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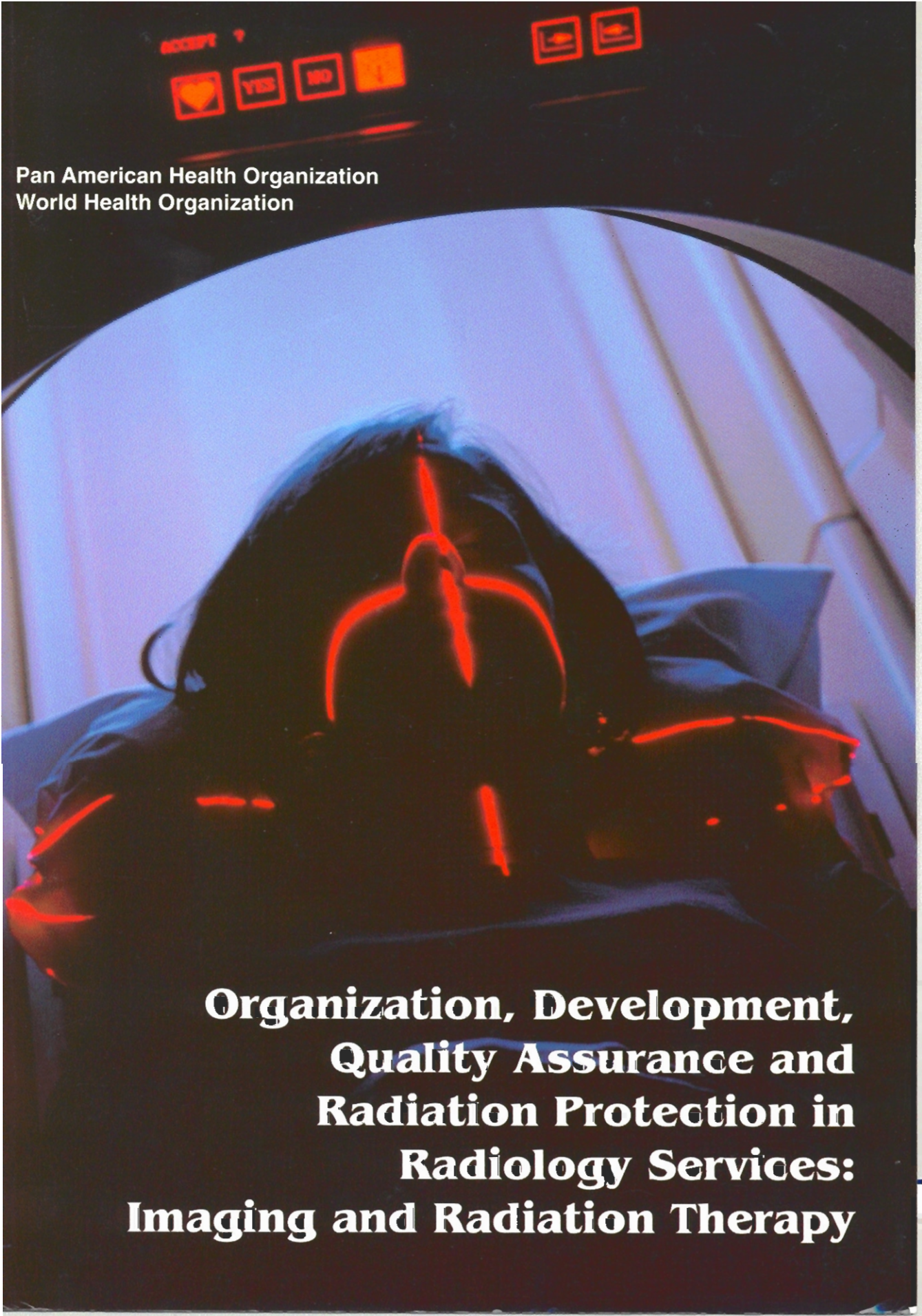

Organization, Development, Quality Assurance and Radiation Protection in Radiology Services: Imaging and Radiation Therapy

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Cari Borrás, DSc, FACR

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To Dr. José María Paganini, who for many years, first as Coordinator and then as Director of the Division of Health Systems and Services Development, insisted on the need for this publication.

Preface

This publication of the Division of Health Systems and Services Development of the Pan American Health Organization/World Health Organization discusses organizational and technical aspects of radiology services within the context of the strategic and programmatic orientations for 1995-1998. It seeks to harmonize the basic principles of decentralized health services with the requirements imposed by the incorporation of advances in medical knowledge and their application in different areas, the ultimate aim being to achieve accessibility, excellence, and safety in health care.

The decision-making processes through which resources are allocated and technological configurations are determined for the provision of health services involve a broad range of actors, including politicians, administrators, planners, and health professionals. In the specific case of radiology services, this process also involves medical physicists, a relatively new profession in the health field. The importance of the participation of these professionals is increasingly recognized in Latin America and the Caribbean.

This publication is aimed at these various professional groups, as well as the ministries of health of the Americas, which, as part of their regulatory function in the exercise of their sectoral steering role, are responsible for establishing guidelines for the organization and operation of health services, including radiology services. To illustrate the concepts developed in the text, the appendices present examples of equipment specifications, legislation on practices and specialties, and information on technical aspects of quality assurance and radiation protection.

It is hoped that the conceptual and methodological elements presented here will help to facilitate the task of those who must reconcile the social objectives of universal health care coverage with the principles of quality assurance and radiation protection, and with the availability of resources in the countries of the Region.

George A. O. Alleyne
Director

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AAPM	American Association of Physicists in Medicine [USA]
ABC	automatic brightness control
ABMP	American Board of Medical Physics [USA]
ABR	American Board of Radiology [USA]
AC	alternate current
ACR	American College of Radiology [USA]
ADCL	Accredited Dosimetry Calibration Laboratory [USA]
AEC	automatic exposure control
AGC	automatic gain control
ALARA	as low as reasonably achievable
ALI	annual limit on intake
AOBR	American Osteopathic Board of Radiology [USA]
AP	antero posterior
ARCRT	American Registry of Clinical Radiography Technologists [USA]
ARRT	American Registry of Radiologic Technologists [USA]
B	base
BRS	basic radiological system
BSS	International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources
CDRH	Center for Devices and Radiological Health [USA]
CEU	continuing education unit
CME	continuing medical education
CRT	cathode ray tube
CT	computed tomography
CTDI	computed tomography dose index
cw	continuous wave
dB	decibel
dc	direct current
DCIS	ductal carcinoma *in situ*
DNA	deoxyribonucleic acid
DSA	digital substraction angiography
EEC	European Economic Commission
ELISA	enzyme linked immuno-sorbent assay
ER	external radiotherapy
EU	European Union
F	fog
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration [USA]
FFD	focus-film distance
FIGO	International Federation of Gynecology and Obstetrics

FOV	field of view
FWHM	full width half maximum
Gy	gray
GYN	gynecological
HCFA	Health Care Financing Administration [USA]
HT	high tension
HV	high voltage
HVL	half-value layer
IAEA	International Atomic Energy Agency
ICD	International Classification of Diseases
ICRU	International Commission on Radiation Units and Measurements
ICRP	International Commission on Radiation Protection
IEC	International Electrotechnical Commission
ILO	International Labor Organization
IQ	intelligence quotient
IRMA	indirect radioimmuno assay
ISO	International Standardization Organization
ISRRT	International Society of Radiographers and Radiological Technicians
I/O	input/output
IUAC	International Union Against Cancer
keV	kiloelectron-volt = 1,000 electron-volt = 10^3 eV
LET	linear energy transfer
Linac	linear accelerator
MeV	megaelectron-volt = 1,000,000 electron-volt = 10^6 eV
MQC	Manual of Quality Control of ACR
MQSA	Mammography Quality Standards Act [USA]
MSAD	multiple scan average dose
MR	magnetic resonance
MRI	magnetic resonance imaging
MTF	modulation transfer function
MU	monitor units
NCRP	National Council on Radiation Protection and Measurements [USA]
NEMA	National Electrotechnical Manufacturers Association [USA]
NEA	Nuclear Energy Agency (OECD)
NIST	National Institute for Standards and Technology [USA]
NM	nuclear medicine
NRC	Nuclear Regulatory Commission [USA]
OB/GYN	obstetric and gynecological
OD	optical density
ODI	optical distance indicator
OECD	Organization for Economic Cooperation and Development

OR	operating room
PA	postero anterior
PAHO	Pan American Health Organization
PC	personal computer
PDD	percentage depth dose
PET	positron emission tomography
PM	photomultiplier tube
PSNM	physician specialized in nuclear medicine
QA	quality assurance
QC	quality control
RBE	relative biological effectiveness
RCPSC	Royal College of Physicians and Surgeons of Canada [Canada]
rf	radiofrequency
RIA	radioimmunoassay
R/L	right/left
RN	radionuclide
ROC	receptor-operator-characteristics
ROI	region of interest
ROT	radiation oncology therapy
RP	radiation protection
RT	radiation therapy
RTO	radiation therapy and oncology
SAD	source-axis distance
SASPS	Under Secretary of Health Services and Programs Administration (Subsecretaría de Administración de Servicios y Programas de Salud) [Argentine]
SCPRI	Central Service for Protection against Ionizing Radiation (Service Central de Protection contre les Rayonnements Ionisants) [France]
SD	standard deviation
SDL	Standards Dosimetry Laboratory. It may have primary (PSDL) or secondary standards (SSDL).
SI	International System —of units (Sistema Internacional —de unidades)
SID	source-image receptor distance
SMPTE	Society of Motion Picture and Television Engineers
SPECT	single photon emission computed tomography
SSD	source-skin distance
Sv	Sievert
TAR	tissue-air ratio
TG	task group
TLD	thermoluminiscent dosimetry
TMR	tissue-maximum ratio

TNM	tumor staging (tumor, nodules, metastases)
TPR	tissue-phantom ratio
UN	United Nations
UNIDO	United Nations Industrial Development Organization
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
WHIS-RAD	World Health Organization Imaging System-Radiology
WHO	World Health Organization

1. Introduction

1.1 Basic Concepts

1.1.1 Health Services

The realm of the health sciences in general and the field of medicine in particular have undergone extraordinary growth in recent decades.

Holistic models have helped considerably to explain the phenomena that determine health, beyond their biological expression, and have opened up new possibilities for preserving and enhancing the health status of individuals and social groups. Recognition of environmental, social, and behavioral factors as primary determinants of health has made it possible to expand spheres of action in relation to health and has opened up new opportunities for the intersectoral application of public policies aimed at enhancing individual and collective well-being.

In the biological sciences, the incorporation of technological progress has substantially changed the practice of medicine. In this regard, the greatest impact of technological development has been improvement of diagnostic methods, both in clinical laboratories and in the practice of various forms of diagnostic imaging.

One hundred years have elapsed since Roentgen discovered ***x rays***[1] (1895) and Becquerel discovered ***radioactivity*** (1896). The celebration of the first centennial of these important contributions to the history of humankind takes place in a context of continuous progress and improvement in the application of their discoveries. In the last two decades, in particular, major changes have occurred, especially as a result of the use of computers, and the applications of ***ionizing*** and non-***ionizing radiation*** have expanded and become extraordinarily complex.

As a consequence, their usefulness has also increased. New modalities for using radiation have appeared, and existing techniques are rapidly being

[1] The words or phrases in italics and bold are defined in the glossary.

replaced or enhanced. Among the most noteworthy developments are computerized tomography, magnetic resonance imaging, and positron emission tomography; in addition, there have been dramatic changes in diagnostic ultrasound and new applications for radiological techniques, such as interventional radiology. All these advances have significantly enhanced the diagnostic and therapeutic capabilities of modern medicine.

As a result of the communications revolution, information on new developments is being disseminated throughout the world, and it is reaching not only professionals but also the public at large. This has created both new expectations and patterns of consumption as people become aware of the existence of these services and demand access to them. Nevertheless, most of the services made possible by technological progress are very costly, and so they remain inaccessible to large segments of the population.

This is the case in numerous countries of Latin America and the Caribbean. Although high-technology installations and equipment exist, they are not accessible to low-income groups, basically due to low coverage, which in turn is due to the way in which health care systems are organized and financed.

It is important to point out, however, that many countries of the Region have initiated processes of health sector reform, which are expected to bring about important changes in health policy and in the institutional, organizational, and financial makeup of health services. These changes should help to correct the deficiencies described above. Among the trends being seen, one of the most significant is ***decentralization*** and the development of local management of services. This is one of the fundamental strategies (*1*) for rectifying the problems relating to distribution of opportunities and resources and the lack of equity in access to services, which today affects almost one third of the Region's population. Another important aspect of sectoral reform processes is the change in the role of the state—which is reducing its active involvement in the delivery of services and is assuming a more regulatory and supervisory role. With this change has come increased recognition of the institutional pluralism that exists in health systems (*2*). This multi-institutional conception of health systems favors the introduction of new and more efficient forms of organization. Reform processes have also entailed changes in the way health care is financed, such as the extension of social security coverage to new population groups, which has given rise to new contracting modalities and new forms of payment for services. All these changes have substantially altered the organizational and operational characteristics of health care and will undoubtedly have an impact on the organization and utilization of radiology services, which in this publication include imaging services and radiation therapy services.

Within this general framework, this publication seeks to place the planning, organization, and operation of imaging and radiation therapy services within the strategy of development of ***local health systems*** (*3*), taking into account the characteristics of the new technological, political, financial, and organizational context of health systems. This will entail revising or reexamining the definitions, concepts, and principles that have formed the basis for the general organization of services for the past several decades. Some of these principles continue to be valid today, but they require new operational interpretations consistent with the new forms of health service organization and financing that have resulted from reform processes and the application of market principles and standards in the health sector.

