

Course Title: Radiological Control Technician
Module Title: Radiological Protection Standards
Module Number: 1.09

Objectives:

- 1.09.01 Identify the role of advisory agencies in the development of recommendations for radiological control.
- 1.09.02 Identify the role of regulatory agencies in the development of standards and regulations for radiological control.
- 1.09.03 Identify the scope of 10 CFR Part 835.

References:

1. ANL-88-26 (1988) "Operational Health Physics Training"; Moe, Harold; Argonne National Laboratory, Chicago
2. U.S. Department of Energy, DOE-STD-1098-99, "Radiological Control Standard"
3. 10 CFR Part 835 (1998) "Occupational Radiation Protection"

HISTORY OF STANDARDS

The task of setting exposure limits is both a vital and yet a very difficult undertaking. It is vital because workers must be protected from the harmful effects of ionizing radiation. It is difficult because of the many factors which enter into the effects which radiation produces. Even though a vast amount of data has been gathered and studied, there are still many areas where much work is needed before firm conclusions can be drawn. Nevertheless, in order to advance in the field of nuclear energy, people must work with radiation. Thus, certain levels must be set which will protect workers from undue exposure.

Because there are still several unknowns which must be evaluated, the setting of limits involves judgments which cannot be wholly based upon the present body of scientific knowledge. For this reason, the concept of an "acceptable risk" is used. In other words, the benefits are weighed against the potential damage and then limits are set at some level at which the most benefit to mankind will accrue. However, since all exposure is assumed to involve risk to the individual, exposures should always be kept as low as practicable. This implies that efforts be continually directed toward improving performance, techniques and safety designs to reduce exposures.

From time to time, these limits will be revised as new knowledge is gained. When some of the assumptions can be replaced by facts, then it becomes prudent to review the limits and perhaps make firmer recommendations. The whole history of the development of exposure limits points out this feature of re-evaluation in the light of current knowledge.

With the discovery of radioactivity and a consequent intensive investigation of the phenomenon, many people were subjected to very high dose rates, and it did not take long for deleterious effects to become manifest. As early as 1897, cases of skin damage began to appear.

Erythema Dose

Early efforts at control were hampered by a lack of quantitative methods. There were no units by which one could assess the amount of radiation. No one even knew what was how much, let alone, too much radiation! As a result of the use of radiation by doctors in treating patients, a unit called the erythema dose came into use. This was a highly qualitative unit; defined in terms of the amount of radiation which would produce a well-defined reddening of the skin. It soon became apparent that this dose unit was not at all satisfactory. It varied not only with the type of radiation and the dose rate, but also with the response of different parts of the body. Thus, two people could receive the same supposed fraction of an erythema dose, yet one might show skin effects and the other none. This lack of a certain value for this unit made protection work more or less of a trial-and-error process.

Around 1914, radiation began to be used in industry. The radium dial-painting process came into being, and x-rays were found useful for showing up flaws in materials. Larger numbers of people were now being exposed. No longer could the vague notion of erythema dose serve the purpose of a protection standard. Yet progress toward better standards still lagged because of lack of knowledge of the many complex factors which enter into radiation effects.

1.09.01 *Identify the role of advisory agencies in the development of recommendations for radiological control.*

ICRU, ICRP, AND NCRP

In 1925, at the First International Congress of Radiology, the International Commission on Radiological Units and Measurements (ICRU) was formed, mainly because of the lack of a suitable dosage unit of international acceptance. In 1928, this group adopted the definition of an international unit, the Roentgen. For the first time measurements throughout the world could be made in terms of the same unit. Over the years the ICRU has been the main force in defining and adopting units for use on an international basis.

At the Second International Congress of Radiology in 1928, the first international body concerned with protection standards was formed. At first known as the International X-ray and Radium Protection Commission, this group is now called the International Commission on Radiological Protection (ICRP). This group discusses and reviews basic protection principles, and these recommendations then serve as a guide from which regulations can be drawn up by each country to suit its needs. Although this group acts only as an advisory board, it has had a tremendous impact on the field of radiation protection.

In 1934, the ICRP made its first recommendation of a tolerance level of exposure: 0.2 R/day. This limit remained in force until 1950. However, because of World War II, the ICRP did not meet between 1937 and 1950. This left much of the study of protection standards during this time to the national committees.

In this regard, one cannot help but mention the work done by the National Committee on Radiation Protection and Measurements (NCRP). This group was formed in the United States in 1929. The work of this body was coordinated by the National Bureau of Standards. The early recommendations of the Committee appeared in the National Bureau of Standards Handbooks. The NCRP recommendations as outlined in Handbooks 20 and 23, which have been superseded by later reports, served as the basis for protection practices during the days of the Manhattan project. This was the name given to the project developing the atomic bomb. Many members of the NCRP were engaged in this program and were helpful in seeing that protection standards prevailed.

