



HEALTH PHYSICS SOCIETY

"Specialists in Radiation Safety"

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Room N-2625
U.S. Department of Labor
200 Constitution Avenue, NW.
Washington, DC 20210

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Dear Sir or Madam:

As President of the Health Physics Society, I am pleased to provide comments on the Occupational Safety and Health Administration's (OSHA) Request for Information (RFI) on the use of, and potential worker exposure to, ionizing radiation in the workplace (70 FR 22828 5/3/05).

The Health Physics Society (herein referred to as the "Society") is a non profit scientific professional organization whose mission is to promote excellence in the science and practice of radiation safety. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits.

The Society has a great interest in advocating for responsible regulation of all occupational exposures to ionizing radiation in the United States, which must include a comprehensive and consistent regulatory framework encompassing all potential occupational exposures. We promote a framework that is protective of workers, with an appropriate margin of safety, and that is consistent across all work places, so all radiation workers have the same degree of protection, independent of the employer or regulatory agency.

The following comments are primarily directed at responding to OSHA's stated interest in "obtaining information that will allow assessment of the appropriateness of revising its standard for occupational exposure to ionizing radiation" (70 FR 22829). The Society will not attempt to respond to the large number of specific questions contained in the RFI, but will provide general

comments that we feel are pertinent to the high-level concerns raised by OSHA's questions.

Comment 1. The Society strongly believes that OSHA should eliminate the current inconsistency in occupational radiation-safety standards by adopting the same standards used by essentially all other federal agencies¹.

This comment is based on the Society's position statement "*Compatibility in Radiation-Safety Regulations*" (a copy of which is attached and is also available at <http://hps.org/documents/regulations.pdf>).

This statement takes the position that the Society "believes the current regulatory framework for establishing and enforcing regulatory radiation-safety standards results in inconsistent, inefficient, and unnecessarily expensive public health protection policies regarding radiation safety." This statement was initially issued thirteen years ago to express concern for the incompatibility that existed in radiation-protection standards, including occupational standards, between federal agencies and state radiation programs. In 2000, this position statement was revised *primarily* to address the fractionated and inconsistent environmental radiation standards promulgated by various federal and state agencies. However, it continues to apply to the only remaining inconsistency among federal agencies with respect to occupational radiation standards, which is the outdated standards existing in OSHA regulations.

Comment 2. The radiation-safety standards recommended in the Federal Guidance document issued January 27, 1987 (i.e., "Radiation Protection Guidance to Federal Agencies for Occupational Exposure," Environmental Protection Agency, 52 FR 2822) are protective of workers, and include an adequate margin of safety. Thus, consistency with these standards is more important than implementing newer recommendations that are inconsistent with them.

The occupational radiation-safety standards used by essentially all other federal agencies are those contained in the Federal Guidance document referenced above. This guidance implemented the recommendations of the International Commission on Radiological Protection (ICRP) and National Council of Radiation Protection and Measurements (NCRP) that

¹ The Society notes that the National Aeronautic and Space Administration has radiation-safety standards for the exposure of astronauts and space flight crews that are different than the other federal agencies. However, these are appropriate for the unusual radiation exposure conditions associated with space flight and they are based on current recommendations of the National Council of Radiation Protection and Measurements.

were existent at that time (i.e., ICRP Report 26 and NCRP Report 91). The RFI states “OSHA will consider the 1987 Federal Guidance document . . . [however] because the data on which this document is based are now at least 27 years old, OSHA will also consider more recent scientific information and ICRP recommendations” (70 FR 22832). In its statement “*Occupational Radiation-Safety Regulations and Standards are Sound*” (a copy of which is attached and is also available at <http://hps.org/documents/occupational.pdf>), the Society takes the position that “occupational radiation-safety standards and regulations have been sound, and protective of radiation workers, since the mid-1950s.” This includes the currently outdated OSHA standards and the 1987 Federal Guidance implemented by essentially all other federal agencies. Because this guidance and standards contained therein are sound and protective, the Society believes that the need for consistency overrides the need for change to newer recommendations.

