9. Radiation Protection Standards and Regulatory Functions

9.1 Overview

In order for radiation protection and safety criteria to be applied systematically to existing radiation ***sources*** in a country, it is necessary to establish, through an appropriate legal instrument (law, decree, etc.), a specific set of compulsory basic standards of radiation protection. This legal instrument should designate a regulatory agency, which will be empowered to grant ***licenses*** to institutions and persons to conduct ***practices*** utilizing ***sources*** of radiation and to monitor compliance with the standards by ***authorized*** institutions and individuals (*26*).

9.2 National or State Regulation

Responsibility for promoting and monitoring compliance with radiation protection standards is exercised by national or state authorities through a ***regulatory authority***. In addition, national authorities generally take responsibility for certain essential radiological safety services and ***interventions*** that exceed the capabilities of persons or institutions authorized to conduct ***practices***.

9.3 National Infrastructures

The essential elements of a national infrastructure are: legislation and regulations; a ***regulatory authority*** empowered to authorize and inspect regulated activities and to enforce the legislation and regulations; sufficient resources; and adequate numbers of trained personnel. The infrastructure must also provide for control of ***sources*** of radiation for which no other organization has responsibility, such as ***exposure*** from ***natural sources*** in some special circumstances and management of ***radioactive waste*** from past ***practices*** (*26*).

National infrastructures must provide for adequate arrangements to be made by those responsible for the education and training of specialists in radiation protection and safety, as well as for the exchange of information among specialists. A related responsibility is to set up appropriate means of informing the public, its representatives, and the information media about the health and safety aspects of activities involving ***exposure*** to radiation and about regulatory processes.

National infrastructures must also provide facilities and services that are essential for radiation protection and safety, but that are beyond the capabilities required of persons authorized to conduct ***practices***. Such facilities and services include those needed for ***intervention***, personal dosimetry, environmental monitoring, and calibration and intercomparison of radiation measuring equipment.

9.4 *Regulatory Authority*

Full and proper application of the *BSS* (*26*) requires that governments establish a ***regulatory authority*** to regulate the introduction and conduct of any ***practice*** involving ***sources*** of radiation. Such a ***regulatory authority*** must be provided with sufficient powers and resources for effective regulation and should be independent of any government departments or agencies that are responsible for the promotion and development of the ***practices*** being regulated. The ***regulatory authority*** must also be independent of ***authorized*** persons by registration or ***license***, and of the designers and manufacturers of the radiation ***sources*** used in ***practices***.

The *BSS* (*26*) are worded on the assumption that a single ***regulatory authority*** is responsible for all aspects of radiation protection and safety in a country. In some countries, however, regulatory responsibility for different ***practices*** or different aspects of radiation safety may be divided between different authorities. Consequently, the term "***regulatory authority***" is generally used in the *BSS* (*26*) to mean the relevant ***regulatory authority*** for the particular ***source*** or aspect of radiation safety in question.

The functions of the ***regulatory authority*** include the following: identification of existing ***sources*** and ***practices*** involving the use of radiation in the country; assessment of applications for permission to conduct ***practices*** that entail or could entail ***exposure*** to radiation; the ***authorization*** of such ***practices*** and of the ***sources*** associated with them, subject to certain specified conditions; the conduct of periodic inspections to verify compliance with the

regulations and standards; and the enforcement of any necessary actions to ensure compliance with the regulations and standards.

9.5 Basic Structure of National Legislation

Countries should enact legislation in the area of radiation protection before encouraging the use of medical devices that emit radiation.

The legislative framework should include three different levels of legislation:

- Laws that provide the legal basis for regulation and control, establish the agency responsible, and define the major objectives of radiation protection.

- Standards and regulations that establish requirements pertaining to the different aspects of radiation protection and that can be adapted over time as scientific and technological knowledge develops.

- Protocols and/or codes of ***practice*** that provide precise instructions for the installation and use of ***ionizing radiation*** in each possible medical application. These should also be flexible and should be regularly updated to reflect progress in medical technology.

The ***authorization*** of a radiology service may involve two types of ***licenses***:

- ***License*** of professionals and technologists to provide radiological services.

- ***License*** of the installation, including the equipment and the physical spaces in which they are located.

In the first case (personal ***license***), the individuals concerned should meet the basic occupational or technical training requirements and should have completed specialized education and practical training in accordance with the needs associated with the various applications. Given the rapid progress of technology and procedures, it is also important to establish a mechanism for periodic relicensing.

In regard to the ***license*** of equipment and installations, radiation safety conditions should be evaluated through a review of the design documentation and verification inspections.

These two types of ***licenses*** procedures together constitute one of the requirements for ***authorization*** of the establishment and operation of each specific installation.

9.6 Organization of Radiation Protection Services

A radiation protection service should fulfill the following functions:

Source and User Registration

- Organize surveys and censuses in order to compile information on ***sources*** and users

- Keep up-to-date records of users and ***sources***

Radiological Health Assessments

- Prepare and develop programs for the assessment of radiation protection conditions in installations that use radiation-emitting ***sources***.

- Carry out actions to ensure compliance with the standards:
  - Inspect installations
  - Review radiation protection information and assessments
  - Provide information to those responsible and issue notices and deadlines for the execution of improvements
  - Monitor compliance through successive inspections

- Provide advice on the radiation protection measures to be adopted in the installation and utilization of ***sources*** of radiation, thereby fulfilling an educational function.

- Check needs for structural ***shielding*** and other protection and safety measures in installations employing ***sources*** of radiation.

- Investigate new evaluation procedures and radiological techniques that will make it possible to reduce the ***doses*** received by patients who undergo radiological studies (*72-75*).

Personnel Dosimetry

- Develop or promote programs for the delivery of personnel dosimetry services.

- Carry out or promote actions that will enable the execution of such programs, namely:
  - Dosimeter preparation
  - Calibrations
  - Distribution to users
  - Periodic replacement of radiation-sensitive materials
  - Processing and reading and interpretation of ***doses***
  - Recording of partial and cumulative ***doses***
  - Communication with those responsible for the facilities and with users

- Advise users on the correct utilization of the dosimetry service, thereby fulfilling an ongoing educational function in this regard.

- Inform those responsible for radiological health assessments of any detected cases of over***exposure***.

- Investigate new personal dosimetry techniques.

- Maintain files of individual ***dose*** records over the period established by the standards.

Quality Control

- Keep the instruments of the service permanently calibrated, interacting for this purpose with the IAEA/WHO SSDL network with regional dosimetry reference centers with primary or secondary standards.

- Plan and organize surveys and/or censuses aimed at evaluating clinical dosimetry conditions in radiation therapy installations.

Training and Promotion

- Organize periodic training courses.

- Organize the preparation and publication of manuals for training courses and informational pamphlets on radiation protection standards and activities of the service.