From the standpoint of protection problems, it is hard to believe the dramatic impact that the war years produced. Of course, most of this effect can be traced to the development of the atomic bomb. Before the war, most of the problems concerned rather low energy x-rays. Now, not only were there these to treat, but also other types of radiation with a wide range of energies. Added to this was the large increase of workers in the radiation field. Also, many new techniques and operations became a topic of real concern. New units would be needed to define the dose contributed by radiation other than x-rays. Large amounts of waste were now produced and methods of disposal would have to be worked out. With reactors in use, not only the workers, but also others not connected with the work, would have to be considered. The scope of the radiation field had enlarged to an undreamed of extent.

The NCRP met in 1946 to reorganize. At this time a number of subcommittees were formed to deal with the new problems more effectively. This resulted in the publication of a number of handbooks after the war which represented changes and additions to the old recommendations. The Committee was replaced by a non-profit corporation chartered by Congress in 1964 and is now known as the National Council on Radiation Protection and Measurements. The Council is the successor to the Committee and was formed to carry on the work begun by the Committee.

The Council is made up of the members and the participants who serve on a number of committees. These committees develop proposed recommendations on various aspects of radiation protection and radiation measurements, which when approved by the Council, are published as NCRP Reports. The initial report issued by the Council was NCRP Report No. 32.

The three organizations, ICRU, ICRP and NCRP, have figured prominently in the development of present day radiation protection practices. Although these bodies act as advisory boards only, much of the radiation protection philosophy which has evolved and which has been adopted by various regulatory agencies throughout the world, had its origins in the recommendations of these organizations.

Radiation Exposure Concerns

Over the years, the development of standards for radiation protection has evolved through several phases. Initially, the concern was for the protection of patients and medical personnel from external radiation from the use of x-rays for diagnosis and therapy. World War II produced a shift in emphasis due to the increase in the number, type and uses of radioactive materials. This introduced considerations about internal exposure and the dose to the general public. Finally, a concern over the potential genetic effects of radiation and the impact of long-term exposure at low dose rates emerged.

Data from biological studies seemed to indicate that one could not assume that all effects had a threshold dose. Also, in the case of gene damage, effects could be expected at very

low doses. This implied that any dose, no matter how low, carried a certain risk of deleterious effects.

Efforts have been directed toward quantifying the risk associated with a certain level of exposure. If one assumes a non-threshold relationship, then any dose carries some risk of producing damage. Under this assumption, all exposure should be kept at the lowest practical levels. However, several factors need to be considered. Namely, the information available for the quantification of risks is imperfect so that our knowledge of the absolute value of the risks involved is not that complete. In addition, the assumptions of a risk by an individual, in general, presumes the willingness to chance the risk in exchange for some resultant benefit, which, ideally, exceeds the risk. Then, the resultant benefit which accrues, in a sense, justifies the risk. However, the resultant benefits in the case of radiation exposure are also poorly known. Therefore, the balancing of risk versus benefit in order to obtain a net benefit is not easily accomplished. For this reason, the prudent approach, adopted by both the ICRP and the NCRP is to keep exposures as low as reasonably achievable (ALARA).

Down through the years since the discovery of radiation, one can see the care and concern with which the problem of radiation protection has been approached. Back in the early days, the main problem was the gross somatic effects. Now, the main concern has switched from these blatant effects to the more subtle effects of radiation. As knowledge has been gained, it has become quite evident that more knowledge is needed.

In any case, the quest for knowledge in this field has not suffered and more and more groups have joined in the search. In addition to the work of the ICRP, NCRP, and ICRU, the National Academy of Sciences National Research Council has undertaken the study of biological effects. This group consists of a large number of scientists throughout the country. The reports issued by this body are in summary form and the group functions as an advisory body. Its purpose is to supply technical information as a basis from which regulations can be developed. On a world-wide scale, the United Nations has established a Scientific Committee. Their report on the effects of atomic radiation has helped to supply much needed background information.

The results of continuing reviews of biological data have revealed two types of radiation effects. Those for which a practical threshold dose for occurrence can be demonstrated and those for which there is apparently no threshold. These are referred to as nonstochastic and stochastic effects, respectively. Nonstochastic effects can be prevented by limiting the dose to the individual to a value below the threshold dose for occurrence of the effects. Since stochastic effects presume that there is no threshold level, and that the probability of the effect occurring increases with dose, any dose represents some probability of producing that effect. For stochastic effects, one can only limit the probability of occurrence to some level (deemed acceptable) by limiting the radiation exposure. The ICRP has based its recommendations for a system of dose limitation on the features discussed above.