The latest recommendations of the ICRP and NCRP have incorporated more recent scientific knowledge in underlying dose assessment techniques, but the fundamental nominal risk estimates that are used to evaluate the effects of the doses received under these recommendations have not changed significantly with the updated information. While the Society endorses radiation-standards consistent with NCRP and ICRP recommendations and believes the most current scientific knowledge should be used in dose assessment, it also believes that changing already protective standards must be done consistently by all regulatory agencies. The Society does not believe implementation of newer ICRP and NCRP recommendations for occupational dose limits is needed, or appropriate, until all regulatory bodies agree to implement new dose limits concurrently. However, OSHA’s regulations should be written with the flexibility to allow employers to use the latest scientific methods for dose assessment when appropriate.

Comment 3. A general RFI for employer-specific information is of little use in forming the basis for setting radiation-safety standards and regulations.

In the RFI, OSHA has asked for a description of a number of employer specific work practices and impacts (see, for example, questions 1 – 5, 9 – 11, 24, and 27 - 50). Although OSHA states it “is specifically seeking information on those operations covered by OSHA regulations” (70 FR 22832), the use of a general RFI is of little use in obtaining employer-specific information.

Getting information from an employer subject to OSHA regulations via an RFI requires the employer to read the RFI, which is usually not done unless they are informed by some other method that the RFI has been published. Alternatively, it requires someone reading the RFI to realize they are subject to OSHA regulations. Although OSHA goes to some length to describe the type of employers subject to its regulations, it does not identify specific employers. Due to the way the exclusions from OSHA regulations are phrased, and the myriad of interpretations of phrases such as “exercise statutory authority” in section 4(b)(1) of the Occupational Health and Safety Act, (29 U.S.C. 653), determination of an employer’s status under OSHA regulations is literally on a “case-by-case” basis. Thus, it is not reasonable to expect the average employer to recognize they are an employer potentially affected by the RFI.²

Additionally, OSHA has encouraged “all interested persons” to respond. Information about employers’ work practices that come from workers may represent how well the workers in that facility are trained, but it is not probative for the purpose of evaluating the adequacy of the practice being described. Such statements of practice must be validated by the employees’ management’s description of the practice, yet there is no assurance an open ended RFI will produce a statement from management to accompany any individual employee’s statement. Along those same lines, information from industries or employers not subject to OSHA regulations may be of value for comparing the consistency across regulatory bodies, but the statement of regulatory requirements and practices must come from the regulatory body. This information is most appropriately obtained by addressing a request for information directly to the other regulatory agencies.

The Society recommends OSHA spend its resources on identifying specific employers subject to OSHA regulations and address appropriate requests for information to them directly rather than spending resources on this open ended RFI mechanism, which will produce little useful information for rulemaking based on employer work practices.

² For example, 49 of the 50 states have regulatory programs for radioactive materials and radiation-producing machines that are not otherwise regulated by federal agencies. It is unlikely that an employer that has material and machines licensed by a state or federal agency will consider that they are also subject to OSHA regulations for these same materials or machines.

Comment 4: The specific questions contained in sections “D. Health Effects” and “E. Risk Assessment” are inappropriate for a general RFI to “all interested parties.” Most of the questions are either basic radiation science questions, the answers to which are known and documented in textbooks (see questions 13 – 15, and 17), or are questions still open to active scientific inquiry. The answers to the latter are not completely known but are under study by appropriate scientific institutions and bodies.