It is of particular interest to review the principles of stratified organization of health services based on the concept of ***levels of care*** (*4*) and to examine their application in the planning of imaging and radiation therapy services in the new multi-institutional and financial context of health systems.

1.1.2 Human Resources

The efficient and safe application of diagnostic and therapeutic procedures utilizing radiation requires that the human resources involved be adequately educated and trained. Clinical physicians, radiology specialists, radiation oncologists, specialists in nuclear medicine, medical physicists, technologists, and nursing personnel should have current knowledge of the potential benefits and ***risks*** of various techniques and should possess the capabilities needed to provide the highest-quality services with the lowest possible ***risk*** to the patient.

A specialty of utmost importance is medical physics, given that radiology procedures involve the use of a physical agent (radiation) to achieve a result through the interaction of this agent with patients. The planning of many procedures involves questions relating to physics which can only be resolved satisfactorily through the work of a medical physicist in close collaboration with the medical specialist.

1.2 Radiology Services

In the planning of health programs, consideration should be given to what types of resources are necessary for the preservation and development of health, as well as for its recovery. With regard to the latter, medicine has

various techniques for the diagnosis and treatment of disease, and some of the most valuable of these techniques utilize different kinds of radiation.

Radiation is a physical agent that involves energy transport. The interaction of radiant energy with the tissues of a patient can generate information on the structure of the tissues, which is usually recorded as an image that makes it possible to diagnose the patient's condition. If the energy transmitted is sufficiently great, changes in or destruction of the tissues may occur, which makes certain treatments possible.

However, it must be taken into account that radiation, in addition to making possible certain highly beneficial diagnostic and therapeutic procedures, can also have negative effects on the health of irradiated patients and other people who are exposed to radiation as a result of their work or proximity.

The various types of radiation are generally classified as ***ionizing*** and non-***ionizing***, depending on whether or not they have the ability to alter the atomic structure of the matter with which they interact. Forms of ***ionizing radiation*** include ***x rays***, radioactive emissions, and radiation produced by particle ***accelerators***. Forms of non-***ionizing radiation*** include those of an electromagnetic nature, such as radio waves, microwaves, ultraviolet rays, and laser, and those of a mechanical nature, such as ultrasound.

In order to prevent or limit the undesirable health effects of ***ionizing radiation***, specialists in the field of radiation protection have developed criteria and techniques for protection and safety to be applied in the design and operation of equipment and installations and to control ***sources*** of radiation.

Facilities employing techniques that utilize ***sources*** of radiation range in complexity from those equipped with the simplest ***x-ray*** machines to those that have equipment for performing positron emission tomography and the associated ***accelerators*** for the production of ***radioisotopes***. In order to ensure that these techniques are used efficiently and safely, they must be taken into account in the planning and development of health programs. Efficiency will depend on the availability and proper selection of resources and ***quality control*** programs. Safety will be contingent on correct implementation of the criteria for radiation protection.

1.2.1 Imaging

Imaging may be used for diagnostic purposes or as a guide in surgical procedures (interventional imaging). Diagnostic imaging techniques make it possible to obtain morphological (static) and physiological (dynamic) information on a patient. For this purpose the following resources may be used: ***x-ray*** imaging, nuclear medicine, diagnostic ultrasound, and magnetic resonance imaging.

Through ***x-ray*** imaging, static studies (radiography) and dynamic studies (fluoroscopy) can be performed. One of the most valuable types of static study is computerized tomography, which yields an extraordinarily large amount of diagnostic information.

Nuclear medicine, through the use of radiopharmaceuticals which are administered to the patient, also makes it possible to perform morphological studies (uptake studies) and physiological studies (through the use of ***gamma cameras***). It also permits *in vitro* diagnostic techniques such as radioimmunoassay.

Diagnostic ultrasound makes it possible to obtain anatomical information, and, through use of the Doppler effect, physiological information can be obtained as well.

In interventional imaging, surgical procedures are carried out with the aid of imaging techniques.

1.2.2 Radiation Therapy

Radiation therapy utilizes the energy of ***ionizing radiation*** to destroy malignant tissues. The ***sources*** of radiation (sealed radioactive ***sources***, particle ***accelerators***, ***x-ray*** machines) may be located at a certain distance from the tissues to be irradiated (teletherapy) or, if they are small ***sealed sources***, they may be placed in direct contact with the tissues to be irradiated (brachytherapy).

Nuclear medicine techniques also make it possible to provide radiation therapy through the administration of radiopharmaceuticals that are absorbed selectively into a certain type of tissue, depending on the metabolic patterns of the chemical substances used.

2. Background and Current Situation

2.1 Status of Radiological Services in the World

The status of imaging and radiation therapy services varies from country to country. The data available on the subject are often not reliable. Nevertheless, for this analysis the information published periodically by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) is quite useful (*5, 6*).

UNSCEAR has classified the countries in four categories, according to levels of health care. In order to avoid confusion with the concept of ***levels of care*** in the organization of health services (*4*), in this publication the term "category" is used in place of "levels," which UNSCEAR uses to classify groups of countries according to their ratio of physicians per 1,000 population. Category I includes countries in which there is at least 1 physician per 1,000 population. Category II encompasses those that have 1 physician per 1,000-3,000 population; category III, those that have 1 physician per 3,000-10,000 population; and category IV, those that have 1 physician per 10,000 population or more. For 1990, the estimates of the population falling into each of these groups were: category I, 1,350 million; category II, 2,630 million; category III, 850 million; and category IV, 460 million. This classification takes account of the association observed between numbers of physicians per unit of population and numbers of radiation treatments or examinations in that same population unit. It should be noted, however, that the association between the number of physicians per unit of population and the number of radiology units is not absolute; hence, the availability of radiology services may be greater or lesser than the category classification of a country would indicate.

2.1.1 Imaging Services

The data from the UNSCEAR report for 1993 (*5*) indicate that the distribution of facilities that provide radiology services in the world is very uneven. The number of these facilities per 1,000 population is 20 to 1,000 less in category-IV countries than in category-I countries. The latter group of countries, which have approximately 25% of the world's population, account for 70% of ***x-ray*** diagnostic exams and 90% of the patients who receive

radiation therapy and nuclear medicine treatments. In the industrialized countries, most of which fall into category I, between 200 and 1,280 ***x-ray*** examinations per 1,000 population are performed each year. In contrast, approximately two-thirds of the world's population lacks access to diagnostic imaging services. With regard to the developing countries, which fall into categories II-IV, the following statistics are worth noting:

- Approximately 80%-90% of all ***x-ray*** machines, radiologists, and radiographers are located in a few large cities.

- In most rural and marginal urban areas people have no access whatsoever to diagnostic imaging services.

- At any given time, about 30%-60% of the imaging equipment that does exist is not in working order.

- Imaging services in most hospitals in large cities are overburdened, and patient waiting times for radiological examinations are long.

- Many simple ***x-ray*** examinations are performed in university or referral-level hospitals because there is no other alternative.

- Diagnostic imaging procedures are often performed without due regard to whether they are really necessary, whether they will yield the required diagnostic information, and whether they will be correctly performed, including limitation of the patient ***dose*** to acceptable levels.

- In most countries, medical students receive little or no practical training in radiology services before they embark upon their professional careers.

- Quality is variable, ranging from very good or excellent in some large hospitals to poor in many other hospitals.

- The cost of radiodiagnostic services is rising, yet no studies have been conducted to determine the association between this trend and control of diseases or recovery of health.

Tables 2.1, 2.2, and 2.3 provide information about numbers of ***x-ray*** examinations performed, machines, and categories of service. The figures presented in these tables are based on data from the UNSCEAR reports for 1988 (*6*) and 1993 (*5*). Although a trend toward improvement of population coverage at the global level may be discerned, it is not clear whether this is due

to a real improvement or to differences in the quality of data collection for the two reports. Shifting of some countries between the categories may also have had some influence on the figures. One noteworthy trend is the relative decrease in population coverage for the lowest category (category IV) of services.

Table 2.1
Approximate Number of X-Ray Machines, *X-Ray* Examinations, and Resulting *Doses*, Worldwide, 1987

Category of Services[a]	Population (millions)[b]	*X-Ray* Machines (thousands)[b]	Population per Machine	Annual Examinations per 1,000 Population	Annual *Collective Effective Dose* Equivalent (10^3 man Sv)
I	1,300 (25)	330 (*78*)	4,000	800	1,300
II	1,759 (35)	88 (19)	20,000	150	350
III	1,220 (24)	15 (3)	80,000	50	85
IV	730 (15)	4 (1)	180,000	< 30	22
World Total	5,000 (100)	440 (100)	11,000	280	1,760

Source: UNSCEAR, 1988 (*6*).

[a] Category I, one or more physicians per 1,000 population
Category II, one physician per 1,000-3,000 population
Category III, one physician per 3,000-10,000 population
Category IV, one physician per > 10,000 population

[b] The numbers between parentheses are percentages

Table 2.3 provides information on sales of ***x-ray*** equipment, including ***computed tomography (CT) scanners***, by geographic region. The figures indicate that close to 90% of the sales occur in three regions (Europe, Japan, and the United States of America), which together account for only 23% of world's population.

With regard to ultrasound, the equipment currently available is smaller, less costly, and easier to operate, and use of diagnostic ultrasound has become increasingly widespread at all ***levels of care*** within health care systems. This diagnostic technique has replaced a large number of x-ray and nuclear medicine procedures, such as obstetric radiology, liver scanning, and cholecystography. In many developing countries, important applications may be found for sonography in the diagnosis of various parasitic diseases, such as amebiasis and schistosomiasis, as well as in the diagnosis of tumors and other lesions located in the abdomen.

Table 2.2
Approximate Number of *X-Ray* Machines, *X-Ray* Examinations, and Resulting *Doses*, Worldwide, 1990

Category of Services[a]	Population (millions)[b]	*X-Ray* Machines (thousands)[b]	Population per Machine	Annual Examinations per 1,000 Population	Annual *Collective Effective Dose* Equivalent (10^3 man Sv)
I	1,350 (26)	470 (65)	2,900	860	1,300
II	2,630 (50)	230 (32)	11,000	140	290
III	850 (16)	15 (2)	57,000	70	40
IV	460 (9)	2 (0.3)	230,000	< 9	20
World Total	5,290 (100)	720 (100)	7,000	300	1,600

Source: UNSCEAR, 1993 (*5*).

[a] Category I, one or more physicians per 1,000 population
Category II, one physician per 1,000-3,000 population
Category III, one physician per 3,000-10,000 population
Category IV, one physician per >10,000 population

[b] The numbers between parentheses are percentages.

Table 2.3
World Market for *X-Ray* and *CT* Equipment, 1991 (*5*)

Geographic Regions	Percent of Revenues[a]	Population Size (millions)[b]
Europe	26.5	852
Japan	23.3	124
United States	45.9	251
Rest of world	7.3	4,158

Sources:

[a] *Medistat*, 1992; B (7).

[b] *World Population Projections 1990*, New York: United Nations; 1991.

Nuclear medicine is an important complementary diagnostic imaging technique, which at the more complex technological levels is used to corroborate ***x-ray*** and ultrasound studies. It is most useful for measuring biochemical reactions and for functional studies, rather than for anatomical imaging, an area in which it is gradually being replaced by alternative methods that offer better image quality, such as ultrasound and computed tomography. According to WHO estimates, nuclear medicine services of some kind—ranging from a single department to fully developed population coverage—are available in approximately 50% of the developing countries.

In category-I countries, the principal use for nuclear medicine is examinations of bone, lung, and cardiovascular systems, while in the countries in categories II, III, and IV, it is used mainly for thyroid, kidney, bone, and liver studies.

Generally speaking, the total number of nuclear medicine examinations has tended to increase over time, as has the age of the persons receiving these examinations, who are older than the general population.

In the industrialized countries, the most frequently used ***radionuclide*** is technetium-99m, as a result of which the population ***collective dose*** in these countries is lower. In the developing countries, the most frequently used ***radionuclide*** is iodine-131, which is the largest contributor to total ***collective dose*** from nuclear medicine in these countries and also an important contributor to ***collective dose*** worldwide. Altogether, nuclear medicine examinations contribute about one-tenth as much as ***x-ray*** examinations to the total worldwide ***collective dose***. Table 2.4, which is based on the 1993 UNSCEAR report (*5*), provides information on the number of nuclear medicine examinations and the associated ***collective dose***.

Table 2.4
Approximate Number of Nuclear Medicine Examinations and Resulting *Collective Effective Doses*, Worldwide

Category of Services[a]	Population (millions)	Annual Examinations per Thousand Population	Annual *Collective Effective Dose* (10^3 man Sv)
I	1,350	16	130
II	2,630	0.5	20
III	850	0.3	6
IV	460	0.1	4
Total Average	5,290	4.5	160

Source: UNSCEAR, 1993 (*5*).