ICRP Basic Recommendations

From time-to-time, the ICRP has altered and updated its recommendations. In its current reports, the ICRP recommends a basic system of dose limitation which includes these three interrelated aspects:

- (1) No practice shall be adopted unless its introduction produces a positive net benefit.
- (2) All exposures shall be kept ALARA, economic and social factors being taken into account.
- (3) The dose equivalent to individuals shall not exceed the recommended limits.

Federal Policy on Radiation Matters

Because of the scope of the nuclear energy field in this country, the Federal Radiation Council (FRC) was formed in 1959 (Public Law 86-373). This body advised the President concerning radiation matters and provided guidance for all Federal agencies in setting standards and in working with the States. While in existence, the Council issued eight staff reports. The FRC was abolished by Reorganization Plan No. 3 in 1970, and its responsibilities were transferred to the newly formed U.S. Environmental Protection Agency (EPA). The Office of Radiation Programs (ORP) of the EPA took over the activities of the FRC.

While in existence, the FRC provided the basic general philosophy of the Federal policy on radiation matters. This guidance was contained in their first two reports. Each Federal agency had the responsibility to determine specific regulations in its area of jurisdiction. In some cases, the guides could be exceeded but "...only after the Federal agency having jurisdiction over the matter has carefully considered the reason for doing so in light of the recommendations in this staff report."

The recommendations of the FRC were approved in 1960 and formed the basis of the Federal radiation protection guidance. In 1981, the EPA drafted proposed revised recommendations in the Federal Register regarding occupational exposure, and solicited comments. Following review of the comments, and discussions during an interagency review, the conclusion was reached to revise the previous Federal guidance. The EPA believes that it is appropriate to adopt the general features of the ICRP approach in radiation protection guidance for use by Federal agencies for occupational exposure. The revised EPA guidance was approved and issued in January 1987. The recommendations replaced portions of the previous guidance which applied to workers exposed to ionizing radiation but did not change the previous guidance for exposure of the general public.

With respect to the Federal policy concerning radiation protection for diagnostic x-rays, the Bureau of Radiological Health of the U.S. Department of Health and Human Services has developed a set of recommendations which serve as the radiation protection guidance.

1.09.02

Identify the role of regulatory agencies in the development of standards and regulations for radiological control.

REGULATING AGENCIES

So far, our attention has been directed to those groups which supply recommendations for exposure levels and safe practices. The rest of this section will be concerned with the organizations which are charged with developing regulations. Of prime interest will be those groups which regulate radiation matters in this country.

Under the Atomic Energy Act of 1954, the United States Atomic Energy commission (AEC) was given the responsibility of regulating the atomic energy industry. The Act authorized the AEC to set up a licensing program to be augmented by whatever rules or regulations are deemed appropriate. The bases for these rules are: to protect the public health and safety, and provide for national defense and security. Under this mandate, the AEC was concerned with the development of regulatory guides.

The Energy Reorganization Act of 1974 abolished the AEC and established two agencies to perform the functions of the AEC. The U.S. Nuclear Regulatory Commission (NRC) has taken over the licensing and regulatory functions. The following materials are licensed and under NRC control: uranium and thorium or ores containing .05 % of these materials, special nuclear material (plutonium, U-233, U enriched in U-233 or U-235), and by-product material (radioactive material resulting from producing or utilizing special nuclear material). The regulations of the NRC are set forth in the Code of Federal Regulations (CFR), Title 10, Part 20, Standards for Protection Against Radiation, deals specifically with the regulations for control of radiation hazards by the licensee. Other parts of Title 10 deal with licensing and regulatory requirements associated with the use of source, special nuclear material and byproduct material.

As part of its duties, the NRC is charged with the task of seeing that these measures prevail. This aspect requires inspection and review in order to assure this. This function is carried out by NRC personnel (inspectors) at regular intervals. Their job is to make the inspections and report their findings. In the event that a failure to comply is noted, the licensee is required to correct this.

Many of the states have taken up the task of setting up their own safety standards. The NRC has been directed to assist the states to assure that the state and Commission programs are compatible. These states are referred to as Agreement States.

