Radiation Safety and Regulatory Compliance

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Regulations
A regulation is a legal statement written into a governmental code, which carries the force of law and is generally written in the form of basic principles and philosophy to cover all possible loopholes in advance. Thus, by using general language, future changes in practice can be handled via interpretations by the regulatory agency.

What is the objective of the regulations?
- The objective is to ensure that the health risks are maintained to be indistinguishable from those due to natural background radiation levels.

Who is responsible for making regulations?
- The uses of radioactive materials and radiation-producing devices are regulated by government agencies to limit exposures for both workers and the general public with a very conservative margin of safety.
- In the United States, federal agencies are responsible for establishing radiation safety regulations. These agencies include:
  - Nuclear Regulatory Commission (NRC)
  - Environmental Protection Agency (EPA)
  - Department of Energy (DOE)
  - Department of Transportation (DOT).
These agencies base their regulations on internationally recognized scientific studies.

Regulatory Guides
Regulatory guides, published by regulatory agencies, are technical aids in the interpretation of some regulations, but do not carry the force of law.

What is the purpose of Regulatory Guides?
- Give guidance to the licensee as to what a compliance inspector expects to see in a radiation safety program.

Standards
Who promotes these standards?
- A standard is promoted by a body of experts and is often incorporated into legal codes by reference. However, a recommendation does not carry the force of law.

Who is involved with the recommendations on Radiation Safety Standards?
- International Commission on Radiological Protection (ICRP)
- International Atomic Energy Agency (IAEA).
- International Commission on Radiological Units and Measurements (ICRU)
- National Council on Radiation Protection and Measurements (NCRP)
- EPA
- NRC
- National Academy of Sciences’ Committee on the Biological Effects of Ionizing Radiation (NAS/BEIR)

Local Involvement

Evolution of Radiation Safety

1925—1st International Congress of Radiology establishes the International Commission on Radiation Units and Measurements (ICRU) to develop a standard unit for measuring radiation.

1928—2nd International Congress of Radiology adopts the Roentgen as the international X-ray unit and provides the first international guidelines for radiation safety. International Commission on X-ray and Radium Protection is formed. This will become the International Commission on Radiological Protection (ICRP) in 1950.

1929—U.S. Advisory Committee on X-ray and Radium Protection is formed. This will become the NCRP.

1934—4th International Congress of Radiology recommends 0.2 Roentgen per day as a tolerance dose.

1946—Atomic Energy Commission (AEC) formed
- The NCRP gives a recommendation of the maximum permissible dose (MPD) of 0.3 rem/week.

1950s—Concepts of the rad and rem become widely used. Radiation standards are set only for persons who receive occupational exposures.

1954—NCRP states that a threshold on exposure can no longer be assumed and that exposure is justified only after a possible risk has been weighed against expected benefits.

In North Carolina the Radiation Protection Section of the Department of Environment and Natural Resources handles regulation of radioactive materials and radiation-producing devices. This agency enforces the “North Carolina Regulations For Protection Against Radiation” as stated in Title 15A Chapter 11 of the North Carolina Administrative Code. This agency has the authority to pursue civil and criminal actions against licensees who violate these regulations.
1954—NCRP adopts the term "permissible dose," and recommends a MPD of 0.3 rem/week for critical organs and 0.6 rem/week for the skin.

1955—ICRP adopts a MPD of 0.3 rem/week for critical organs for radiation workers and recommends limiting radiation to people not exposed on the job.

1957—NCRP recommends limiting occupational exposure to 5 rem/year.

1958—NCRP introduces the concept of no occupational exposure below age 18, i.e. 5(n-18).

1957—AEC issues 10 CFR Part 20, stating a MPD of 0.3 rem/week to radiation workers.

1957—NCRP recommends limiting occupational exposure to 5 rem/year.

1957—ICRP issues 10 CFR Part 20 to incorporate the 1987 EPA guidance. As part of its revised rule, NRC adopts a radiation dose limit for members of the general public of 0.1 rem/year (effective on January 1, 1994)

1959—The Federal Radiation Council (FRC) is formed.

1960—FRC issues its first set of radiation safety guidelines.

1970—Environmental Protection Agency (EPA) is created and the FRC dissolved.

1971—NCRP recommends a limit on the dose equivalent to the U.S. population of 0.17 rem/person/year for whole body and gonad exposure, and limits fetal exposure to 0.5 rem during the gestation period as a result of the mother's occupational exposure.

1973—Office of Management and Budget issues memorandum clarifying the roles of the AEC and EPA with regard to standards for the uranium fuel cycle.

1974—Energy Reorganization Act splits the AEC into the Nuclear Regulatory Commission (NRC) and Energy Research and Development Administration (ERDA).

1977—ICRP revises basic recommendations, introduces the concept of "effective dose equivalent" (which combines external and internal dose), adopts the policy of As Low As Reasonably Achievable (ALARA) and recommends an effective dose equivalent limit of 5 rem per year for radiation workers.

1987—EPA issues guidance to federal agencies regarding regulations to ensure protection of workers who are occupationally exposed to radiation

1991—EPA proposes an update to its guidance to federal agencies on dose limits for the general public. The proposed guidance generally reflects the 1991 ICRP recommendations.

1995—BEIR VII committee concludes that sufficient data has become available since 1991 to warrant reexamination of the health effects of low levels of ionizing radiation. The study is scheduled for 60 months with completion expected in October 2003.

1997—BEIR VII committee is formed to determine if sufficient new scientific data is available to warrant reassessment of low-level ionizing radiation health effects

1998—BEIR VII committee concludes that sufficient data has become available since 1991 to warrant a reexamination of the health effects of low levels of ionizing radiation. The study is scheduled for 60 months with completion expected in October 2003.

1995—Department of Energy initiates a 10-year program of research on molecular responses to low level radiation exposure.