]

doi:10.1289/ehp.5650 available via *http://dx.doi.org/*

Social regulations are laws to control activities that may negatively impact the environment, health, and safety. Without regulations, organizations may not take into account the full social costs of their actions. Government intervention is necessary to assure that workers have adequate information about workplace health and safety hazards and to impose cost controls so that organizations do not excessively pollute the environment (Gausch and Hahn 1999). Nuclear regulations are a subset of social regulations that deal with controlling ionizing radiation exposure from radiation-producing equipment and from radioactive materials. Nuclear technologies overall have an impressive safety record. The Three Mile Island nuclear power plant accident in 1979 caused serious damage to the plant, but there were no deaths or injuries to workers or to the general public as a result of releases of radioactive material to the environment. In contrast, the Chornobyl accident in 1986 caused serious environmental and public health effects because of deliberate inactivation of safety systems. This resulted in massive releases of radioactive material to the environment from a reactor with minimal containment capabilities. Excellence in nuclear safety is due primarily to the work of radiation safety professionals and to a protection system that has kept pace with the rapid technologic advancements in electric power generation, engineering, and medicine. The price of success, however, has led to a regulatory organization and philosophy characterized by complexity, confusion, public fear, and increasing economic costs. From 1980 to 2000, regulatory costs in the nuclear sector have increased more than 250% in constant 1995 U.S. dollars (Figure 1).

Simplifying nuclear regulations without compromising worker or public health and safety would serve two purposes. First, costs of regulatory compliance could be reduced sharply, particularly when health and environmental benefits of risk reduction are questionable (Figure 2). For example, a 2000 U.S. General Accounting Office (GAO) report estimated public expenditures in excess of $100 million to clean up radioactively contaminated soil at the Nevada Test Site to levels less than 10% of the natural radiation background (GAO 2000). Allocation of limited economic resources should be based on a careful risk–benefit analysis that reduces overall risk to maximize health and safety.

Second, the current system of protection leads to confusion, public fear, and difficulty in public communication. For example, the International Atomic Energy Agency estimated that 100,000–200,000 women in Western Europe had abortions based on their perception of harmful effects of the Chornobyl disaster. In Greece, as in other parts of Europe, many obstetricians initially thought it prudent to interrupt otherwise wanted pregnancies. In some cases they were unable to resist requests from worried pregnant women. This fear occurred despite the fact that doses were much lower than necessary to produce *in utero* effects (Trichopoulos et al. 1987). Although popular fear of radiation has many causes, clearly the belief that any dose of radiation may be harmful (the current philosophic approach in regulatory decision-making) is a major influence.

Three key nuclear regulatory areas should be closely examined and modified to improve regulatory effectiveness and efficiency. First, the system of radiation protection should be changed from a risk-based system to a dose-based system. The International Commission on Radiological Protection (ICRP) introduced a risk-based system in 1977 as a solution to the problem of combining doses from different sources. However, the system has created more problems than it has resolved. Second, the U.S. government should adopt the modern metric system. Metrification will facilitate international communication and public understanding. Currently there are too many dose-related quantities and units in use in radiation protection. Third, a single independent office is needed to coordinate nuclear regulations established by federal agencies and departments. Today, a dozen or more federal agencies and departments have nuclear regulatory responsibilities. Dose limits and estimates of radiation risks vary because agencies differ in their regulatory approaches and protective strategies. The resulting federal regulatory framework is characterized by inconsistencies, overlaps, and gaps in nuclear regulations (GAO 1994).

Nuclear Regulations Should Be Dose-Based Rather Than Risk-Based

Regulatory organizations should structure a practical system of radiation protection in the simplest way possible and base it on sound scientific assumptions in order to apply it effectively and efficiently. However, establishing such a system is difficult because ionizing radiations (e.g., alpha particles, gamma rays, neutrons) have different radiobiologic properties, and tissues and organs have different radiation sensitivities [United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) 2000]. Because of differences in patterns of energy deposition in tissues, alpha particles and neutrons are biologically more effective than gamma rays per unit absorbed dose. Furthermore, doses from internally deposited radionuclides that accumulate in particular tissues (e.g., radon gas in the lungs) cannot be added to whole-body doses from external radiation exposure.

