



OCCUPATIONAL RADIATION-SAFETY STANDARDS AND REGULATIONS ARE SOUND

HEALTH
PHYSICS
SOCIETY

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

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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.

REFERENCES

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* The Health Physics Society is a nonprofit 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.