The question of biological response to low doses of radiation exposure has been the subject of intensive scientific study for decades. The most relevant studies and consensus scientific documents have been cited in the RFI. Because the dose response relationship relevant to low dose and dose rates, which may be either adverse or beneficial, is so small or non-existent, it is not observable by direct measurement in epidemiological studies with any consistency. Thus, the conclusions about health effects, whether adverse or beneficial, must be left to appropriate consensus scientific bodies with the appropriate expertise to evaluate these issues. These scientific bodies include national and international committees such as the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the National Academy of Science’s Biological Effects of Ionizing Radiation Committee (BEIR). These committees rely upon peer-reviewed and published scientific studies by research and academic institutions to formulate their conclusions. International and national scientific advisory organizations, such as the ICRP and NCRP, use the conclusions of these scientific committees, taking social and economic factors into account, to make recommendations for radiation-safety standards.

It is the opinion of the Health Physics Society that individual regulatory agencies, like OSHA, should not be drawing conclusions on a subject of such intense scientific study and complexity independently of all other national and international agencies and committees. In particular, OSHA should not be compiling its own set of studies and scientific information outside the well-established hierarchy that serves this country and the international community as an independent source of consensus scientific knowledge.

This independent source of consensus scientific knowledge in the radiation protection industry negates the need for regulatory agencies to search for studies that may controvert the conclusions of the consensus scientific bodies.

Comment 5: The Society believes that the radiation-safety standards issued in the 1987 Federal Guidance document meet the requirement in the Occupational Health and Safety Act (the Act), § 6(b)(5) relating to “significant risk determination,” and are compatible with the cases interpreting that section of the Act.

OSHA specifically requested comment “on how the risk assessment information contained in the scientific documents referenced in the docket should be interpreted in the context of the significant risk determination required by the Act and cases interpreting it” (70 FR 22833). The radiation-safety standards issued in the 1987 Federal Guidance document are informed by the consensus scientific literature and therefore reflect standards based on the risks determined from this literature.

In one of the cases cited by OSHA as interpreting the “significant risk determination” requirement, that is *Industrial Union Department, AFL-CIO v. American Petroleum Institute* (Benzene), the Supreme Court held that lowering an existing Benzene standard by OSHA was invalid because the lower standard “*was based, not on any finding that leukemia has ever been caused by exposure to 10 ppm of benzene and that it will not be caused by exposure to 1 ppm, but rather on a series of assumptions indicating that some leukemia might result from exposure to 10 ppm and that the number of cases might be reduced by lowering the exposure level to 1 ppm.*” That is, the basis for the lower standard was not based on known health effects, but was based on postulated health effects using the linear no-threshold (LNT) dose response extrapolation from higher doses.

Radiation protection standards also assume an LNT dose response for estimating risk at low doses of radiation. However, it must be recognized that there is no consensus scientific literature demonstrating that adverse health effects have been caused by radiation doses at or below the occupational radiation-safety standards contained in the 1987 Federal Guidance document, that is, a dose maintained As Low As Reasonably Achievable (ALARA) below the limitation dose of 50 millisieverts per year.

The latest report of the BEIR Committee (BEIR VII, referenced in the RFI) reports excess cases of cancer among adults in the Japanese atomic-bomb survivor studies were only detected when the dose received was above 100 millisieverts. However, the average annual dose to U.S. radiation workers is less than 2 millisieverts per year. (NCRP Report 93, *Ionizing Radiation Exposure of the Population of the United States*, reports an average dose to exposed radiation workers in 1980 of 2.2 millisievert. UNSCEAR (2000) reports that the average annual effective dose for the U.

S. nuclear power industry is about 1.5 mSv. Although recent data are not yet available in general, individual industries have continued to report an ever declining average annual dose to radiation workers in their respective industry since 1980.) Therefore, if OSHA offered a standard lower than the current standard based on an assumption of LNT dose response, it would appear to be in conflict with the ruling of the Supreme Court in this case.