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Received 21 March 2002; accepted 18 June 2002.

Accordingly, absorbed doses cannot be combined into a single number that can be compared to dose limits.

To address this problem, the ICRP recommended that levels of acceptable risk, rather than dose limits, should be the basis for the development of radiation safety standards (ICRP 1977). This system was revised and updated in the ICRP's Publication 60 (ICRP 1991). In this new system, risks can be combined into a single number, assuming that risks from exposure to different radiation types are independent and that risks should be equal whether the whole body is irradiated homogeneously or nonuniformly (ICRP 1977). In this system, appropriate tissue weighting factors are used to account for differences in tissue-specific risks when the body is irradiated nonuniformly. The tissue weighting factor is the proportion of the tissue-specific risk to the whole-body risk. By this calculation, doses from internally deposited radionuclides may be added to doses from external sources to estimate the total dose to an exposed individual. The U.S. Nuclear Regulatory Commission (NRC) used this methodology as a basis for the 1991 revision of its standards for protection against radiation (U.S. NRC 1991).

Although this risk-based system allows for the calculation of a single dose value for comparison with limits, there are serious problems with its utility in radiation protection. First, there is substantial statistical uncertainty in the values of tissue weighting factors. The ICRP recognized these uncertainties but, nevertheless, assigned single values to these factors to facilitate dose calculations. These factors are based on risk estimates derived from populations exposed to high doses (> 200 mSv) delivered at high dose rates (perhaps 100 mSv/hr and higher) but are applied to occupational situations that involve low doses (< 10 mSv) delivered at low dose rate (perhaps 1–5 mSv/year) (UNSCEAR 2000). Age, sex, other host factors, and the shape of the dose–response curve modify risk significantly. At doses near natural background radiation levels (approximating many occupational exposure situations), the range of uncertainty in the lifetime radiogenic cancer mortality risk is large, and the lower bound of uncertainty likely includes zero (National Research Council 1990). Although assigning specific values to tissue weighting factors facilitates calculations, it is overly simplistic and fails to account for the influence of known risk determinants.

Second, risks may not necessarily be equal when the whole body is irradiated as compared to a nonuniform exposure scenario. This is important when internally deposited radionuclides concentrate in particular tissues. Radiogenic lung cancer as a consequence of radon gas exposure is an example where the calculation of a whole-body equivalent risk is inappropriate. Lung cancer is the only known health effect of radon gas exposure (National Research Council 1999). Extrapolation of the lung cancer mortality risk to a whole-body risk is not consistent with epidemiology because radon does not result in excess cancers in other tissues and organs of the body.

To be valid, the risk-based methodology should be symmetrical. If the specific tissue dose is multiplied by the appropriate tissue weighting factor to obtain the equivalent whole-body dose, then dividing the equivalent whole-body dose by the tissue weighting factor should yield the specific tissue dose. In the case of radon exposure, risk is limited only to the lung; there is no equivalent whole-body dose that results in the same risk. The National Council on Radiation Protection and Measurements (NCRP) has used the ICRP risk-based methodology to determine that radon gas accounts for two-thirds of the total natural background radiation dose based on a comparison of equivalent whole-body doses from radon and from cosmic radiation and terrestrial radionuclides (NCRP 1987). Because radon gas has been linked only to lung cancer, it is inappropriate to calculate equivalent whole-body doses. Accordingly, radon gas and its progeny should be considered separately from other natural background radiation sources. In occupational settings involving external and internal exposures, it may not be possible to calculate a single dose for the same reasons.

Authoritative bodies such as the ICRP and NCRP and standard-setting organizations should consider adopting a dose-based system of protection whereby each type of radiation and source is considered separately. Doses from external exposures and from internally deposited radionuclides are considered and calculated individually. To determine compliance with dose limits, doses are calculated as a fraction of the prescribed limit and summed over all radiations and exposure scenarios (e.g., internal vs. external exposures) to determine if the sum is less than unity (a unity rule).

Standard-setting organizations should establish an array of dose limits that incorporates differences in radiation types and tissue radiosensitivities. The current risk-based methodology is unsatisfactory because there is no appropriate way of combining radiation doses from internal and external exposures. Further, application of tissue weighting factors is problematic because of the large uncertainties in the values. Considerable discussion is needed to develop dose limits for all tissues and radiation types. Radiation and tissue weighting factors may be used in the development of dose limits, but there is no need to use any quantity other than absorbed dose.