The 1974, the Energy Research and Development Administration (ERDA) assumed responsibility of the remaining functions of the AEC. These activities related to energy research and development. In 1977, the U.S. Department of Energy (DOE) replaced ERDA. The DOE had issued occupational radiation protection standards which pertained to its own activities and to those of its contractors, not subject to licensing. These standards appeared in the DOE Orders, which replaced the Manual Chapters of the AEC. Standards specifically applicable to radiation protection were contained in DOE Order 5480.11. "Radiation Protection for Occupational Workers," and DOE/EH-0256T, the "Radiological Control Manual"; however DOE Order 5480.11 was replaced by 10 CFR 835 and the Radiological Control Manual is now a DOE standard (guidance) (DOE-STD-1098-99).

1.09.03 *Identify the scope of 10 CFR 835.*

10 CFR 835

Rule 10 CFR 835, "Occupational Radiation Protection," was implemented because of the Price-Anderson Amendments Act (PAAA). Rule 10 CFR 835 allows DOE to convert the contractual standards in Orders to enforceable rules, thus enhancing contractor accountability for safety. The rule is supported by DOE issued Guidance Documents and a site-specific Radiation Protection Program (RPP). Full compliance with the rule was required by January 1, 1996. Similar to the NRC, the DOE is charged with inspections and enforcement of its contractors to see that they are in compliance with DOE Orders and rules. DOE may assess civil penalties (including fines and jail time) to any person who has by action or omission knowingly and willfully violated, caused to be violated, attempted to violate, or conspired to violate any section of 10 CFR 835.

10 CFR 835 requires DOE activities be conducted with a written radiation protection program. And, some sites may still be contractually obligated to adhere to provisions of the DOE Radiological Control Standard.

The scope of 10 CFR 835 establishes radiation protection standards, limits, and program requirements for protecting individuals from ionizing radiation resulting from the conduct of DOE operations.

Safety in the shipment of radioactive substances is principally the responsibility of the U.S. Department of Transportation (DOT). Title 49 Transportation, of the CFRs, deals with hazardous shipments including radioactive materials.

From time-to-time, changes need to be made in various regulations. The CFR is revised through submission of changes proposed by an agency and the Federal Government to other governmental and private agencies and to the general public. Except for emergency

rules, CFRs are revised by 1) identifying changes in the Semi-Annual Regulatory Agenda; 2) requesting comments in the Federal Register, with a schedule for receiving them; 3) holding public meetings (if required); 4) publishing a preliminary rule; 5) allowing a comment period; 6) publishing a draft rule; 7) allowing a comment period; and 8) publishing a final rule with an effective date. Other agencies of the Federal Government having an interest in the regulations for the shipment of radioactive substances are: Interstate Commerce Commission, Coast Guard, Federal Aviation Agency, Postal Service, DOE and the NRC. The Department of Transportation has made an effort to make its labeling system conform with the regulations of the International Atomic Energy Agency.

SITE SPECIFIC DOE ORDERS/STANDARDS

Insert site specific information addressing DOE Orders/Standards applicable to radiological control at the site, based on contracts.

DOE RADIOLOGICAL CONTROL STANDARD (RCS)

Radiological Control Policy

A key element of the Radiation Protection Guidance to the Federal Agencies for Occupational Exposure approved by President Reagan on January 20, 1987, and a fundamental principle underlying the RCS is:

"There should not be any occupational exposure of workers to ionizing radiation without the expectation of an overall benefit from the activity causing the exposure."

The Department of Energy is firmly committed to having a Radiological Control Program of the highest quality. This applies to those DOE activities that manage radiation and radioactive materials and that may potentially result in radiation exposure to workers, the public or the environment.

ALARA

Personal radiation exposure shall be maintained As-Low-As-Reasonably-Achievable (ALARA). Radiation exposure of the work force and public shall be controlled such that radiation exposures are well below regulatory limits and that there is no radiation exposure without commensurate benefit.

Ownership

Each person involved in radiological work is expected to demonstrate responsibility and accountability through an informed, disciplined and cautious attitude toward radiation and radioactivity.

Excellence

Excellent performance is evident when radiation exposures are maintained well below regulatory limits, contamination is minimal, radioactivity is well controlled and radiological spills or uncontrolled releases are prevented. Continuing improvement is essential to excellence in radiological control.

Standard Applicability and Control

The RCS recommends practices for the conduct of radiological control activities. The RCS states DOE's positions and views on the best courses of action currently available in the area of radiological controls. Accordingly, the provisions in the RCS should be viewed by contractors as an acceptable technique, method or solution for fulfilling their duties and responsibilities. The RCS should be used by DOE in evaluating the performance of its contractors.

The RCS is not a substitute for Regulations; it is intended to be consistent with all relevant statutory and regulatory requirements and shall be revised whenever necessary to ensure such consistency. Some of the RCS provisions, however, challenge the user to go well beyond minimum requirements. Following the course of action delineated in the RCS will result in achieving and surpassing related statutory or regulatory requirements.