In the Benzene case, the Supreme Court also held that *“A workplace can hardly be considered “unsafe” unless it threatens the workers with a significant risk of harm. Therefore, before the Secretary can promulgate any permanent health or safety standard, he must make a threshold finding that the place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices.”* The court supported this finding by citing, among other things, that § 6(b)(8) of the Act *“requires the Secretary, when he substantially alters an existing consensus standard, to explain how the new rule will “better effectuate” the Act’s purposes.”* As already stated, there is no scientific consensus that asserts that workers exposed to doses within standards in the 1987 Federal Guidance document have been exposed to “significant risks” that “can be eliminated” by a change in practice. Because of the hierarchy of radiation-protection standard setting described earlier, the 1987 Federal Guidance document can be considered a consensus standard, which would have to be shown to result in an unsafe workplace before the standard could be changed.

In the other case cited by OSHA, *American Textile Manufacturers Institute, Inc. v. Donovan* (Cotton dust), the U. S. Supreme Court held that OSHA does not have to do a cost versus benefit analysis in setting a standard for limitation of a toxic or physical hazard. Since radiation-safety standards for the annual limiting dose do not consider cost, there does not appear to be an impact of this case on these standards.

I hope you find these comments helpful. Please do not hesitate to contact me if you have any questions about these comments or other issues in which the Health Physics Society can be of assistance.

Sincerely,



Ruth E. McBurney, CHP
Attachments



HEALTH
PHYSICS
SOCIETY

COMPATIBILITY IN RADIATION-SAFETY REGULATIONS

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

Adopted: January 1992

Revised: August 2000

Reaffirmed: March 2001

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The Health Physics Society believes the current regulatory framework for establishing and enforcing regulatory radiation-safety standards results in inconsistent, inefficient, and unnecessarily expensive public health protection policies regarding radiation safety. Therefore, the Society advocates the establishment of a regulatory framework with the following requirements:

1. A single, independent U. S. Federal agency (herein called the Agency) shall have the responsibility and authority to establish all ionizing radiation-safety standards for all controllable sources¹ of occupational and public exposures.
2. The Agency shall have the responsibility and authority to oversee enforcement of all radiation-safety programs implementing these radiation-safety standards.
3. Provisions shall be made for the Agency to delegate enforcement authority to other governmental entities or agencies similar to the current provisions for Agreement State Programs under the Atomic Energy Act of 1954 as amended.
4. Delegation of authority under the previous provision shall be for enforcement responsibilities only. The regulatory radiation-safety standards for these lower tiered programs would be those established by the Agency.
5. Radiation-safety standards shall be consistent with the recommendations of the International Commission on Radiological Protection (ICRP), the National Council of Radiation Protection and Measurements (NCRP), and scientific consensus standards.

Footnotes

¹ A controllable source is any source of radiation exposure for which reasonable actions can be taken to limit radiation exposure without resulting in adverse effects on individuals. Examples of controllable sources include:

- Any source of man-made radiation exposure in the workplace (i.e., occupational exposure).
- Any facility or other operation that results in releases of man-made or technologically enhanced, naturally occurring radionuclides to the environment.
- Exposures from radiation-producing machines.
- Any localized areas of environmental contamination resulting from planned or accidental releases of radioactive material or disposal of radioactive waste.
- Technologically enhanced, naturally occurring radioactive material.
- Medical exposures to individuals who are not the subject of the medical procedure resulting in the exposure.
- Indoor radon

Examples of sources that are not controllable include:

- Natural terrestrial background radiation.
- Cosmic radiation.
- Naturally occurring radioactive material present inside the body.
- Medical exposures to individuals who are the subject of the medical procedure resulting in the exposure.
- Global fallout of radionuclides from atmospheric testing of nuclear weapons.
- Regional or global radioactive contamination from accidental releases of radioactive material.

* The Health Physics Society is a non profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to approximately 6,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the department of defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society. The Society may be contacted at: 1313 Dolley Madison Blvd., Suite 402, McLean, VA 22101; phone: 703-790-1745; FAX: 703-790-2672; email: HPS@BurkInc.com.