[a] Category I, one or more physicians per 1,000 population
Category II, one physician per 1,000-3,000 population
Category III, one physician per 3,000-10,000 population
Category IV, one physician per > 10,000 population

In view of expected future needs for diagnostic imaging, the new imaging modalities such as ultrasound, computed tomography, and magnetic resonance imaging are raising a number of issues in developing countries (*7*). The collaboration of institutions that have special expertise in the planning of

services and facilities, training, ***quality assurance***, and evaluation of images and results will be invaluable. A related area in which collaboration among centers in the developing countries may be more important than collaboration with developed countries is that of rationalization (*8, 9*) and optimization (*10*) of the combination of imaging modalities. In any health care system, there is a spectrum of imaging requirements and needs of associated equipment, which may range from the most basic, such as the WHO Basic Radiological System (WHO-BRS) or its updated version, (the WHIS-RAD), or a simple ultrasound unit, to the most complex, such as computerized tomography or magnetic resonance imaging. Appendices I-A and I-B list summaries of specifications for the WHIS-RAD and the ultrasound units, respectively. The issues that must be addressed have to do with the clinical decision-making process that leads to the performance of imaging examinations and the optimum combination of diagnostic imaging modalities in a health care system.

2.1.2 Radiation Therapy Services

After cardiovascular diseases, cancer is currently considered to be the most serious health problem in the industrialized countries. According to WHO (*11*), cancer affects 9 million people and causes 5 million deaths annually. In developed countries it is the second most common cause of death, and epidemiological evidence points to the emergence of a similar trend in developing countries. The principal factors contributing to this disease pattern are the increasing proportion of elderly people (among whom cancer is more prevalent) in most populations, the greater ability of medical science to control once-fatal communicable diseases, and the rising incidence of certain forms of cancer, notably lung cancer resulting from tobacco use. It is probable that 300 million new cases of cancer and 200 million deaths from the disease will occur in the next 25 years, almost two-thirds of them in developing countries.

Thanks to medical advances, one-third of all cancers are now preventable and another one-third, if diagnosed early enough, are potentially curable. Moreover, appropriate palliative care of the remaining one-third of cancer patients can bring about substantial improvements in the quality of life.

It is estimated that radiation therapy, alone or in conjunction with surgery or chemotherapy, is required for more than half of all cancer patients. According to the UNSCEAR report (*5*), the frequency of treatment with teletherapy and brachytherapy is estimated at around 2.4 per 1,000 population in countries classified in category I. For categories II, III, and IV, the figures would be the equivalent of 25%, 4%, and 2%, respectively, of the estimate for

category I. With increases in life expectancy, there will be greater demand for cancer therapy, and as the countries develop, they will be able to acquire more equipment. This will mean wider use of radiation therapy.

Yet, in many countries appropriate technology (*12*) and the human resources needed to provide accurate ***dose*** calculations, treatment planning, and good patient care are lacking. Table 2.5 shows the results of a recent assessment of the availability of high-energy radiation therapy facilities (cobalt-60 or higher energy) in the various regions of the world (*13*).

Table 2.5
High-Energy Radiation Therapy Resources by WHO Region

WHO Region	Countries with High-Energy Radiation Therapy Facilities	Number of High-Energy Radiation Therapy Facilities	Approximate number of High-Energy Machines in Developing Countries, 1993
Africa[a]	12	14	30
Americas[b]	23	250	550
Eastern Mediterranean	20	40	70
Europe[c]	35	500	350
South East Asia	7	80	170
Western Pacific[d]	11	200	450

[a] Does not include South Africa
[b] Does not include Canada or the United States
[c] Does not include the former Soviet Union
[d] Does not include China

These figures indicate that in some parts of the world, such as the large regions of Africa and South East Asia, there may be only one high-energy radiation therapy machine for 20-40 million people, and one machine may be used to treat more than 600 new patients per year. Many cancer patients have no access to radiotherapy services.

The major factor that currently limits radiation therapy in the developing world and that will stand in the way of meeting future needs is the shortage of equipment and personnel for operation and maintenance. People in many areas of Africa and South East Asia have virtually no access to this beneficial treatment modality. Essential services must therefore be developed. (See Appendix I-C).

In other parts of the world, including many countries of Latin America where radiotherapy has been available for many years, international cooperative efforts must be directed toward improving the delivery of

treatment. All these efforts must be intensified as the importance of cancer as a public health priority becomes increasingly evident to the responsible authorities.

2.2 Imaging and Radiation Therapy Services in Latin America and the Caribbean (*14*)

2.2.1 Overview

A review of the Region's health systems shows that few countries have well-defined policies for the development of resources for imaging and radiation therapy that take into account both the public and private components of their health services. Any policy definitions that exist in the countries tend to be at the institutional level and do not apply to the sector as a whole. Consequently, in Latin America and the Caribbean the incorporation of major technological advances in the area of medical imaging and radiation therapy has not been a regulated process, which has led to notable imbalances among the various categories of health establishments.

This situation is closely linked to the political and economic changes that have taken place in the Region in the last decade. The downsizing of the State and privatization, coupled with the lack of policies for promoting balanced investments in the sector, have favored the importation of imaging and radiation therapy equipment primarily for use in private hospitals and other private facilities. In a number of countries, these circumstances have limited technological capabilities and weakened public services, with negative repercussions for the population served by these establishments. Indeed, the lack of coherent policies in the area of imaging and radiation therapy services development has added a new dimension to inequity in health care because it has meant that large segments of the population with limited economic means are denied access to the diagnostic and therapeutic resources of present-day medical technology.

The failure to adopt policies for the development of these services has also had an adverse impact on the selection and acquisition of equipment, which may be inappropriate for the type of service or the diagnostic or therapeutic modality required in the particular epidemiologic situation. Either the resources and equipment are inadequate to respond to the needs of the community, or, at the other extreme, they exceed the demand for services.

In the final analysis, decisions regarding the selection of technology should be based on criteria of cost-efficiency, effectiveness, and suitability for dealing with the prevailing problems and on safety considerations—that is, the equipment and its use should not generate additional ***risks*** or dangers. The regulation and supervision of these processes is the responsibility of the ministries of health. Except in a few instances, government agencies in the Latin American and Caribbean countries have not arranged to receive the input of an interdisciplinary group of consultants, which is indispensable in this area. In addition to health planners and administrators, such groups should include medical physicists, specialists in diagnostic radiology and radiation therapy, maintenance engineers, and others as appropriate. In only a small number of countries has the technology selection process been carried out with the participation of such an interdisciplinary group and been duly regulated. In most cases, several different institutions are involved, and it is usually difficult to get them to coordinate their actions.

Policies on diagnostic and therapeutic resources that utilize ***ionizing*** and non-***ionizing radiation***, given their nature, should include definitions and directives to regulate their use and also to protect both the general population and ***workers*** who are exposed to radiation ***sources*** on the job.

In many Latin American countries, responsibility for compliance with radiation protection standards is shared by two agencies. Health agencies, such as the ministries of health, are usually in charge of controlling and monitoring radiation ***sources*** for medical use. As a rule, however, these agencies have limited physical resources and staff, and the latter are sometimes untrained in the latest technologies. Typically, the health agency is responsible for monitoring ***x-ray*** equipment used for medical or dental purposes. Meanwhile, control of radiation therapy and nuclear medicine is often exercised by nuclear energy agencies, which are also responsible for monitoring nuclear reactors used for power, production, and research purposes; linear ***accelerators*** for both medical and industrial use; and ***radionuclides*** used in industry (for example, irradiators for the sterilization of products), in research (for example, tracers), and in medicine (teletherapy, brachytherapy, and nuclear medicine). The atomic energy agencies in these countries tend to enjoy much more political and economic support than their counterparts in the health area, and often their personnel are trained in the industrialized countries, which provide sizable contributions to support their activities.

The Latin American countries that have dual regulation are Argentina, Brazil, Chile, Cuba, Mexico, and Venezuela. The countries in which radiation regulation is done exclusively by the ministry of health are Costa Rica and Panama. In Bolivia, Chile, the Dominican Republic, Ecuador, Guatemala,

Peru, and Uruguay total responsibility for monitoring of the use of ***ionizing radiation*** rests with an atomic energy agency. The other countries, which all use radiation ***sources***, lack infrastructure for radiation protection, even though in some cases a law assigns this responsibility to the ministry of health or a nuclear energy commission.

In the Caribbean area, only Barbados, Guadeloupe, and Martinique have laws that specifically address the subject of radiation protection.

2.2.2 Organization and Coverage of Imaging and Radiation Therapy Services

The mere existence of a health service, especially diagnostic imaging and radiation therapy, does not give an indication of the extent to which the population is covered. An accurate interpretation of the coverage provided by these services needs to also take into account such criteria as relative selectivity, the differential suitability of one or another type of diagnostic technique for particular pathological conditions, and the ways in which these techniques complement each other.

Evaluation of the coverage provided by imaging and radiation therapy services in the Latin American and Caribbean countries should be based on an analysis of the equipment and human resources available and their adequacy *vis-à-vis* the needs of the population. It should also look at the use of clinical management protocols, the resultant statistics, and the existence of programs for ***quality assurance***, radiation protection, and maintenance. However, because of the lack of appropriate data, the information that the countries generate on the coverage of imaging and radiation therapy continues to equate such coverage with the proportion of the population served by health units or establishments. For example, the 1993 UNSCEAR report indicates that for the period 1985–1990 the average number of ***x-ray*** machines per 1,000 population in the world ranged from 0.0042 to 0.35; the annual number of radiological examinations (not including dental x-rays), from 9 to 860 per 1,000 population; the number of patients treated with teletherapy and brachytherapy, from 0.05 to 2.4 per 1,000; the number of nuclear medicine diagnostic exams, from 0.1 to 16 per 1,000; and the number of patients treated with radiopharmaceuticals, from 0 to 0.4 per 1,000. Figures for several countries in the Region are given in Table 2.6.

Data on the physical availability of services are frequently supplemented with figures on activities that correspond roughly to utilization indexes. These

figures should be interpreted with caution, since, for example, the reports of radiology services do not necessarily distinguish between films exposed, exams performed, or persons attended, nor do they take into account the quality of the image or the effectiveness of the study. These inconsistencies make it difficult to determine the true coverage, and they also hinder comparative analyses, even within the same country.

Table 2.6 (*14*)*
Annual Number of Radiological Examinations, Radiation Therapy Treatments, Nuclear Medicine Examinations, and Radiopharmaceutical Treatments per 1,000 population, 1985-1990, Region of the Americas

Category and Country	Radiological Exams	Radiation Therapy Treatments		Nuclear Medicine Exams	Treatments with Radio-pharma-ceuticals
		Teletherapy	Brachytherapy		
Category I[a]					
Argentina	—	—	0.2	11.5	0.16
Canada	1,050	2.9	—	12.6	0.88
Cuba	620	0.2	0.05	—	—
USA	800	—	—	25.7	—
Category II[b]					
Barbados	160	0.6	0.2	1.0	0.15
Brazil	93	—	—	1.7	—
Ecuador	53	0.08	0.02	0.8	0.0065
Jamaica	—	0.1	0.07	2.0	0.005
Nicaragua	13	—	—	—	—
Peru	15	0.1	0.04	0.2	0.011
Category III[c]					
Belize	83	—	—	—	—
Dominica	180	—	—	—	—
Saint Lucia	130	—	—	—	—

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Source: UNSCEAR, 1993 (*5*).

[a] Category I, one or more physicians per 1,000 population
[b] Category II, one physician per 1,000-3,000 population
[c] Category III, one physician per 3,000-10,000 population

Table 2.7, compiled by the PAHO Regional Program on Radiological Health, lists the ***radiation generators*** and cobalt therapy units in use in 1994. No comparable information is available on ***unsealed sources*** of radiation for nuclear medicine or ***sealed sources*** for brachytherapy. Partial information on the latter for the countries of the Caribbean, compiled in 1991, appears in Table 2.8.

Table 2.7
Medical Radiation *Sources* in Latin America and the Caribbean, 1994

Country	X-Ray Units (excluding dental)	Co-60 Units	Linear *Accelerators*
Anguilla	2	0	0
Antigua	4	0	0
Argentina	12,000	85	23
Bahamas	5	0	0
Barbados	20	1	0
Belize	12	0	0
Bolivia	1,458	5	0
Brazil	18,000[a]	109	60
British Virgin Islands	1	0	0
Chile	1,350	14	5
Colombia	1,500	24	6
Costa Rica	190	3	0
Cuba	1,000	11	1
Dominica	6	0	0
Dominican Republic	180	4	0
Ecuador	811	8	0
El Salvador	136	3	0
Grenada	3	0	0
Guatemala	95	6	0
Haiti	20[a]	2	0
Honduras	87	3	0
Jamaica	30[a]	2	0
Mexico	10,000[a]	78	20
Netherlands Antilles	8[a]	1	0
Nicaragua	50	1	0
Panama	216	3	0
Paraguay	100[a]	3	0
Peru	1,286	10	3
St. Kitts & Nevis	3	0	0
St. Lucia	14	0	0
St. Vincent & the Grenadines	4	0	0
Trinidad & Tobago	20[a]	0	0
Uruguay	350[a]	14	1
Venezuela	3,000	27	16

[a] Estimate

Table 2.8
Brachytherapy in the Caribbean Countries, 1991

Country	*Source Activity* (mCi)[a]			
	Ra-226	Cs-137	Co-60	Ir-192
Barbados	—	530	—	10 Ci/3 mo[c]
Cuba	—	—	—	—
Dominican Republic	398 + 116[b]	387	—	—
Guadeloupe	—	988	—	1,750 mCi
Haiti	205[b]	—	2.5 Ci[c]	—
Jamaica	1,705	~1,000	—	—
Martinique	—	623	—	14 cm wires 10 mCi/cm
Trinidad & Tobago	141[b]	510 + 377[b]	—	—

[a] 1 mCi= 37 MBq
[b] Removed from the country
[c] High *dose* rate afterloading equipment
[d] Low *dose* rate afterloading equipment, no longer in use

2.2.2.1 Availability of Imaging Services (*14*)

The availability and utilization of imaging equipment vary widely, as does its complexity. For example, in Argentina, Brazil, Colombia, Costa Rica, Mexico, and Venezuela, the numbers and the variety of radiological studies performed in university and regional hospitals are comparable to those done in similar centers in more developed countries. In large countries with high levels of urbanization, the main hospital centers tend to be private, and these establishments have more modern and sophisticated imaging services.