1. The RCS is a living document. DOE intends to review and update provisions on a periodic basis to incorporate lessons learned and suggestions for improvement. The Assistant Secretary for Environment, Safety and Health is responsible for this task. Recommendations to correct or improve the RCS are encouraged and should be sent to the Radiological Control Program Advisor of the Program Secretarial Official responsible for the affected work activity. Information copies should also be sent to the other members of the Radiological Control Coordinating Committee. The Program Secretarial Official will transmit such recommendations to the Office of Environment, Safety and Health for consideration. The recommended wording of the change, as well as the basis and justification for the change, should be included.

2. The Department of Energy intends to incorporate by reference the provisions in the RCS into contracts or regulatory plans, as appropriate. These incorporated provisions shall be enforceable pursuant to the contract or underlying regulations. When incorporating a provision, DOE should approve an implementation plan that includes a compliance schedule.

3. In those cases where contractors or subcontractors are used to conduct DOE-funded radiological activities at DOE and non-DOE sites or facilities, and such organizations do not possess a U.S. Nuclear Regulatory Commission (NRC) or Agreement State license for the proposed activity, the application of the RCS is recommended. The lead Program Secretarial Official and the Office of Environment, Safety and Health should be included in the review and concurrence process in these situations. In those cases at non-DOE sites or facilities where a specific activity is being conducted pursuant to an NRC or Agreement State license, the provisions of the RCS are not binding to that activity.
4. The RCS should be kept current and should be entered into the contractor document control system.
5. The provisions of the RCS do not apply to facilities and activities of the Naval Nuclear Propulsion Program, which are separately covered under Executive Order 12344 (42 U.S.C 7158, note) and patients undergoing medical treatment at a DOE or DOE-funded facility.

Compliance

The RCS is a guidance document and compliance is not mandatory, unless the contractor is contractually obligated to follow provisions of the RCS.

Site-Specific Manual

1. A Site-Specific Radiological Control Manual should be issued and endorsed by the contractor senior site executive. The Site-Specific Radiological Control Manual does not require review or approval by the DOE. One approach in the development of Site-Specific Radiological Control Manuals is to invoke the provisions of the RCS as written with site specific additions, supplements and clarifications clearly indicated, included in the appropriate chapters and directly referenced to the corresponding Article. The contractor senior site executive is that person at a DOE contractor-operated facility or site who has final on-site corporate authority and is often called President, General Manager, Site Manager or Director.
2. Management policies, requirements, expectations and objectives for the site Radiological Control Program should be clearly and unambiguously stated.
3. The Site-Specific Manual should be kept current and entered into the contractor document control system.
4. Where a site has multiple facilities, there should be one manual for the site and one Radiological Control Organization. If a prime contractor manages several DOE sites, effort should be made to have one corporate Radiological Control Manual that applies to all of that prime contractor's DOE sites. For a site that has multiple

prime contractors, a common manual, with facility, contractor or building specific guidance to accommodate unique considerations, should be issued and endorsed by each contractor's senior site executive. For prime contractors who manage several sites but who also operate sites with more than one prime contractor, the site manual should take precedence over the corporate Radiological Control Manual.

5. Subcontractors should comply with the Site-Specific Radiological Control Manual.
6. Where DOE employees are conducting the transport of nuclear devices or components, a Program Specific Radiological Control Manual, based upon the provisions of the RCS, should be issued and approved by the DOE Field Office Manager. Controlled copies of such Manuals should be provided to the lead Program Secretarial Official.

Application of Requirements

1. The RCS assumes that most facilities or sites have organizations in place that generally meet the requirements presented in the text. It is not the intent of the RCS to unnecessarily create new or separate organizations if those functions can be incorporated into existing ones. For example, the Radiological Awareness Committee functions may be performed by an existing safety committee. It is expected, however, that the existing committee charter be revised to reflect the requirements and emphasis of the RCS. Similarly, titles such as Radiological Control Manager and Radiological Control Technician that are used in the RCS may locally be designated differently. A phased approach to transition to the use of the titles of positions in the RCS should be adopted. Corresponding position descriptions and organizational charts should be revised to accurately reflect required radiological responsibilities.
2. The degree of program formality and extent of the associated administrative process are expected to be commensurate with the radioactive material contamination and dose potential. For example, a site with an annual collective effective dose equivalent of one person-rem or less, that works with small quantities of unsealed radioactive material, would not be expected to have an ALARA program as complex as one required at higher dose sites. At low dose sites some program elements may be satisfied by brief policy statements.