OCCUPATIONAL RADIATION-SAFETY STANDARDS AND REGULATIONS ARE SOUND

HEALTH
PHYSICS
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POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

Adopted: March 2000
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EXECUTIVE SUMMARY

The Society believes occupational radiation-safety standards and regulations have been sound, and protective of radiation workers, since the mid-1950s. This position is based on consideration of the following:

- 1. Since the 1920s there has been a public and independent system consisting of scientific committees, scientific organizations, and regulatory authorities/agencies for recommending and establishing basic radiation-safety standards at the international and national level.*
- 2. Dose limits represent an acceptable level of potential risk and do not represent a level that will necessarily be unsafe if they are exceeded.*
- 3. The reduction of individual dose limits is not evidence the earlier dose limits were inadequate.*
- 4. Average doses received by radiation workers have been, and continue to be, below the individual dose limits existent at the time.*
- 5. The most reliable studies of the effects of radiation exposure at the low levels received by occupational workers have not been able to detect adverse health effects associated with lifetime exposures smaller than approximately 10 rem (0.1 Sv)¹.*

The Society believes the implementation of radiation-safety standards and regulations has been responsible and adequate in providing for a safe industry, taking into account changes in occupational work practices over the last 50 years. This position is based on consideration of the following:

- 1. From the beginning of the widespread use of radiation and radioactivity in the United States, specific responsibilities have existed for those individuals and agencies charged with regulating the safe use of these materials.*
- 2. Since the mid-1950s radiation-safety standards have included provisions for incorporating the philosophy of As Low As Reasonably Achievable (ALARA) in radiation-safety work practices.*
- 3. The application of ALARA is founded in the professional judgement of radiation-safety managers and personnel and is not, therefore, able to be used as a measure of whether or not a particular radiation-safety program is adequate in comparison with other programs.*
- 4. The citation of a deficiency, regulatory violation, or area for improvement does not necessarily provide an indication of an unsafe condition or an unsafe facility.*
- 5. Implicit within regulations is the expectation that employers recognize unsafe conditions and cease operations that have been determined to be unsafe.*
- 6. Final designation of an unsafe working environment is most appropriately done by those specifically entrusted with that responsibility, i.e., the regulatory authority.*

The Society believes employers should be held accountable to conduct radiation-safety programs that comply with regulations and requirements. However, the rigor of an ALARA program, the degree of compliance with regulatory requirements, and worker perceptions of the adequacy of the safety of the program may be measures of the employer's commitment to radiation safety but are not necessarily measures of worker safety.

SYSTEM FOR ESTABLISHING OCCUPATIONAL RADIATION-SAFETY STANDARDS AND REGULATIONS

Within a decade of the discovery of x rays in 1895 and radioactivity in 1896, scientists had developed uses for radiation, primarily in the area of medical diagnosis and treatment. This scientific endeavor has continued to the present, resulting in the current beneficial use of radiation and radioactive materials for the improvement of human life. The research, development, and use of radiation and radioactive materials by man necessarily results in the researchers and users of this technology being exposed to radiation in the course of their work, i.e., occupational radiation exposure. From the earliest days of experimenting with radiation it became known there were levels of exposure at which injury to human tissues could occur, such that occupational radiation exposure needed to be controlled for the safety of radiation workers.

The potential for peaceful uses of radiation and radioactivity began to be developed in earnest in the 1950s, resulting in an entire industry with occupationally exposed radiation workers by about 1960. Individuals in the first major group of radiation workers are now approaching the end of their careers and lifetime. This, combined with changes in social and political attitudes regarding occupational safety standards, has led to the examination of the adequacy of the historical, and current, occupational radiation-safety standards and regulations in various political, legal, and regulatory venues.

This Position Statement provides the position of the Health Physics Society on the adequacy of occupational radiation-safety standards, the adequacy of the regulatory system to enforce these standards, and the responsibilities of employers in conducting radiation-safety programs.