In countries with intermediate-sized populations, the range of diagnostic equipment and services available is usually not as great. A study conducted in Honduras in July 1992 illustrates this type of situation (Table 2.9). The survey of diagnostic imaging centers revealed a heavy concentration of equipment and specialized personnel in the capital and in one regional center; in comparison, figures were much lower in the other cities. This pattern is repeated in a number of countries of the Region, and it helps to explain why the population gravitates to the large urban centers, where they can find, in some form, the care they need. The small and intermediate establishments tend to be poorly equipped and understaffed.

From the data in Table 2.9 it is possible to identify other typical situations of the geographical distribution and organization of the services. Personnel dosimetry services were found in only two of the seven facilities visited in

Honduras; three had partial provisions for ***quality control***, while four had no such programs at all; and three of the centers did not have any identifiable organization responsible for maintenance programs.

The distribution of imaging facilities differs dramatically among areas within the countries which points to serious breakdowns in the planning process. A survey of institutions that provide chest radiography in Argentina showed that in Santa Fe Province, which had nearly 2.5 million inhabitants in 1990, there were 900 medical centers with 1,500 medical ***x-ray*** machines, 1,200 dental ***x-ray*** machines, 12 ***computed tomography (CT) scanners***, 2 magnetic resonance imaging units, 12 conventional radiation therapy units, 6 cobalt-60 units, and 1 linear ***accelerator***. This broad availability of services contrasts sharply with the situation in other provinces: Santa Cruz, for example, with less than 200,000 people, had 30 conventional ***x-ray*** machines, 1 mammography unit, and 1 ***CT scanner***.

In the English-speaking Caribbean countries, which have small populations, imaging resources are located mainly in the capitals. Table 2.10 gives data on resources in public health facilities in Barbados, Dominica, and Saint Lucia based on a 1991 study of the availability of services. The organization of the individual services tends to be fairly homogeneous, although some of the same problems seen in other subregions are also observed here, especially with regard to maintenance, the availability of qualified staff, and the limited development of ***quality assurance*** programs.

An important advance has been the development by WHO of the Basic Radiology System (BRS) (*15-19*), designed to improve the availability of radiology services. The units are capable of performing more than three-fourths of all ordinary radiological examinations, including those done in teaching hospitals. Even though the system is very easy to use, its adoption by health services has fallen short of expectations. In 1997 there were only 39 of these units in nine countries of the Americas.

Table 2.9 (*14*)*
Summary of Diagnostic Radiology Departments Visited in Honduras, July 1992

Indicators	Teaching Hospital, Tegucigalpa	San Felipe Hospital, Tegucigalpa	Santa Teresa Hospital, Comayagua
Population covered (No. of persons)	Total country	Total country	80,000
No. of *x-ray* units			
Radiographic (fixed)	4 + 4 [N]	3	1 + 1 [N]
Fluoroscopic	1 + 3 [N]	1	1
Mammographic	1 [R]	—	—
Skull	1	—	—
Radiographic (mobile)	8 ?	1	1
Automatic processors	1 + 1 [N]	1	Manual only
Ultrasound units	1	1	—
No. of radiologists	4	3 [P]	—
No. of radiology technicians	24	4	5
No. of patients/year	62,605	23,000	—
No. of x-ray exams/year	84,074	—	10,380
No. of films/year	113,763	26,000	—
Type of film	Kodak (blue)	—	Fuji
Type of screen	Dupont Quanta III	—	Wolf
No. of sonograms	3,727	—	—
Maintenance service	Dept. of Biomedicine	—	—
Personnel dosimetry service	Pocket dosimeters	No	No
Structural ***shielding***	Room 5 window lacks lead	Good ?	Good ?
Lead aprons (A), gloves (G)	8 A	—	No
Quality control program	Films only	No	Films

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[R] = Need repair [P] = Part-time [N] = Not working, not in use

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Table 2.9 *(continuation)*

Indicators	Area Hospital, La Paz	Anti-Cancer League, San Pedro Sula	M. Catarino Rivas Hospital, San Pedro Sula	Western Hospital, Santa Rosa de Copán
Population covered (No. of persons)	80,000	350,000	400,000	340,000
No. of imaging units				
Radiographic (fixed)	1	1	3 + 1 [N]	2
Fluoroscopic	—	1 [N]	1 + 2 [N]	1 [N]
Mammographic	—	—	—	—
Skull	—	—	1	—
Radiographic (mobile)	1 [N]	—	1 + 1 [N]	2
Automatic processors	Manual only	Manual only	1 + 1 [N]	Manual only
Ultrasound units	—	—	1 [N]	—
No. of radiologists	—	1 [P]	2	—
No. of radiology technicians	2	1	15	6
No. of patients/year	2,212	—	25,896	10,970
No. of x-ray exams/year	3,000	—	41,000	—
No. of films/year	3,120	—	—	15,616
Type of film	Fuji	—	Fuji	Fuji, Konika
Type of screen	Ilford	—	Universal	Kodak
No. of sonograms	—	—	—	—
Maintenance service	Ministry	Francisco Santiso	Dept. of Biomedicine	—
Personnel dosimetry service	No	Pocket dosimeters	No	No
Structural ***shielding***	Window lacks lead	Good ?	Good ?	Walls and windows lack lead
Lead aprons (A), gloves (G)	No	No	8A	3A + 1G
Quality control programs	No	No	Processor	No

[N] = Not working, not in use [P] = Part-time

Table 2.10 (*14*)*
Summary of Diagnostic Imaging Services, Caribbean Subregion, 1991

Indicators	Barbados		Saint Lucia	Dominica
Population	240,000		150,000	71,000
No. of imaging units:	Public	Private		
Photofluorographic	1 [N]	—	1 [D]	—
Radiographic (fixed)	4 + 1 [R] + 1 [N]	2	2 + 1 [O] + 2 [P] + 1 [N]	2 + 1 [N]
Fluoroscopic	1 + 1 [R] + 1 mobile	2	2 [R] + 1 [O]	1 [R]
Mammographic	1	1	1 [O] + 1 [P]	-
Radiographic (mobile)	3	—	1 + 1 (R or D)	2 [N]
Portable	—	1	1	1
Processors (automatic)	3 + 2 [N] + 2 [R]	>3	3 + 1 [D]	1
Ultrasound	2	2 + 5 (GYN)	1 + 1 [R] + 1 [D] + 1 [O]	2 public + 1 private
CT scanner	1	1	1 [P]	—
Dental	≥1	—	None public	1 [R] + 4
No. of radiologists	3 + registrar	2	1 [O]	0 (1 available for consultation)

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[N] = Not in use [D] = To be discarded [R] = Need repair [O] = On order [P] = Planned

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Table 2.10 *(continuation)*

Indicators	Barbados		Saint Lucia	Dominica
Population	240,000		150,000	71,000
	Public	Private		
No. of radiographers	19 + 3	2	2 + 2[L]	3
No. of assistant/student radiographers	—	—	2 + 1[L] + 1[O]	1
Technique charts/written protocols	Yes	—	Yes (St. Jude)/ No (Victoria Hosp.)	No
No. of patients/year	35,246	—	6,600 (St. Jude) + 9,700 (Victoria) = 16,300	10,816
No. of radiological exams/year	39,178	—	6,924 (St. Jude) + 12,120 (Victoria) = 19,000	12,860
No. of films/year	93,100	—	7,500 (St. Jude) + >24,000 (Victoria) = >30,500	>24,154

continues on the next page

[L] = May be leaving [O] = On order

Table 2.10 *(continuation)*

Indicators	Barbados		Saint Lucia	Dominica
Population	240,000		150,000	71,000
	Public	Private		
Type of film (excluding mammo)	Kodak, Dupont, OG	Kodak, Dupont	Fuji/Dupont Cronex IV	Curix/Kodak/ Fuji/Dupont
Type of screen (excluding mammo)	Fuji Medium speed, Cronex VII+IV, Lanex	Kodak, Dupont	Fuji G-4 (400 speed), Fuji G-8 (200 speed) Quantum II, Quantum Detail, Par speed	Optex-Hi plus (200 speed)
Maintenance services	Local/Medicaraibe	—	Local/Witico/P. St. Dennis/Medicaraibe	Local/Martinique (Philips only)
Personnel dosimetry services	Siemens/planning own	—	Landauer/Gardray (USA)	SCPRI [o]
Structural ***shielding***	OK	—	OK, needs additional in renovated areas	OK
Lead aprons/gloves	Yes	—	6/4 (St. Jude), 5/2 (Victoria)	3
Gonadal shields/other	Yes	—	Yes/4	1 + thyroid + glasses
Pediatric restraining devices	Yes	—	No	No
Resuscitation carts	Yes	—	Yes	No
Quality assurance	Yes	—	No	No

[o] = On order

Table 2.11 (*14*)*
Radiation Therapy Resources, Countries of Central America, circa 1992

	Costa Rica	El Salvador	Guatemala	Honduras	Nicaragua	Panama
Centers	2	2	2	2	1	2
Cobalt-60 units	3	3	5	3	—	2
Activity (Ci) (1993)	6,000–6,250	—	3,500 (average)	1,900–5,000	—	2,200–6,000
Brachytherapy ***sources***						
Ra-226 (mg)	42–275	—	—	95–492	160	—
Cs-137 (mg Ra eq)	35–525	—	350	12–180	25–58 GBq	—
Radiation therapists	2	5	5	3	1	4
Radiation therapy technicians	—	12	12	7	2	3
Medical physicists	2	1	—	1	—	1
Quality control	Limited	No	No	1 center yes 2 centers no	No	Yes

* Reproduced, with permission of PAHO's Publications Department, from chapter 6 Volume 1 of *Health Conditions in the Americas* (*14*).

2.2.2.2 Availability of Radiation Therapy Services

Radiation therapy equipment and services are very unevenly distributed in the Latin American and Caribbean countries. As of 1994 there were approximately 500 cobalt-60 units, 10 cesium-137 units, and 124 linear ***accelerators***. The services tend to be concentrated in the larger countries of South America (especially Argentina, Brazil, Colombia and Venezuela) and in Mexico. A similar pattern prevails in the countries of the English-speaking Caribbean: the most well-equipped services are found in Barbados, Jamaica, and Trinidad and Tobago. The Radiation Therapy Department at Queen Elizabeth Hospital in Barbados also provides these services to patients from other countries, although the long waiting lists indicate that there is difficulty in meeting the demand. This is a practical arrangement, since the other countries do not have large enough populations to justify the cost of investing in and operating their own services of this kind. The improvement of coverage by such means depends on agreements signed between countries, as well as cooperation between institutions in the development of joint programs.

Table 2.11 gives data on the availability of radiation therapy services in the countries of Central America. The availability and type of equipment are generally similar throughout the subregion, but the same cannot be said of certified personnel. The largest numbers of radiation therapists work in Costa Rica and Guatemala; qualified radiation therapy technicians are only found in Honduras; and the only medical physicists work in Costa Rica (2), El Salvador (1), and Honduras (1).

2.2.2.3 Availability of Nuclear Medicine Services

The availability of nuclear medicine services in the Region reflects even greater disparities. In some of the countries—for example, Nicaragua and a few of the island nations in the Caribbean—***radionuclides*** are not used at all for medical purposes. At the other end of the spectrum, Argentina has 600 nuclear medicine centers, over 180 ***gamma cameras***, 30 ***single photon emission computed tomography*** (***SPECT***) units, and 1 ***positron emission tomography*** (***PET***) unit, as well as radioimmunoassay services.

Table 2.6 gives data on the utilization of nuclear medicine in the Region, including Canada and the United States of America.

2.2.3 *Quality Assurance* and *Control* Activities

Problems often cited in connection with the organization and operation of imaging and radiation therapy services include excessive number of studies, use of complex equipment and overqualified personnel for simple examinations, unsuitable conditions in the facilities that affect the quality of the studies, lack of standards for radiation protection, lack of clinical protocols, and others. These problems reflect managerial and administrative shortcomings and the absence of effective ***quality assurance*** programs. Activities to address these problems are only beginning in most of the countries, and they tend to focus on specific issues rather than approach the situation comprehensively.

However, several important initiatives have emerged, among them the establishment in 1992 of a Pilot Center for Radiological Physics within the Hospital of the Central University of Venezuela in Caracas. This center was created in collaboration with the Secondary Standards Dosimetry Laboratory of the Venezuelan Institute for Scientific Research. In 1994, the National Center for Radiological Physics was established within the Autonomous National University of Honduras in Tegucigalpa, and post-graduate programs in medical physics were initiated in the Clinical University Hospital of San Martín, associated with the University of Buenos Aires, Argentina. These centers, with technical support from the Pan American Health Organization, seek, as one of their central objectives, to promote the practice of radiological physics as a fundamental component of diagnostic radiology, radiation therapy, and nuclear medicine services. For this purpose, they offer a number of educational activities, including seminars, workshops, and courses, as well as in-service training for clinical specialists, physicists, dosimetrists, and technologists.

Quality assurance programs, which are intended to optimize the quality of radiological images and guarantee the accuracy and precision of radiation therapy treatments, may need to be formalized by regulatory provisions or laws in order to be successful. In 1991, Argentina adopted regulations for a law that created the Advisory Commission on Mammography at the national and provincial levels and set detailed standards for the performance of examinations. The standards establish the technical specifications of the installations and the training required by the medical staff; there is also a ***quality control*** program that includes the determination of patient ***doses***. The Argentine Mammography Standards appear in Appendix II-A.