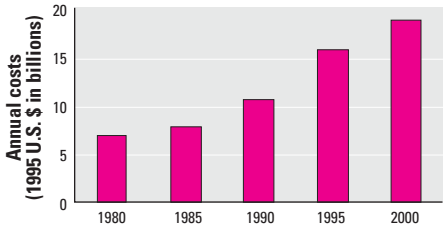

Figure 1. Estimated costs of social regulations in the nuclear power sector. Regulatory costs (in constant 1995 U.S. dollars) have risen steadily. Costs in 2000 are more than 250% higher than 1980 costs (Guasch and Hahn 1999). It is assumed that regulatory costs in the nuclear power industry account for about 7% of all social regulation costs (Hopkins 1996).

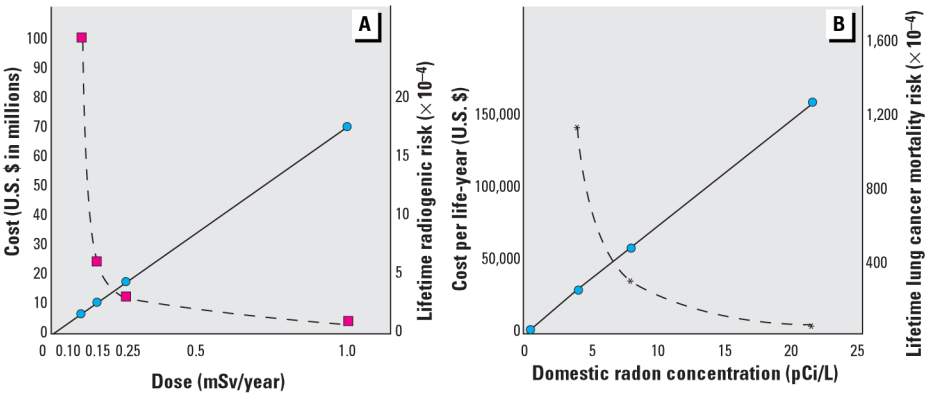

Figure 2. Economic costs of risk reduction. Costs of reducing environmental and public health effects of ionizing radiation exposure can be enormous. (*A*) Shows the costs of environmental cleanup at the Nevada Test Site (GAO 2000). Below 0.25 mSv/year (average natural background is ~ 1 mSv/year excluding radon), the cleanup costs (dashed line) rise precipitously despite very small theoretical reductions in lifetime radiogenic risk; the solid line assumes a lifetime cancer mortality risk of 5%/Sv (National Research Council 1990). (*B*) Shows the cost effectiveness of radon remediation in homes (Tengs et al. 1995). Below a radon gas concentration of about 7 pCi/L (about 95% of U.S. homes have radon levels below this level), the costs of averting radon-induced lung cancer mortality (dashed line) rise significantly despite very small theoretical reductions in lifetime radiogenic lung cancer risk (solid line). The dashed line is derived from the BEIR VI Report (National Research Council 1999).

Absorbed dose is the appropriate quantity because the radiation weighting factors and tissue weighting factors are simply used as dimensionless modifiers of absorbed dose. As additional information about biologically derived weighting factors becomes available, regulatory agencies may modify dose limits as appropriate.

A dose-based system of protection simplifies the current system by depending only on the absorbed dose to the whole body or to the specified tissues. Absorbed dose is a quantity measured directly. Dosimetry is accurate to levels approximating 0.1 mSv, well within the range of doses typically encountered in environmental and occupational exposure settings, and about 3 orders of magnitude lower than doses associated with measurable health risks (Mossman 1998). Incorporating weighting factors into dose limits eliminates uncertainties inherent in using tissue weighting factors in the risk-based system. Dose limits, by definition, have no uncertainty.

The creation of a large matrix of dose limits is an administrative rather than practical problem. Regulatory decision-makers need to consider carefully what weighting factors should be used to address radiobiologic effectiveness of different radiation types and radiosensitivity differences in tissues and organs. Once the dose limit matrix has been established, practical implementation is relatively straightforward by comparing individual or population doses directly to relevant limits.