The system for establishing and implementing occupational radiation-safety standards today is essentially the same as that formulated in the 1920s. This system consists of various independent committees, scientific organizations, and agencies operating within a structure that is designed to use the best scientific knowledge of radiation health effects to establish radiation program regulations that are protective of the worker. This hierarchical system consists of (1) international and national scientific committees publicly developing consensus scientific *reports* on the effects of radiation exposure based on the works of independent scientists and researchers, (2) international and national scientific organizations using these reports to publicly develop *recommendations* for radiation-safety standards that provide a level of occupational risk that is acceptable for a radiation worker and (3) regulatory authorities/agencies using these recommendations to establish legally binding *regulations*.

The continuing independent scientific, and public aspects of this system for development and establishment of *reports*, *recommendations*, and *regulations* results in an inherent provision that the radiation-safety standards and regulations have minimal influence from the radiation industry and employers and are protective based on the consensus scientific knowledge and state-of-the-art practices at the time of establishment.

Therefore, criticisms that vital health-effects knowledge has been withheld from the public by the industry does not have validity in the radiation industry, either now or in the past. This is particularly true in the United States since the formal establishment of a radiation-protection regulatory structure by the Atomic Energy Act of 1954 (and subsequent amendments).

PRINCIPLES OF THE SYSTEM FOR RADIATION PROTECTION

In the 1920s, the first formal recommendations for radiation protection were promulgated by the International X-ray and Radium Protection Commission (established by the Second International Congress of Radiology in 1928) and the United States Advisory Committee on X-ray and Radium Protection. These recommendations were based on the concept of a “Tolerance Dose.” This concept was based on the state of knowledge of radiation effects at that time and was intended to set limits that prevented the occurrence of clinically observable radiation effects (like reddening of the skin). The recommended “Tolerance Dose” was gradually reduced over the next couple of decades in recognition of the growing use of radiation and the growing realization that chronic effects, like cancer or genetic effects, may also be induced by radiation. However, in the mid-1950s, with the realization of the potential expansion of the radiation industry and the number of workers that may be exposed, the “tolerance dose” levels were reduced again and the concept of maintaining exposures below the limits as low as practical was adopted. This formed the guiding principles of the radiation-protection system still in use today by the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP), the international and national scientific committees charged with

development of radiation-protection *recommendations*. These guiding principles are those of *justification*, *dose limitation*, and *optimization of dose at levels that are as low as reasonably achievable* (the ALARA principle).

Justification of the use of a source of radiation or radioactivity is accomplished through regulatory reviews, licensing processes, political will (such as national security uses), etc. Therefore, the principles of the system that are directly applicable to a radiation-safety program providing protection for a worker are those of *dose limitation* and the ALARA philosophy.

Since the inception of the current system for radiation-safety standards in the mid-1950s, the *dose limitation* principle has been included to meet “the need to apply individual dose limits to ensure that the procedures of justification and ALARA do not result in individuals or groups of individuals exceeding levels of acceptable risk” (NCRP 1993).

That is, the dose limits represent an acceptable level of potential occupational risk and do not represent a level that will necessarily be unsafe if they are exceeded.

Similarly, optimization of actual dose levels through the inclusion of the ALARA principle has been to meet “the need to ensure that the total societal detriment from such justifiable activities or practices is maintained ALARA, economic and social factors being taken into account” (NCRP 1993).

OCCUPATIONAL DOSE LIMITS

Post-war occupational radiation-protection standards contained individual dose limits for two separate modes of worker exposure, i.e., external irradiation and internal irradiation. These dose limits were set with the understanding they were controlled separately and the actual exposure to an individual could be the combination of exposure from each mode. The separate control of external and internal exposure continued in the United States until the adoption of a risk-based system recommended by the ICRP in 1977 and the NCRP in 1987. This system, which has a method for combining external and internal exposures into one system of control, was endorsed by Presidential Guidance to Federal Agencies in 1987 and implemented by United States regulatory agencies by 1994.