In 1994, the United States of America enacted the Mammography Quality Assurance Standards Act, which requires all United States institutions to have

strict ***quality assurance*** programs with clinical, technical, and physical components. The most important points of this law are reproduced in Appendix II-B.

The application of such standards requires well-organized supervisory mechanisms as well as the technical and administrative means to ensure enforcement. Action is needed in both these areas in most of the countries of Latin America and the Caribbean.

2.2.4 Available Resources

The structural changes that have taken place in the health systems of many countries have affected the configuration and availability of physical resources and equipment. In a number of cases budgetary limitations have prevented the needed upgrading of imaging and radiation therapy equipment, with the result that these services now lag behind technologically. Except in new establishments, the equipment in most of the diagnostic radiology services dates back to the 1970s and has become obsolete, leading to reduced productivity, decreased efficiency, and higher cost and poor quality. This frequently observed situation is a legacy of the lack of policy definitions cited at the beginning of the present section.

The biomedical equipment in use in the health establishments, especially the diagnostic imaging equipment, typically represents an enormous range of commercial brands. Because of this diversity, replacement parts are more difficult and more costly to get and maintenance becomes extremely complicated to carry out. The absence or poor performance of equipment maintenance programs continues to constitute the main problem in many of the hospital-based diagnostic radiology departments and radiation therapy centers throughout the Region.

These maintenance problems—which affect the physical plant along with diagnostic, therapeutic, and film processing equipment—together with shortages of supplies, are the most frequent causes of interrupted services. The problems stem primarily from limited budgets and from structural weaknesses in the health systems, which tend to give very low priority to management and administration. Another factor is the shortage of human resources trained in various types of maintenance. Even though a growing number of countries have well-trained technicians, engineers, and other professionals, there are still problems in the geographical and institutional distribution of this personnel.

3. Organization and Planning of Imaging and Radiation Therapy Services

3.1 Overview

Conventional basic and specialized diagnostic radiology, interventional radiology, diagnostic ultrasound, diagnostic and therapeutic nuclear medicine, and various forms of radiation therapy today play an essential role in clinical health care processes. The high cost of these services—given the size of the initial investment and the projected operating costs—makes it necessary to plan their development carefully. Due account must be taken of the political and economic characteristics of the health system, the organizational and administrative framework in which the services are provided, and the epidemiological factors that condition the utilization of these services.

In the last decade health care systems in the Region of the Americas have felt the impact of the profound political and economic changes that have occurred on the global level. These changes have had different implications for the organization of health services in each country, but generally speaking there has been a trend toward change in the tradition of state-sponsored public services and a reduction of the preponderant role of governmental agencies in the delivery of health services. For several decades in the Region, especially in Latin America and the Caribbean, direct state action has been the dominant feature of health care. However, in the current context of health reform processes, health services are conceived of from the political and economic standpoints as activities of society which are subject to the conditions of the marketplace. Institutional and financial pluralism in the health system, the quest for efficiency through competitiveness, cost recovery, and other economic values are taking on increasing importance and are gradually becoming the criteria that govern public management of health services.

Although the concept of a single, unified health system is maintained in this new political and institutional framework, that concept is acquiring new dimensions and forms of expression. Private activity is being increasingly recognized as an important component of the health services system, which implies acceptance of a multi-institutional system. The functional elements that link the various institutions have become more important than the structural and

hierarchical considerations that prevailed in the past. Contracting, payment, and remuneration modalities in health care units and schemes of sharing diagnostic, therapeutic, and general logistic support services, among others, have become important means of functional interaction between the entities that make up health systems.

The role and functions of central state agencies are also changing. Ministries of health, in particular, are tending to be less directly involved in the organization and delivery of services, while at the same time they are playing an increasingly important role in managing the process and in coordinating public and private national resources for health care.

In the financial sphere, also, significant changes have occurred. The efforts to curb public spending and downsize governments that characterize current public management have brought about a sizable reduction in direct public funding as a health care financing mechanism. Public health care services, which up to now have predominated in most of the countries of Latin America and the Caribbean, are now being strongly influenced by cost-recovery and rate-setting schemes, the incorporation of semi-private services, and shared payment plans. The end result is a system of mixed public and private financing, in which the extension of government-funded social security to new population groups accounts for an increasing portion of the public component.

All these ongoing changes in the health systems of the Region are creating new interrelationships between the institutions involved in health services delivery. These changes, in turn, affect the traditional modalities by which investment and the operation of health services have been financed and they must necessarily be reflected in the planning and organization of services as important and costly as imaging and radiation therapy.

3.2 Local Development and Organization of Services according to *Levels of Care*

The ***decentralization*** of public administration and recognition of the need to promote and strengthen local actions are other fundamental manifestations of the process of change taking place in the health systems of the countries of the Region (*20*). The strategy of ***local health system*** development and its progressive incorporation in the conceptualization of national health systems is transforming the organizational frameworks for health services and has contributed significantly to the establishment of a new conceptual and technical basis for the planning and programming of health services development (*21*).

In this context, in keeping with the general trend toward stratification of health services according to ***levels of care***, it is necessary to establish the basis for organization and utilization of imaging and radiation therapy services and to specify the scope and possibilities for their contribution to the improvement of the accessibility and quality of health care. To that end, the concept of ***levels of care*** and its application in the organization of radiology services are reviewed in this section.

3.3 Conceptual Elements Relating to the Organization of Health Services according to *Levels of Care*

The notion of ***levels of care*** refers to a stratified approach to the grouping and utilization of resources in order to carry out actions aimed at achieving a specific purpose or meeting a specific need.

In health services, the ***levels of care*** approach has been promoted for several decades as a form of organization that makes it possible to achieve a balance between the quantity, variety, and quality of the resources available for health care, through a process of allocation and distribution of these resources according to needs and capabilities for providing care. The purpose is to develop a harmonious and interrelated set of services that will ensure timely and equitable accessibility to comprehensive health care for an entire population.

In keeping with this orientation, health services must be capable of providing many types and modalities of care, covering a very broad range in variety, intensity, and complexity. For individuals, these services should respond to their specific needs; for the community, they should meet the collective needs of its members.

Application of the concept of ***levels of care*** in health services implies recognition of two components that are quite distinct but must be closely coordinated through planning and programming of service development (*22, 23*). The first of these components is health care needs, i.e., the situations or health problems that affect individuals and groups of people in the community. The second is the responses, or the services—which may be of greater or lesser complexity—that are implemented in order to meet those needs.

Hence, applying the concept of ***levels of care*** means recognizing the increasing complexity of health situations, as well as their relative frequency in a given population; it also means acknowledging the natural relationship that exists between the complexity of a given health situation and the complexity of the methods and resources necessary to address it.

The frequency of the health problems or situations that require attention varies with the sex, age, socioeconomic status, place, time, etc. of the population group in which they occur and the physical and social environment in which the group lives.

For example, diarrheal diseases, gastroenteritis, and acute respiratory infections are more frequent in developing countries and especially in rural areas and the peripheral areas surrounding large urban centers. These health problems can be treated through relatively simple means. However, in these communities there are also pathologies such as brain tumors and cardiovascular conditions that require more complex forms of treatment. In addition, accidents, violence, and injuries are significant causes of morbidity and have begun to displace other pathologies in the general epidemiological profile of these population groups as their living conditions and possibilities for survival improve.

Those situations that affect health in a community determine the demand for services and their relative frequency, and they affect the growing complexity of the resources that need to be mobilized in the health care process. It is thus possible to relate the concept of ***levels of care*** to the geographic location of health care establishments or units, in order systematize the supply of services according to the size, characteristics, and needs (or demands) of different population groups.

In other words, the consideration of these sets of factors makes it possible to relate the notion of ***levels of care*** to the development of a stratified hierarchy of services that complement one another and whose coordinated operation makes it possible to organize and systematize responses to the health care needs of the population.

3.4 Application of the Concept of *Levels of Care* in the Planning and Organization of Radiology Services

The term ***levels of care*** has been used in very different ways in different countries. In some cases, it has referred to the degree of medical specialization required or utilized in the delivery of a given service; in others, it has meant the units or institutional strata of organization and administration of health services. Sometimes the term has been used in relation to the quality of services; in these cases, reference is made to different levels of quality and it is assumed that specialized care, because it is more complex, is of higher or better quality. Quality, however, does not mean sophistication or complexity. Quality has to do with how the service is provided, not with where or with what type of equipment it is provided, nor with who provides the care.

The expression ***levels of care*** actually refers to the technological plane on which problems are solved. It cannot be considered a synonym for the hierarchy of administrative or personnel strata or of the units or establishments that provide services. However, there is a relationship among these various types of levels, inasmuch as, for programming purposes, a given level, and consequently the whole set of levels, will determine the selection and systematization of the most appropriate types of health care units or establishments, depending on the availability of resources for the health system.

Methodologically, the process of establishing ***levels of care*** begins with the identification and ranked classification of health problems and the determination and characterization of the interventions or care functions that are possible with the resources available in the health system in question.

Different criteria may be applied in categorizing or classifying sets of variables: demographic and epidemiological characteristics and the existence of technological, financial, and human resources in the environment in which the delivery of services will take place.

This process of categorization should yield groups of health problems, the first comprising common and simple pathologies that can be treated with basic technology and capabilities, the second made up of other, less frequent and more complex pathologies that require intermediate-level capabilities and technology, and the third composed of infrequent and highly complex pathologies that require specialized care and advanced technology. Although

there may be other systems of categorization, the three-tier system of ***levels of care*** described above is most common.

Once this initial categorization has been accomplished, it is necessary to assign the activities, functions, and responsibilities of the entities that will deliver the services—i.e., the physical facilities in which care will be provided. Through this assignation of activities, the concept of ***levels of care*** is operationalized. It is in this phase that the types of personnel and equipment required are determined and the other elements necessary for carrying out the assigned actions are identified. In other words, it is in this phase that the technological characteristics of the establishments in which care will be provided are defined.

The foregoing implies that the services to be provided by the various ***levels of care*** are not the same in all situations, nor even within a single country. Moreover, not all the establishments in which services are provided or the units they comprise have the same characteristics, even when they fall into the same category.

With these characteristics, it is evident that the functional interpretation of the ***levels of care*** approach provides a solid conceptual basis for planning and organizing the various components of radiology services as essential elements in the strategy of ***local health system*** development.

3.5 Planning of Radiology Services according to *Levels of Care*

This section looks at three interrelated components that form the basis for interpretation of the concept of ***levels of care*** in the specific area of radiology services.

- The general approach, i.e., the fundamental conceptual elements.
- The analysis of needs, which in this case, given the characteristics of radiology services, takes into account primarily data on utilization and utilization trends.
- Resources, or the availability of technological solutions in the different areas of radiology which can be applied and combined, depending on the characteristics of the health services system in question.

3.5.1 General Approach

Decisions regarding ***levels of care*** are based, first, on the identification and analysis of health problems and, second, on the possibilities for combining available resources to achieve an adequate supply of services.

The identification of health problems is not an easy task, and there are no exact indicators for all manifestations of these problems. The events that experts interpret as problems are frequently not viewed by the population as such. The reverse may also occur. In the process of establishing what the real needs are, it is essential to achieve the greatest possible congruence between these interpretations through broad participation by the various groups that make up the population.

Once the health problems have been identified, the next step is to determine their frequency, magnitude, and severity. In addition, it is necessary to identify the geographic distribution of these problems, the population affected by them, and their evolution and trends. The basic tools for carrying out this analysis are epidemiology and its various techniques, whose appropriate utilization will make it possible to rationalize the definition of programming objectives and establish priorities for resource allocation.

Taking into account the particular characteristics of each country or region, the area served by a ***local health system*** is the natural focus for these epidemiological analyses. Knowledge of the population served by a ***local health system*** will allow greater specificity in the diagnosis of diseases and better selection of interventions in order to ensure accessibility and coverage.

The second essential component in the technological determination of ***levels of care*** is resource availability. In this regard, the variety of situations observed is also very broad. The primary factors that influence these situations are the degree of development of the countries; the urban-rural distribution of the population; the characteristics of the health system, in particular its institutional and financial make-up (i.e., the public-private mix); and the availability of health personnel. This last factor is particularly important in local areas, where the availability and participation of the various kinds of health personnel, especially physicians, nurses, and dentists, is a critical consideration in the determination of the set of services to be provided at the first ***level of care***.

It is widely recognized today that the population's first contact with health services should not necessarily be through the physician. Other health workers—physician's assistants, paramedical personnel, volunteers, etc.—can

provide the initial attention. In fact, this is what occurs in day-to-day reality. In rural areas of some countries, there may be no intermediate step between care by a non-physician health worker and hospital care. However, according to the functional interpretation of the concept of ***levels of care*** used in this publication, the initial contacts and actions carried out by auxiliary health personnel and community workers should be considered extensions of professional medical activity.

In other words, the set of services available at the first ***level of care*** should include diagnostic capabilities and treatment by medical professionals. This is an important consideration in relation to the establishment of radiology services at the first ***level of care***.

Professional medical activity at the first level may be carried out by general practitioners or by various combinations of specialists, in particular obstetricians, internists, and pediatricians. In some countries family or community medicine schemes or other similar schemes have been established for this purpose. The demand for and utilization of radiology services will vary depending on the types of medical professionals practicing at the first ***level of care***.