Discussions of dose limits should consider reference to natural background. A key recommendation of a 1999 international Airlie House conference was that reference to natural background radiation should be included in policy discussions on the regulation of radiation sources delivering low-level radiation (Mossman et al. 2000). Natural background radiation has been used frequently as a standard for comparison with anthropogenic sources of radiation exposure because background radiation is the largest source of human radiation exposure. The major sources of natural background radiation are cosmic radiation and primordial radionuclides (including radon).

Using natural background radiation as an approach to setting radiation standards is not new. Adler and Weinberg (1978) proposed that the standard deviation of the average annual natural background radiation level be used as the exposure standard. They argued that the health detriment of a small additional anthropogenic dose would be undetectable and acceptable. However, a limit of 0.20 mSv/year is unnecessarily restrictive. This is similar to the 0.25 mSv/year dose limit established by the U.S. NRC in its final ruling on radiological criteria for licensing termination (U.S. NRC 1997). This is about 3 orders of magnitude below doses associated with statistically significant radiogenic health risks in adult populations (Mossman 1998). Others have proposed a less restrictive approach by recommending the annual natural background level rather than the standard deviation of the average annual level as a basis for setting standards (Clarke 1999; Mossman 1998).

Natural background radiation has been well characterized. Radiation levels vary by geographic location and altitude and have been measured with great accuracy. The general public understands the natural radiation background even though it is complex and consists of multiple radiation sources. Dose limits can be set as multiples and submultiples of natural background radiation levels. Setting an appropriate reference annual natural background radiation level for the purposes of establishing population dose limits must take into account global variability in the natural background. In the United States levels may vary by a factor of 2 or more, with the highest levels in the Rocky Mountain region and the lowest in the mid-Atlantic states.

Epidemiologic studies of health effects in populations living in high background radiation areas show no increase in public health effects that may be attributed to radiation exposure (National Research Council 1990). Certain high natural background radiation areas such as Ramsar, Iran, have annual radiation levels exceeding occupational exposure limits (Ghiassi-nejad et al. 2002). Anchoring dose limits to the natural background does not preclude the use of cost–benefit analysis and other tools in regulatory decision-making. It would also diffuse the idea that any dose of radiation is potentially harmful. As a consequence, public health concerns associated with environmental cleanup and radioactive waste disposal might largely disappear.

Radiation Quantities and Units Should Be Simplified to Facilitate International Communication and Public Understanding

The system of quantities and units used in radiation protection is complex and cumbersome. There are numerous dose-related quantities (categorized as either dosimetric or protection quantities) in use in radiation protection. Debate continues about the stability of radiation protection quantities and units and the appropriateness of protection quantities such as equivalent dose. Recent name changes in quantities have generated confusion within the scientific and technical community and the general public. The ICRP's change from effective dose equivalent (ICRP 1977) to effective dose (ICRP 1991) and the shift from dose equivalent to equivalent dose has created chaos in the nomenclature (Strom and Watson 2002). Furthermore, the same units are used for multiple quantities. The sievert is a unit common to both equivalent dose and effective dose. Unless the specific quantity is identified, use of sievert is problematic. The failure of the United States to adopt the modern metric system only adds to the confusion.

The radiation protection community should give serious thought to simplifying the system of radiation quantities and units. In a dose-based system of protection, the dosimetric quantity "absorbed dose" is the only one needed. This assumes that differences in relative biological effectiveness and tissue radiosensitivities are accounted for in the dose limits. Protection quantities such as "equivalent dose" and "effective dose" are not measured directly and are not independent from absorbed dose (Table 1). Since radiation and tissue weighting factors are dimensionless, there is no need to use other quantities to describe what is simply a weighted absorbed dose. Radiation protection should be based on direct measurements of absorbed dose because it is the energy absorbed per unit mass of tissue that determines risk. However, for protection purposes, the ICRP prefers to use the average tissue dose.

Table 1. Radiation quantities and units.