The external dose limit has always been expressed as an allowable dose over some calendar period. The external whole body dose allowed in a calendar year in the mid-1950s was 15 rem. This was reduced in 1960 to 12 rem per calendar year if detailed lifetime exposure records were maintained and the individual’s lifetime exposure did not exceed an average of 5 rem per year. If lifetime exposure records were not maintained, the limit was 5 rem per calendar year. With the adoption of the new system in 1994, the dose limit became a limitation of the total estimated risk from both external and internal exposure equal to the estimated risk from an external exposure of 5 rem per year.

Prior to the adoption of the risk-based system in 1994, internal exposure was controlled by controlling the amount of radioactive material that could be taken into the body. These limits were based on the estimated annual dose to the irradiated organs that would exist after 50 years of continuous intake. The organ, or organs, receiving the highest dose was referred to as the “critical organ.” Most generally, the amount of allowable intake was based on not exceeding 15 rem per year to any “critical organ” after 50 years of continuous intake. The primary exception was in cases where the bone was the critical organ, in which case the limit was related to an equivalent intake of radium, and not directly related to dose. The current risk-based system for controlling internal exposure is based on controlling (1) the estimated risk that the exposure

delivered over the next 50 years to an irradiated organ from an intake will result in a cancer or, in the case of the gonads, a genetic effect and (2) the exposure to prevent an “acute” injury to the organ. Since each organ has a different estimated risk of developing a cancer or a genetic effect, the allowable doses to an organ under the new system can range from approximately 20 rem to 500 rem, based strictly on the risk of one of these effects. However, an additional limit of 50 rem is imposed to prevent an acute injury from occurring.

Therefore, in general the internal exposure allowed under the earlier separate dose limitation scheme was lower than that allowed in the newer, risk-based scheme of dose limitation.

The gradual reduction in the external dose limit is often cited as a concern for the adequacy of the earlier dose limits. However, the change in individual dose limits over time is the result of three interrelated considerations. One consideration is the continually increasing scientific knowledge of radiation health effects that permitted evolution from a system based on prevention of injury to one based on reduction of risk. Second is the advances in technology that have resulted in the actual reduction of the average annual doses to occupational workers. The third consideration is the state of occupational safety in general as it relates to an “acceptable” occupational risk.

Therefore, the existence of a changing individual dose limit is not evidence the earlier dose limits were inadequate.

In the mid-1970s the international and national scientific committees charged with developing the consensus *reports* on radiation health effects (NAS 1972, UNSCEAR 1972) provided the first attempt at quantifying the risk of delayed effects (i.e., genetic effects and cancer induction) from radiation exposure. The attempt to refine the quantification of the probability of these effects has continued over the years. However, even today genetic effects are only able to be observed in animal studies and increases in cancer induction are only able to be seen in groups of people exposed to high doses of radiation at high rates, such as the survivors of the Japanese atomic bomb blasts. Therefore, the use of these animal studies and atomic bomb survivor studies for assessing the adequacy of occupational radiation standards requires the extrapolation of the study results from animals to humans and from high-dosed populations of Japanese civilians to low-dosed populations of United States workers.

Numerous populations (referred to as cohorts) of radiation workers in the United States, and in other countries, have been studied to look for diseases related to occupational radiation exposure. To date, the most reliable studies of the effects of radiation exposure at the low levels received by occupational workers have not been able to detect adverse health effects associated with their radiation exposure except at the higher doses, i.e., greater than approximately 10 rem.

AS LOW AS REASONABLY ACHIEVABLE (ALARA)

ALARA is a philosophy of striving for excellence in the practice of health physics. The concept of ALARA has been an important aspect of radiation-safety regulations, but has also led to misunderstanding and misuse of the standards. The NCRP has stated “ALARA is simply the continuation of good radiation-protection programs and practices which traditionally have been effective in keeping the average and individual exposures for monitored workers well below the limits” (NCRP 1993). The application of ALARA clearly includes the specification that economic and social factors be considered. Thus, the application of ALARA will inherently be different, i.e., is not able to be standardized across different sources or facilities.