In general, when health service use patterns are analyzed in the planning process, it is essential to bear in mind that both the services provided to protect the health of individuals and social groups and the use that the population makes of these services will depend to a large extent on the interaction of health workers with the population.

This points up two important needs. First, it is imperative to maintain controls in order to avoid inappropriate utilization of the services, which occurs very frequently. Second, it is necessary to facilitate the population's participation in those areas in which it is appropriate.

Although the need for community participation is recognized, it is not always easy to achieve, especially in some types of services, as is the case with imaging and radiation therapy. Radiology services are highly "technical" and are therefore generally beyond the population's grasp. Health education and innovation are required to make information in this area accessible and thus enable users of the services to participate, especially in the development of appropriate service use patterns. It is also necessary to define the objectives of community participation and to determine who should participate and how they should participate in order to achieve those objectives. The role of experts should be to provide information and support health education programs.

3.5.1.1 Analysis of Needs and Demand

Imaging and radiation therapy services are support elements in the clinical process. The degree to which they are used depends to a large extent on the decisions made in this process. Through these decisions the diagnostic and therapeutic resources available in the health system are mobilized. Hence, as in any process of health service planning, the first step in planning imaging and radiation therapy services must be analysis of morbidity and mortality, accompanied by a review of the patterns of utilization of the various radiological procedures, which, in practice, express the demand for those activities. The morbidity and mortality analysis, and the specific national and local manifestations of the corresponding indicators, will make it possible to establish needs and arrive at an overall decision regarding the types of services that will be required in each situation.

It is not within the scope of this publication to delve into the various qualitative and quantitative methods that are available for this purpose. It should be noted, however, that morbidity data alone are not sufficient to define the course to be taken in developing certain services.

In the case of radiology services, as with other diagnostic and therapeutic support services, measures or indicators of demand are a more objective basis for planning. That demand is established through analysis of utilization patterns and trends, which makes it possible to project future requirements for these services and thus establish a basis for making decisions about the corresponding health care centers. In this regard it should be pointed out that the annual frequency of radiological procedures per person varies considerably from country to country.

As is shown in Tables 2.1 (*6*) and 2.2 (*5*), there are differences of up to 30 times per year in individuals' use of these services in developing countries, compared with the industrialized countries.

It is generally accepted (*5*) that chest x-rays are the most frequent radiological exams in all the countries. In category-I countries, between 60% and 70% of the radiological studies carried out are simple chest x-rays. Another 10% might be x-rays of limbs and other parts of the skeleton. Examinations of the abdomen and digestive tract, including cholecystographies and urographies, might also account for 10% of the total. Hence, only about 10% of all the radiological examinations performed require a greater degree of specialization.

The proportions of chest and limb x-rays in the developing countries, tends to be higher, and the proportion of specialized studies is therefore quite lower —usually under 10%.

According to the UNSCEAR report for 1993 (*5*), the diagnostic imaging service use trends indicate:

- An increase in the frequency of all the types of radiological examinations, especially in the developing countries.

- In particular, there has been a rising trend in the number of chest x-rays, which have increased from 10 to 100 and from 20 to 50 per 1,000 population in the least developed countries (those in categories III and IV, respectively). Fewer chest x-rays tend to be performed in the most developed countries (those in categories I and II), apparently due to the decrease in mass screening x-ray studies.

- In countries with an intermediate degree of development, the greatest increases have been in the use of computed tomography and x-rays of the skull and the abdomen.

- Mammography has shown a sharp rising trend as its advantages as the only method for early diagnosis of breast cancer have become recognized.

- The numbers of x-rays of limbs, the backbone, and the digestive tract, as well as cholecystograms and urograms, have tended to remain stable in recent periods of 2 to 5 years.

- However, there has been an increase in the use of ultrasound for abdominal diagnosis, which has led to more rational utilization of simple imaging studies.

- In the countries in categories II to IV, the proportion of children is greater than in those in category I. This is reflected in a larger proportion of x-rays studies performed on children in the former countries.

- Among children, the most frequent radiological examinations performed are x-rays of the thorax, limbs, skull, pelvis, hip, and abdomen, and urography.

- With regard to the sex of the patients, there are no significant differences in utilization trends, although a greater number of women undergo cholecystography.

As for nuclear medicine, the information from UNSCEAR indicates that most examinations of this type are performed on adult patients. On the average, the population examined with nuclear medicine techniques is older than the general population and also older than those on whom ***x-ray*** examinations are performed.

The UNSCEAR report notes that the number of nuclear medicine examinations increased in the industrialized countries during the 1970s and remained relatively constant during the 1980s. In the developing countries, the frequency of nuclear medicine examinations is expected to increase.

An important trend in this area is the introduction of complex biological agents such as monoclonal antibodies tagged with ***radionuclides***, which have become not only a very useful diagnostic tool for locating tumors and detecting metastasis, but also a therapeutic tool for localized treatment of certain tumors. Another noteworthy trend is the increasingly widespread use of ***SPECT*** and ***PET*** units. One of the most recent trends is interventional radiology, whose use is gradually supplanting surgical procedures (*24*) and thus reducing days of hospitalization. In the area of radiation therapy, the highest degree of technological complexity is seen in intraoperatory radiation therapy facilities and in the proliferation of high-***dose***-rate remote afterloading brachytherapy devices.

These developments and their increased use will undoubtedly lead to higher per capita rates of radiation use.

Although use and trend analyses must take account of differences in national and local situations, these overall appraisals would seem to indicate that the most frequently used installations will be those that perform simple chest and limb x-rays.

Such installations should therefore be part of the set of services available at the primary ***level of care***.

There will also be need for a second set of services to make it possible to carry out more complex radiological studies, such those of the digestive tract, and radiation therapy treatments with low-megavoltage equipment, such as cobalt-60 units, which will be used somewhat less frequently. A third, more

specialized set of services will be used even less frequently. The respective services should be placed in secondary- and tertiary-level services.

3.5.1.2 Analysis of Available Resources

As was noted above, the general availability of resources for health care varies with the countries' degree of development and the organizational and financial characteristics of their health services systems. The availability of resources also varies depending on whether the environment is urban or rural.

With regard to radiology services, the necessary resources include physical facilities, equipment, personnel, organization, management, and technology. The latter comprises the techniques and procedures used for diagnostic and therapeutic purposes. In the determination of ***levels of care***, these technological resources and their possible combinations constitute one of the central elements in the stratified organization of services. Consequently, the resources need to be identified carefully and consideration must be given to the specific types of resources needed for imaging, radiation therapy, and nuclear medicine, as appropriate.

3.5.2 Imaging

In terms of imaging, the available technological resources can be grouped as follows:

- Conventional radiography, which permits studies of anatomical structures; specialized radiography, which is distinguished from conventional radiography mainly by the use of various types of contrast media. One form of specialized radiography that does not use contrast media is mammography, which is used to diagnose breast cancer and detect preclinical breast cancer in asymptomatic women.

- Fluoroscopy, now with image intensification, which permits functional studies. Fluoroscopy is also used in interventional radiology as a guide before, during, or after surgical procedures or in conjunction with other examinations or treatments. For example, fluoroscopy may be used in procedures involving the insertion of catheters or instruments for drainage, removal of calculi, occlusion, dilatation, or rechanneling of blood vessels; or infusion of drugs.

- Recording of fluoroscopic images, using radiographic film in a spot film device, on 16 mm film using a motion picture camera, or by electronic means. Fluoroscopic images can also be manipulated digitally—as in the case of digital substraction angiography (DSA)—or produced directly by digital means. For example, most of the equipment used in interventional radiology utilizes digital fluoroscopy (*24*).

- Computed tomography, in which multiple ***x-ray*** beams transmitted from several angles toward the patient are captured by radiation detectors and processed by a computer in order to obtain tomographic images.

- Diagnostic ultrasound, which uses ultrasonic mechanical waves to visualize anatomical structures. When the Doppler effect is also utilized, it is possible to perform functional studies, that is, studies of the physiology of organisms and their systems.

- Magnetic resonance imaging, which produces images by utilizing the ability of certain atomic nuclei to selectively absorb electromagnetic radiofrequency energy when they are placed in a powerful magnetic field.

- Nuclear medicine, in which radioactive substances are administered to the patient and their spatial location and temporary concentration are detected through the use of detectors and equipment capable of producing morphological images on one or several planes and curves of metabolic function.

In this schematic review of technological resources for imaging, special emphasis should be given to the Basic Radiological System developed by PAHO/WHO—now called WHIS-RAD (*19*).

3.5.2.1 The Basic Radiological System (BRS)

Because approximately two-thirds of the world population lacked access to diagnostic imaging services, during the period 1975-1985, PAHO and WHO focused their efforts on the development of the Basic Radiological System (BRS) (*15*). The BRS consists of a simple but rugged radiography unit that incorporates design elements that make it capable of producing high-quality ***x-rays*** with little maintenance.

Although WHO had been working on this problem from the early 1960s, it had been unsuccessful in its attempts to develop an ***x-ray*** machine that was more suited to the needs of developing countries than the ***x-ray*** machines that were available at the time. By 1970 the consensus of the experts was that a more basic ***x-ray*** unit was needed.

The broad spectrum of requirements for a basic radiological system were considered, and after a meeting held at PAHO in 1975 the specifications for a simple high-quality ***x-ray*** machine were developed (*15*).

In regard to the equipment, the BRS ***x-ray*** unit consists of a high-quality ***x-ray generator*** and tube, together with a focused grid and a unique tube stand, all of which are linked together in a sophisticated manner to produce an optimum but simple ***x-ray*** system.

Three training manuals are an integral part of the system, and WHO produced official versions of them in Arabic, English, French, and Spanish. The set of three manuals includes: the *Manual on Radiographic Interpretation for General Practitioners* (*16*); the *Manual on Radiographic Technique* (*17*), and the *Manual on Dark-Room Techniques* (*18*).

In addition, the manufacturer is expected to prepare and deliver with every machine a manual on maintenance and detection of failures.

In 1980 a laboratory was established to test BRS prototype ***x-ray*** machines at the St. Lars Roentgen Clinic of the University of Lund in Sweden. This laboratory, which is part of the WHO Collaborating Center for General and Radiological Education located within the Department of Radiology of the University of Lund, serves as focal point for the development of the WHO-BRS.

The essential elements of the WHO diagnostic imaging system were clarified during a WHO consultation meeting that took place at the University of Lund, Sweden, in June 1993. Among those participating in the meeting were radiologists, radiological technologists, radiological physicists and engineers, and representatives of the industry (*19*).

The WHO diagnostic imaging system, once it is completely developed, will consist of units, accessories, and training manuals for the diagnostic imaging modalities of radiography and ultrasound, as well as a system for the management of images produced through computerized tomography, magnetic resonance imaging, and nuclear medicine.

The radiographic unit of the WHO diagnostic imaging system (known by the acronym WHIS-RAD) is an updated version of the WHO-BRS unit. Changes were made at the suggestion of radiologists and technologists responsible for supervising examinations performed with the WHO-BRS. As a result of a few simple modifications, the new WHIS-RAD has become even more versatile and more appropriate for use in the industrialized world as well as in the developing countries.

The WHIS-RAD produces the same high-quality results that made the WHO-BRS the unit of first choice in many situations. Building on the success of the WHO-BRS, the developers of the WHIS-RAD introduced modifications that would make it possible to use the unit in a broader range of situations in which a fully trained radiological technologist was available to supervise its operation.

The specifications for the WHIS-RAD equipment appear in the Appendix I-A (*19*). This appendix also contains a list of specifications for general-purpose diagnostic ultrasound equipment (I-B) (*7*). The WHO publication *Manual of Diagnostic Ultrasound* (*25*) is currently being translated into Spanish and French.

3.5.3 Radiation Therapy

Radiation therapy, together with surgery and chemotherapy, is one of the pillars of cancer treatment. It is estimated that radiation therapy is used in the management of approximately 40% to 80% of all cancer patients, either as the sole method of treatment or in conjunction with surgery, chemotherapy, and/or hyperthermia.

The main technological resources available in this field are:

- Teletherapy, in which the irradiation ***source*** is external. Superficial and orthovoltage ***x-ray*** units (the latter are now practically nonexistent), ***radionuclide*** units such as cobalt-60 units, and linear ***accelerators*** are the main types of equipment used.

- Brachytherapy, which utilizes ***sealed*** radioactive ***sources*** in intracavitary, interstitial, or superficial implants.

- Therapeutic nuclear medicine, in which the patient is given radioactive substances that irradiate the organ which takes them up. The

radionuclides most commonly used are iodine-131 for carcinoma of the thyroid, strontium-89 for treatment of bone metastases, and several monoclonal antibodies tagged with various ***isotopes*** for treatment of colon cancer and other malignancies.

The use of ***ionizing radiation*** for therapeutic purposes is a complex process, which requires the collaboration and interaction of personnel trained in various disciplines. A critical step in this process is the initial evaluation of the patient and his/her tumor. These circumstances make it essential for these services to be located in complex-care units of the health system.

4. Organization of Health Care Centers in Radiology Services

4.1 Stratification of Services

The foregoing considerations point up the importance of the various diagnostic and therapeutic techniques as fundamental tools in the clinical process. They also show that the development and organization of radiology services should be approached from the perspective of stratified planning of supply. In this context the fundamental criterion for the organization of services is the formation of health care centers or nuclei of increasing technological complexity incorporated within the general organization of health services in accordance with their stratification by ***levels of care***.

The characteristics of these radiology service centers will vary according to countries or regions. They may or may not combine elements of imaging and radiation therapy, as appropriate. In any case, however, there should be a definite correlation between the technological complexity of these services and that of other diagnostic and therapeutic resources available in the same establishment or unit of the health care system. This technological harmonization is essential in order to achieve the necessary coordination of the services provided at the different levels and in order to optimize the possibilities for utilization of radiology resources.