Current system of measurement	Proposed system of measurement	Comment
Many quantities to measure individual and population doses are in use including absorbed dose, equivalent dose, and effective dose.	Only a single quantity-absorbed dose should be used.	Absorbed dose, equivalent dose, and effective dose are not independent quantities. Absorbed dose is the only quantity that is actually measured. Equivalent dose and effective dose are weighted absorbed doses.
Modern metric and English units are in use in the United States	Only modern metric units (International System of Units) should be used.	The U.S is the only industrialized country in the world that has not officially adopted the modern metric system.
Effective dose is the quantity used for dose limits.	Absorbed dose should be used for dose limits.	Dose limits should incorporate radiation and tissue weighting factors to account for differences in relative biological effectiveness and tissue radiosensitivity.

The ICRP argues that the absorbed dose (calculated at a point in tissue) is an unsatisfactory predictor of risk because it does not account for the average tissue dose or differences in tissue radiosensitivity. The magnitude of the average tissue dose depends on weighting factors and assumptions in dose models (ICRP 2001). These factors introduce large uncertainties in the calculations. Because radiation risk estimates have much greater uncertainties at low doses delivered at low dose rates (National Research Council 1990), it is unclear that reducing the uncertainty in the dose estimate by using average tissue dose will have any practical consequence. Accordingly, it is prudent to adopt the simpler approach (using absorbed dose) when alternative strategies are not likely to improve overall protection.

The refusal of the United States to adopt the modern metric system continues to cause communication problems, particularly in the international arena. The United States is the only industrialized country in the world not officially using the modern metric system. Because of its many advantages, including easy conversion between units of the same quantity, the modern metric system has become the internationally accepted system of measurement units. The U.S. government should adopt it with the gray (Gy) as the fundamental unit of absorbed dose. The NRC has already initiated an effort to use the metric system. Since 1993, the agency has published new regulations, regulatory guides, and other agency documents in dual units (English system and modern metric system) to facilitate use of modern metrics by licensees (U.S. NRC 1996). This is not a perfect solution, but it is a worthwhile effort to get licensees and others to use the metric system. By doing so, the United States will align itself with the rest of the world. As the Chornobyl accident clearly demonstrated, we need to think globally rather than locally about radiological health and safety.

The Regulatory Framework Should Be Reorganized within the Federal Government

The U.S. government has recognized the need for a comprehensive program to coordinate control of all sources of ionizing radiation in the federal sector for more than 40 years (Morgan et al. 1959). Differences in radiation limits, risks, and protective strategies reflect a historic lack of a unified framework for radiation protection (GAO 1994). In 1959 President Eisenhower created the Federal Radiation Council (FRC) to advise the president on matters of radiation safety and to provide general standards and guidance to help protect the public health from radiation hazards. The FRC came about because of public concern over radioactive fallout and its public health consequences as a result of atmospheric weapons. The FRC was composed of members from different federal agencies and departments. Their different views and the FRC's lack of binding authority over other agencies severely limited the council's effectiveness.

In 1970 the FRC was abolished, and federal guidance authority was transferred to the U.S. Environmental Protection Agency (EPA). The intent was to place many of the environmental functions of the federal government into a single federal agency. However, after abolishment of the FRC there was no formal effort to coordinate nuclear regulatory responsibilities among all federal agencies and departments charged with nuclear regulatory responsibilities.

In 1984, the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) was established and chartered under the Federal Coordinating Council for Science, Engineering and Technology, Office of Science and Technology Policy (OSTP), Executive Office of the President. Its overall charge was to coordinate radiation matters among federal agencies and departments, evaluate radiation research, and provide advice on the formulation of radiation policy. Like the FRC, the CIRRPC often reflected discord among agency representatives. The CIRRPC's effectiveness was seriously compromised by the lack of appropriate authority to provide effective policy coordination among agencies.

A 1994 GAO report concluded that effective coordination of regulatory programs was lacking (GAO 1994). The CIRRPC's inability to forge consensus on acceptable radiation risks and to coordinate regulations among agencies led to its demise. The Interagency Steering Committee on Radiation Standards (ISCORS) replaced the CIRRPC in 1994. ISCORS is composed of federal agencies that facilitate consensus on acceptable levels of radiation risk to the public and workers. It is co-chaired by the U.S. EPA and the NRC and promotes consistent risk approaches in setting and implementing standards for protection from ionizing radiation. The committee aims to foster early resolution and coordination of regulatory issues associated with radiation standards. However, ISCORS lacks both a reporting line and binding authority over federal agencies and departments.