The application of ALARA is founded in the professional judgement of radiation-safety managers and personnel and is not, therefore, able to be used as a measure as to whether or not a particular

radiation-safety program is adequate in comparison with other programs. Additionally, the ALARA concept does not provide a numerical limit below which the ALARA concept is achieved.

A measure of the impact and influence of including the ALARA principle in the system of radiation-protection regulations is the actual occupation exposures received, regardless of the individual dose limits. The NCRP cites reports that in the mid-1950s, when the annual individual dose limit was 12 to 15 rem, average exposures for workers in the Atomic Energy Commission facilities was on the order of 0.2 to 0.4 rem and for medical workers and industrial radiographers on the order of 0.5 to 5 rem. Later, under the more restrictive annual individual dose limit of 5 rem in 1975, the workers with measurable exposure constituted about 37% of all radiation workers and their average exposure was on the order of 0.4 rem (NCRP 1987).

Therefore, actual exposures to radiation workers have been, and continue to be, below the individual dose limits existent at the time.

REGULATORY CONTROL OF RADIATION-SAFETY PROGRAMS

The Atomic Energy Act of 1954, and subsequent amendments, clearly established the radiation industry in the United States as a regulated industry. That is, from the beginning of the widespread use of radiation and radioactivity in the United States, specific responsibilities have existed for those individuals and agencies charged with regulating the safe use of these materials. The regulatory framework has undergone significant, and sometimes frequent, change over the years. The regulatory framework has come under varying criticism as the political and social structure of the United States has changed. The current regulatory framework is complex, with multiple agencies having responsibilities that overlap and are, in some cases, in conflict. However, this does not detract from the existence of a basic regulatory environment in which occupational radiation exposure has been received.

The basic tenet of a regulatory framework is the designation of agencies and/or individuals as those responsible for assessing the adequacy, and safety, of the regulated program. From the inception of the regulatory framework for radiation-safety programs in the United States, the regulatory authority has had several aspects to its mission. First, they are to identify conditions that are unsafe and stop operations until safety is restored. Second, they are to identify conditions that are deficient and oversee correction of the deficiency consistent with its nature and the nature of the facility. Deficiencies may be deviations or noncompliance with regulations and still not constitute an unsafe condition. Third, they are to identify areas that are not deficient or unsafe but could be improved and suggest, or oversee, the improvement of the radiation-safety program.

With this multilevel responsibility in mind, citation of a deficiency, regulatory violation, or area for improvement does not necessarily provide an indication of an unsafe condition or an unsafe facility.

Rather, the determination and designation of an unsafe working environment is most appropriately done by those specifically entrusted with that responsibility, i.e., the regulatory authority.

RESPONSIBILITIES OF EMPLOYERS

An employer has the responsibility to conduct a radiation-safety program that does not result in the injury of a radiation worker. Individual radiation injury can be avoided by compliance with the basic individual dose limitations that have been in existence since the mid-1950s. Beyond this most basic responsibility, employers should have a program in place to reduce individual exposures below the dose limits in accordance with the ALARA philosophy.

However, the rigor of an ALARA program, the degree of compliance with regulatory requirements, or worker perceptions of the adequacy of the safety of the program may be measures of the employer's commitment to radiation safety but are not necessarily measures of worker safety.

Implicit within regulations is the expectation that employers recognize unsafe conditions and cease operations that have been determined to be unsafe. Final designation of an unsafe working environment is most appropriately done by (1) those specifically entrusted with that responsibility, i.e., the regulatory authority and (2) comparison of individual doses to doses at which health effects are able to be observed.

FOOTNOTE

¹ The sievert (Sv) is the international (SI) unit of effective dose equivalent. The HPS endorses the use of SI units; however, because U.S. regulatory agencies continue to use the traditional units in regulations, this position statement uses the traditional unit for effective dose equivalent, i.e., the rem, throughout the document. 100 rem = 1 Sv.

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