Similarly, in the organization of radiology centers the functional links between centers of differing degrees of complexity should be clearly established in order to ensure smooth referral and counterreferral processes and guarantee continuity of care for patients who require it.

The criteria for the geographical and institutional placement of imaging and radiation therapy centers should be determined within each health services system in accordance with its parameters of accessibility and its definitions of ***levels of care***.

4.2 Operation of the Radiology Services Subsystem according to *Levels of Care*—Health Problems to be Treated at Each Level

The characteristics of the various types of centers, whose possible technological configuration is outlined in later sections, should be defined in accordance with each national or regional situation.

Within the overall system of health services, these radiological health care centers should be functionally interrelated in order to form a true subsystem of diagnostic and/or therapeutic support services, in which referral and counter referral of patients is possible and technical support is provided to the least complex centers. This interrelationship should exist even in systems of open and pluri-institutional services, in which there is no hierarchical relationship between the various operational units.

The establishment of diagnostic services will not be sufficient if they are not coordinated with appropriate therapeutic services. The various components of these centers may be combined in different ways depending on the characteristics of the health centers, polyclinics, ambulatory care units, and hospitals in which they are located. In principle, at each ***level of care*** the capacity should exist to diagnose and treat the problems listed below:

Level 1

- Respiratory disorders
  - Infectious lung diseases, including tuberculosis, histoplasmosis, and pneumonia
  - Chronic obstructive pulmonary disease and related diseases such as asthma and extrinsic allergic alveolitis
  - Pneumoconiosis
  - Tumors in the lung fields
  - Sinusitis
- Bone tumors
- Fractures
- Some joint disorders

Level 2

- Digestive disorders
  - Of the esophagus
  - Gastroduodenal (ulcers, tumors)
  - Intestinal (diverticula, Crohn's disease, ulcerative colitis, intestinal obstruction)
  - Liver, gallbladder, and biliary disorders
  - Other disorders such as abdominal tumors and abscesses

- Diseases of the genitourinary system
  - Renal and ureteral lithiasis
  - Hydronephrosis
  - Tumors

- Prenatal monitoring

- Thyroid diseases

- Breast disorders

Level 3

- Diagnosis and staging of neoplasms
  - Of head and neck
  - Intrathoracic
  - Abdominal
  - Hematological

- Diseases of the central nervous system
  - Malformations
  - Tumors
  - Vascular pathology
  - Infections
  - Consequences of injury

- Cardiovascular diseases
  - Arteriosclerosis, vascular occlusions, thrombosis, vasculitis, arteriovenous malformations

- Breast disorders

- Facial injuries (including injury to the eye)

- Injuries to the orbital and the ear

- Degenerative diseases of the spinal column (lumbar disk injuries)

Level 4 (in cases in which one exists)

If, for reasons of over- or underspecialization, or because of other local characteristics, it is decided to organize a fourth level of radiological care, the health situations to be resolved at that level might include diagnosis and treatment of infrequent diseases and of diseases unresolved at levels 1, 2, and 3.

- Disorders of the spinal cord

- Disorders of the central nervous system in which computed tomography does not yield a diagnosis (multiple sclerosis, temporal epilepsy)

- Vascular disorders that can be treated endovascularly

- Staging of some tumors that may affect the bone marrow, primarily or secondarily

- Detailed studies of vascular mechanics in aortic injuries

- Sophisticated radiation therapy treatments

It should be reiterated that these ***levels of*** radiological ***care*** may be combined in a single establishment. In practice this occurs in the configuration of radiology departments or units in hospitals of high and medium technological complexity. In the former, there may be facilities that correspond to the third, second, and even first levels. In the latter, second- and first-level services are usually combined. What is most important is that these resources be utilized appropriately.

4.3 Configuration of Radiology Service Centers

Based on these general guidelines, possible configurations for four types of radiological service centers of differing degrees of complexity are presented below. For greater clarity, the imaging and radiation therapy components are treated separately; however, the respective elements of nuclear medicine are

included under each of these components. It should be stressed that these are the minimum characteristics that each level should have. The diagnostic and therapeutic components not only can but should be closely coordinated, and whenever possible they should be located within the same establishment or unit. This is especially true for centers of medium and high technological complexity.

In the configuration of these centers it is necessary to take into account the functions or services that should be available, the equipment, the personnel, and the institutional setting. It is necessary in addition to establish general parameters with regard to the population to be covered and to specify other requirements of a general administrative nature.

In the selection of equipment for the various types of centers described, it is essential to consider the costs, including both the initial investment and operating costs. In the case of the latter, the cost of maintenance and education and training of the personnel who will operate the equipment is an essential element. Another important cost factor that must be taken into account to prevent ***accidents*** is the cost of safely disposing of equipment that is no longer to be used.

Finally, it must be pointed out that although it is important and necessary to consider cost factors in planning these services, concern for costs should not lead to bad investments or the acquisition of equipment and other elements that will rapidly become obsolete. Owing precisely to the importance of these services and the magnitude of the investment required, it is essential to make decisions based on sound reasoning and with an eye to future needs.

4.3.1 Imaging Centers

The function of an imaging department is not solely to obtain images. It should also be an expert service in this field of knowledge, capable of advising the clinical personnel of the unit or hospital on the selection of studies or examinations to be performed on a patient with a given problem in order to arrive at a diagnosis or facilitate surgical intervention.

As noted above, equipment that uses ***ionizing radiation*** must meet radiological safety requirements, and the facilities in which it is installed must also fulfill safety standards.

Imaging centers might be categorized as follows, according to the degree of complexity of the resources utilized:

4.3.1.1 General Imaging Centers—Technological Complexity Degree I

These centers will constitute the basic units of the imaging subsystem.

Services Available

They will have the facilities needed to perform:

- General radiography
- General diagnostic ultrasound

Equipment (see Appendix I)

- Basic Radiological System (today WHIS-RAD) developed by PAHO/WHO, or similar units (*19*)
- Appropriate facilities and equipment for manual or automatic film processing, depending on the volume of work
- Ultrasound scanner (*7*)

Personnel

It is not essential to have a full-time radiologist, but the medical personnel of the establishment should be trained in the interpretation of the images that the system can produce, and they should have easy access to radiology specialists for consultations. An x-ray technician or operator with specific training in the operation of the corresponding equipment is necessary. A technologist specializing in general diagnostic ultrasound is also required. Access to a radiation physicist is desirable.

Location and Population to be Served

General radiological diagnostic facilities may be located within health centers, polyclinics, or similar selected ambulatory care units that also possess other diagnostic capabilities, such as a general clinical laboratory, basic electrocardiography, etc.

The radiological centers at the first degree of technological complexity, the basic units in the subsystem, may also be located within a general hospital, in which case their diagnostic capacity may be expanded through the incorporation of fluoroscopy with image intensification. The incorporation of this additional technological capacity makes it essential to have specialized radiologists on the regular staff of the service.

In hospitals in large urban conglomerates and in health facilities located in the peripheral areas of large cities, these radiology centers of technological complexity degree I may be part of a set of diagnostic services that are capable of carrying out more complex procedures. However, the basic nature of their function should be preserved in order to enhance the general efficiency of the diagnostic support subsystem.

The population served by a diagnostic imaging center of technological complexity I might number around 15,000. The minimum and maximum population figures to be covered might be 10,000 and 20,000, respectively. However, these figures are only general guidelines. In practice, the population to be served must be determined in keeping with the characteristics of each health system.

4.3.1.2 Basic Radiological Specialty Centers—Technological Complexity Degree II

These centers will be imaging facilities of intermediate technological capacity.

Services Available

They should have appropriate facilities for performing:

- Radiography that requires the use of contrast media and/or specialized techniques
- Mammography (although the technique and equipment are relatively simple, interpretation of the images requires specialized training)
- Studies that require fluoroscopy, including basic angiography and, potentially, DSA
- Computed tomography

- Specialized diagnostic ultrasound, including the Doppler module, whenever possible
- Diagnostic nuclear medicine with ***gamma camera***
- In vitro studies with radiopharmaceuticals

Equipment

- Radiography/fluoroscopy units with currents of no less than 500 mA with image intensifiers and film spot devices
- A dedicated ***x-ray*** machine for mammography
- Processing equipment, preferably automatic. In small units, manual development may be acceptable
- ***CT scanner***
- Ultrasound scanner(s) for complex studies, including the Doppler module
- ***Radionuclide calibrator***
- ***Gamma camera***
- Well-type scintillation detector

The numbers of the various types of equipment needed and their functional and technical characteristics will depend on the total population to be served and on the health care unit or establishment in which the imaging center is located.

Personnel

These level-two centers must be staffed by imaging specialists in numbers appropriate to the size of the unit and the volume of work.

It is also necessary to have radiology and nuclear medicine technologists in sufficient numbers according to the workload.

Depending on the numbers of studies to be carried out, one or several specialists in nuclear medicine will be required, as will one or more radiologists specializing in mammography.

A full-time radiation physicist may also be required. depending on the size of the center. In medium-size centers or units periodic visits by a radiation physicist may be sufficient.

Location and Population to be Covered

These imaging centers of intermediate technological capacity (complexity degree II) may be located within outpatient diagnostic centers that function autonomously or that are part of a complex of services organized for this purpose.

These centers may be also located in a mid-size general hospital (with no fewer than 300 beds) with a large volume of specialized outpatient consultation.

They may also be combined with centers of degree-I complexity in order to achieve greater efficiency in the use of resources. However, such a combination should not alter the intermediate-type functional characteristics of the center. The population to be served would number between 100,000 and 500,000, perhaps averaging around 200,000.

As in the previous case, these figures are only indicative and must be adjusted to national and/or regional realities.

Administration

Given the characteristics of these centers of intermediate technological capacity, appropriate organization and administration are essential, and it is therefore necessary to incorporate personnel from these disciplines and to develop the necessary administrative techniques and procedures.

4.3.1.3 Highly Specialized Radiological Diagnostic Centers—Technological Complexity Degree III

These centers will be imaging facilities with a high degree of technological complexity.

Services Available

They should have the necessary facilities, equipment, personnel, and organization to perform:

- Special radiographic studies, including mammography
- Radiological studies that use various contrast media, generally through invasive procedures that can only be performed by professionals with specialized training
- DSA
- Bone densitometry
- Computed tomography
- Interventional radiology
- Specialized diagnostic ultrasound, including the Doppler module
- Studies with ***gamma camera*** and ***SPECT***
- Techniques using labeled monoclonal antibodies
- Magnetic resonance imaging

Equipment

The following equipment is necessary:

- Complex radiological installations equipped with the necessary elements for specialized invasive studies with contrast media, including mammography units
- Bone densitometer(s)
- ***CT scanner(s)***
- Ultrasound scanners with Doppler module
- Automatic film processors appropriate to the characteristics of the department or unit in which these services are located

- ***Gamma cameras*** and ***SPECT*** units

- ***Radionuclide calibrator***

- Equipment for monoclonal antibody techniques

- Magnetic resonance imaging equipment

The number, characteristics, and technical specifications of these various types of equipment, and the possible combinations thereof, will depend on the population to be served, the availability of resources in the respective health care system, and the volume of studies to be carried out in a given unit of time.

Personnel

These centers of high technological complexity require specialists in diagnostic and interventional radiology or, preferably, subspecialists in the various fields: neuroradiology, vascular radiology, pediatric radiology, etc., and in nuclear medicine. Their number and training should be in accord with the services established and with the volume of studies to be carried out per unit of time.

It is also necessary to have appropriate numbers of well-trained radiology and nuclear medicine technologists.

Full-time medical physicists are necessary as well, in appropriate numbers according to the size and volume of work of the unit. They should have appropriate specialized training in the various services offered and use of the corresponding equipment. It is also desirable to have a chemist or biochemist specializing in nuclear medicine or a radiopharmacist.

In addition, personnel from other technical and administrative disciplines are needed, according to the characteristics and the size of the respective center.

Location and Population to be Served

Centers of this type (technological complexity degree III) should be interrelated with other services of equivalent complexity. Accordingly, they might be located in the following institutional settings:

- Highly specialized hospital

- National or regional referral center, depending on the characteristics of the country

- University center, with highly specialized programs in medicine and related disciplines

In these hospitals and university referral centers, radiological facilities of differing degrees of complexity generally coexist. This type of arrangement may even be viewed as necessary in order to rationalize the use of complex resources and achieve greater efficiency in the overall system.

Administration

Centers or units of this type require an appropriate administrative organization, with personnel from various administrative fields, depending on their size, volume of services, and linkages with other units.

4.3.1.4 Regional and National Radiological Referral Centers—Technological Complexity Degree IV

In most national situations, stratification of imaging services in three categories according to degrees of complexity would be appropriate in order to rationalize accessibility and opportunities for receiving care. However, in countries with large populations and several important urban centers that compete with the capital city, within the group of centers at the third degree of technological complexity described above it may be desirable to differentiate a fourth group. The differences between the two will probably be apparent in certain specific areas in which it is possible to achieve a greater degree of sophistication. An example would be a ***PET*** system with an *in situ* cyclotron. Nevertheless, creation of a fourth degree in no way invalidates the general principle of stratified organization according to technological complexity.

Centers of technological complexity degree IV are generally institutions that are highly specialized in one or more fields of radiology and that serve as regional or national referral centers.

In the planning and development of these various types of imaging centers, it is essential to consider the complementarity that must exist between the elements of diagnosis and treatment.