The U.S. EPA continues to retain presidential federal guidance authority. Federal guidance is a set of guidelines developed by the U.S. EPA for use by federal and state agencies responsible for protecting the public from the harmful effects of radiation. The U.S. EPA develops guidelines for the president's review and approval.

The 2000 GAO report (GAO 2000) on continuing differences between the U.S. EPA and the NRC over resolution of issues associated with cleanup of licensed sites strongly suggests that the same problems that hampered the effectiveness of the FRC and the CIRRPC continue with ISCORS. The U.S. EPA and the NRC have duplicative oversight of nuclear energy facilities. Because of the inability of the agencies to resolve differences, the GAO recommended congressional intervention (GAO 2000). Congress (U.S. House of Representatives 1999) has directed the two agencies to develop a memorandum of understanding. Such a memorandum was signed by the U.S. EPA on 30 September 2002 and by the NRC on 9 October 2002 (U.S. EPA 2002).

A single, independent office is needed to oversee nuclear regulations established by federal agencies. Centralization and coordination of regulatory programs is necessary because of inconsistencies, overlaps, and gaps in the nuclear regulatory framework. At present at least a dozen federal agencies with different enabling legislations have nuclear regulatory responsibilities. The 1999 Airlie House conference concluded that consistent and coherent radiation policy on the national level is necessary for the effective implementation of radiation safety (Mossman et al. 2000). One solution is to create a central office within the OSTP. It would work closely with, but separate from, the recently established Office of Information and Regulatory Affairs to coordinate nuclear regulatory decision-making among federal agencies. The office would facilitate the establishment of a coherent, comprehensive, and integrated system that avoids overlapping and conflicting regulations. A key to the success of this OSTP office would be the transfer of the federal guidance authority from the U.S. EPA and binding authority over federal agencies and departments with nuclear regulatory responsibilities. The ineffectiveness of the FRC, the CIRRPC, and ISCORS can be traced directly to the absence of these authorizations.

Creating a unified regulatory framework by establishing a central coordinating office will be challenging. The effectiveness of such an office will depend on identifying competent administrative and technical staff and resolving agency turf battles and jurisdictional controversies. The U.S. EPA is not likely to relinquish federal guidance authority without a fight unless the agency receives appropriate compensation, perhaps in the form of authority to expand existing radiation programs and support for new initiatives. Agencies and departments are not likely to agree to a broad requirement for external approval of regulations by a central office unless they are guaranteed that agency autonomy and regulatory decision-making will be conserved.

In restructuring nuclear regulations, a useful model to consider is the Federal Common Rule for the protection of human subjects

from research risks (Department of Health and Human Services 1991). This rule essentially establishes a set of common regulations in each federal agency and department. Creation of a comprehensive federal nuclear regulatory policy using a common rule model would facilitate coordination of regulations by focusing on areas of common responsibility including worker and public health and safety.

ICRP Review of Current System of Radiation Protection

The ICRP is reviewing its system of radiation protection and developing new recommendations that will replace the 1990 recommendations (ICRP 2001). The ICRP Main Commission is now considering what it views as a simpler approach to radiation protection based on an individual-oriented philosophy. The principal change involves emphasis on the dose to an individual from a controllable source. This represents a shift from the utilitarian philosophy emphasizing societal-oriented criteria that are the basis of the current framework. However, it is unclear that diverting completely from a utilitarian perspective simplifies radiation protection. The proposed radiation protection framework is still unnecessarily complicated. The dosimetric and protective quantities introduced in the 1990 recommendations (ICRP 1991) are slated for retention, but the next recommendations will clarify differences in quantities. The ICRP admits that the current set of radiation and tissue weighting factors is more complex than can be justified, and the next set of recommendations will attempt to simplify the weighting factors (ICRP 2001). The proposed system also introduces a complex generalized structure of individual doses linked to protective actions. The various protective actions are linked to levels of concern (called "bands") that are defined in terms of multiples and submultiples of the natural background radiation dose (ICRP 2001). The ICRP should give serious consideration to simplifying quantities used in radiation protection. The proposed use of submultiples and multiples of the natural background as a basis for protective actions is a sound basis for developing a system of dose limits based on natural background radiation levels.

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