When diagnostic facilities are established, facilities for carrying out appropriate treatments must also be available. This does not mean that these

diagnostic and therapeutic resources must be located in the same place. But it is indispensable that access to the two types of services be ensured. It makes no sense to have the capabilities to diagnose cancer through images if the necessary treatment is unavailable.

4.3.2 Radiation Therapy Centers

Therapeutic radiology services have characteristics very different from those of imaging services. Hence, the process of planning of these services and the parameters used to determine their characteristics of complexity, location, etc., will also be different. Therapeutic services also have lower utilization rates than diagnostic services, and the radiological safety standards established by the responsible radiation protection authorities are more stringent than in the case of diagnostic services (*26*). These circumstances must be given special consideration when the organization of these services in the framework of the ***local health system*** development strategy is being contemplated.

As was previously indicated, there are three types of radiation therapy services: teletherapy, brachytherapy, and treatment with ***radionuclides***. The first two are complementary, and there are specific guidelines for all three.

In the organization of these services, stratification in two categories of facilities or centers with clearly differentiated technological complexity is generally considered sufficient. In some large countries, depending on the distribution of the population, it may be advisable to consider establishing centers which would eventually constitute a third level of technological complexity.

The basic parameters for planning radiation therapy services are established in relation to cancer morbidity. The proportion of cases requiring radiation therapy ranges, according to various authors, between 40% and 80%.

It is generally agreed that, as a minimum, the coverage of radiation therapy services in any country should be sufficient to treat 50% of the new cases of cancer diagnosed each year. To this it is necessary to add 15%, which represents the prevalence of cancer cases for which treatment continues from one year to the next. With these figures, a formula for calculating the needs for this type of facility can be proposed.

The maximum number of patients per machine/year requiring high-energy radiation therapy treatments ranges, according to various authors, between 250

and 350 (*27*). This figure might be as high as 420 in the case of high-energy ***accelerators***. Nevertheless, it should not be forgotten that these machines require constant care and maintenance, which somewhat diminishes their usefulness for providing treatment.

Since the typical cancer incidence is 75 to 150 new cancer patients per 100,000 population, in order to serve a population of 4,400 million patients (assuming 4.4 million new cases of cancer per year—50% of which require radiation therapy— and one machine for each 500 new cases of cancer treated) the total current need is 4,400 machines. By the year 2015, barring the unexpected discovery of a spectacular new cure for cancer, a total of 10,000 machines will be needed to provide treatment for some 10 million new cases of cancer each year in the developing countries.

Cognizant of this need and recognizing the problems associated with the existing teletherapy equipment, PAHO, in collaboration with WHO, the International Atomic Energy Agency (IAEA), and the United Nations Industrial Development Organization (UNIDO), organized an advisory group meeting in Washington in 1993 to assess the current situation and make recommendations for the development of megavoltage ***x-ray*** machines that would be simpler to operate and maintain than the linear ***accelerators*** currently in use. The Executive Summary of the resulting publication appears in Appendix I-C (*12*).

With respect to the number of specialists in radiation oncology that may be required, most authors agree that the number of new patients that can be treated each year by a radiation therapy specialist is 250. This figure may be lower depending on the number of hours the specialist devotes to patient care each day and on whether he/she engages in other activities such as teaching or research. Assuming that these possible variables are not present, the figure of 250 new cases per radiation oncologist per year would be used as a basis for calculation (*27*).

One radiation therapy physicist for every 400 new patients each year is also required. In addition at least one dosimetrist every 300 new patients a year and two radiation therapy technologists (radiation therapists) for every high voltage unit are needed.

Based on the figures cited above, by simply applying these formulae to the total population of a country or region, the need for radiation therapy facilities and human resources can be estimated. Taking into consideration the geographical distribution of the population and other characteristics related to population mobility, the location for radiation therapy facilities can be determined.

In general it is considered advisable to organize radiation therapy services into two types of centers.

4.3.2.1 Basic Radiation Therapy Centers—Technological Complexity Degree I

Services Available

Basic radiation therapy: teletherapy and manual afterloading brachytherapy.

Equipment

At least one cobalt-60 teletherapy unit, manual afterloading brachytherapy applicators with caesium-137 ***sources***, and an adequate radiodiagnostic unit or simulator for tumor localization and treatment simulation. Dosimetry equipment should also be available for calibration of ***sources***.

Personnel

Ideally, three radiation oncologists, one physicist, five radiation therapy technologists and one dosimetrist would be required in total.

Inpatient Care Facilities

Approximately seven beds for inpatient care will be needed. A manual afterloading brachytherapy section might be placed so as to take advantage of the operating room in the hospital in which the center is located, and two shielded rooms might be installed for relatively simple treatments: gynecological, breast, and cutaneous.

Location

Preferably, this basic radiation therapy center would be located in a general hospital of intermediate complexity. It should be interconnected with a radiation therapy center of degree-II technological complexity for the development of treatment protocols and the advanced training of specialists.

4.3.2.2 Specialized Radiation Therapy Centers—Technological Complexity Degree II

Services Available

- Teletherapy and brachytherapy
- Radiation therapy with ***radionuclides***.
- Intra-operative radiation therapy (optional)

Equipment

- 3 cobalt-60 teletherapy units or 4-6 MV ***accelerators***
- 1 15-20 MV ***linear accelerator***, with ***photons*** and ***electrons***
- 1 ***linear accelerator*** for intra-operative radiation therapy with ***electrons*** (optional)
- 1 simulator
- 1 computer for treatment planning with peripherals
- 1 brachytherapy section with an ***x-ray*** equipped operating room, six beds with radiation shields, and a remote afterloading brachytherapy device.
- Dosimetry equipment with three-dimensional ***dose*** measurement and isodose generation capacity.
- ***Radionuclide calibrator*** (for brachytherapy ***sources***)

Personnel

For teletherapy and brachytherapy, eight radiation oncologists, three physicists, one or two dosimetrists and two radiation therapy technologists would ideally be necessary for each treatment unit and shift. In addition to the specialized dosimetry and brachytherapy personnel, specialized technologists in simulation, computerized treatment planning, maintenance, instrumentation, manufacturing of accessories, etc., would be desirable.

For radiopharmaceutical therapy, several physicians specializing in nuclear medicine; a chemist, biochemist, or pharmacist specializing in radiopharmacy;

a physicist specializing in nuclear medicine; and specialized nuclear medicine technologists would be needed.

Should intraoperative radiation therapy be available, the number of specialists will have to be increased in accordance with the volume of work.

Inpatient Care Facilities

In regard to inpatient care, a 25-bed unit would be required. As mentioned above, six would be used for brachytherapy and the rest for teletherapy.

It would also be necessary to have a room for inpatient care of nuclear medicine patients with facilities adapted to prevent ***contamination*** with radiopharmaceuticals.

Location

These centers should be located in referral hospitals or in tertiary care hospitals specifically equipped to provide treatments with specialized techniques and to carry out research.

These degree-II radiation therapy centers could meet the needs of a population of approximately one million inhabitants.

In determining the characteristics of these centers, it is necessary, finally, to take into account increases in the numbers of cancer cases being diagnosed early, increases in the incidence of cancer, trends in radical vs. conservative treatment, and population growth. All these factors are increasing the need for both equipment and specialists every year.

5. Responsibilities, Training, and Continuing Education of Human Resources

5.1 Human Resources in Radiology Services

Medical services that use radiation ***sources*** for diagnosis or treatment require specialized equipment, which must be operated by sufficiently qualified and experienced personnel. During the last two decades the complexity of some types of equipment has increased markedly and its use now requires much more extensive training and experience.

The success or failure of a procedure depends largely on the training of the human resources who prescribe and execute the procedure. Training of the staff responsible for maintenance and ***quality control*** of the equipment is also important.

It must be borne in mind that services that use ***sources*** of ***ionizing radiation*** involve physical processes that result in the irradiation of patients. In diagnostic procedures, the ***dose*** of radiation received by patients can produce long-term effects and in some instances, as in interventional radiology, even short-term effects (*24*). In radiation therapy procedures, the ***dose*** received by the irradiated tissues are large enough to destroy the tissues and induce immediate acute effects, in addition to the long-term effects.

With regard to nuclear medicine, the particular nature of this specialty and the diagnostic and therapeutic techniques associated with it make it advisable to give separate treatment to aspects relating to the human resources who work in this field.

The education of professionals and technologists should be oriented not only toward obtaining results in terms of the highest attainable quality but also toward ensuring that procedures involving ***sources*** of ***ionizing radiation*** will be carried out with the least possible harm to the health of patients. Both purposes can be fulfilled through correct selection of diagnostic or treatment methods.

Services that utilize ***sources*** of ***ionizing radiation*** can also cause harm to the health of those who work in the field, and they may also pose a threat to public health if they are not adequately designed, operated, and maintained. Those responsible for the facilities and the persons in charge of their maintenance and operation must have adequate training in elements of radiation protection so as to avoid such effects (*26*).

This chapter discusses the responsibilities of the personnel involved in radiology services and outlines the principal contents for training programs, including programs for training in maintenance. Appendix III contains several examples of the curricula for studies in these specialties in Spain.

5.2 Training and Continuing Education

In each of the various types of radiology services, it is necessary to have teams of professionals and technologists with well-defined functions and responsibilities.

It is important that the minimum education and training necessary for each professional specialty and level be established. In the case of services that use ***sources*** of ***ionizing radiation***, the regulatory agencies responsible for radiation protection should define or approve the education and training requirements for personnel working in each service, or at least for those responsible for the management of those services (*26*).

Local health systems should have the capacity to train and educate human resources. Continuous technological change makes it necessary to retrain personnel, and it is therefore important to adopt policies of continuing education in order to ensure that the professionals and technologists involved in the delivery of services have up-to-date knowledge.

Retraining is of special importance in the case of technologists, given the rapid evolution of radiological technology and the fact that technologists generally have fewer opportunities to participate in courses or educational activities after they obtain their diplomas. Updating in radiation protection should be part of such retraining.

5.3 Specific Requirements

5.3.1 Referring Physician

This is the professional who decides to request that a medical specialist perform a diagnostic or therapeutic procedure for a patient under his/her care. This physician determines whether or not the procedure is justified taking into account the benefits, at least presumptive, that it will have for the health of the patient, as well as any possible ***detriment*** that it might cause (*26*).

Due consideration should be given to any special circumstances, such as pregnancy, that might have a bearing on the analysis of whether or not the procedure is justified. In case of doubt, the referring physician should consult the radiologist about the required procedure.

Education

The referring physician should be aware of which imaging (*10*) and radiation therapy (*11*) techniques may be appropriate and the benefits and ***risks*** associated with them, particularly in special circumstances such as in pregnancy.

In the course of their university education, physicians should receive instruction in radiation biology and patient protection. They should also be given information on the relative contributions of the various ***sources*** of radiation to human ***exposure*** and on the significance that ***medical exposure*** has for the ***collective dose*** incurred by the population.

It is important to cultivate an understanding among physicians of the concept of collective detriment and benefit. During their professional lives, physicians make a great many decisions, a large number of which will contribute to an increase in the ***collective dose*** of radiation to the population. Although physicians must make each decision on the basis of considerations relating to the health of each individual patient, by adopting a collective perspective they will be better able to weigh the ***risks*** associated with radiation and will thus develop a cautious approach to making decisions about whether each procedure is justified.

Graduate courses should be offered to update physicians' knowledge, and new developments in radiation biology and radiation protection should be presented and discussed at scientific meetings. The physician should have sufficient knowledge to be able to prescribe a radiological procedure and give

specific indications regarding what is required from the specialist in imaging or radiation therapy.

5.3.2 Imaging

General practitioners and a variety of specialists, dentists, radiologists, medical physicists, diagnostic radiology technologists, and nursing personnel are all involved in the ***practice*** of imaging.

5.3.2.1 General Practitioner

At the first ***level of health care***, a physician specializing in radiology may not be available. A general practitioner with sufficient experience can fulfill the functions of this specialist. The general practitioner must possess the knowledge and experience necessary to interpret radiological images.

Education

The physician should have a good clinical background and basic knowledge of radiology, diagnostic ultrasound, and radiation protection. According to WHO, a general practitioner should perform a minimum of 200 obstetric and abdominal examinations using general-purpose diagnostic ultrasound equipment in order to be considered sufficiently trained to interpret sonograms.

5.3.2.2 Radiologist

The radiologist is responsible for all the aspects of imaging procedures. The studies should be planned individually, taking into account the characteristics of each patient and the needs expressed in the medical prescription. This is not always possible if the workload is very heavy, but the radiologist should at least ensure that such planning takes place in the case of procedures that involve a relatively high ***dose*** for the patient, such as in interventional radiology.

The radiologist should be able to decide which technique is most appropriate to fulfill the objectives specified in the prescription in cases in which several techniques might be used but they would entail significantly different ***dose*** values for the patient, such as in interventional radiology.

Education

The education of the radiologist, as a specialist, should include sufficient background in general physics as well as radiation physics, dosimetry, radiation biology, both general radiation protection and patient protection, and thorough knowledge of the equipment currently available in terms of its capabilities and limitations, radiological ***risks***, and the radiological techniques that can be used with each unit. The radiologist should possess a clear understanding of ***quality assurance***. Appendix III-A shows an example of a curriculum for this specialty.

Experience is crucial, and a radiologist should not be put in charge of a radiology service unless he/she has at least one year of practical experience.

5.3.2.3 Medical Imaging Physicist

The medical physicist plays an important role in selecting equipment that is appropriate to the needs of the service; overseeing equipment maintenance, ***quality control***, and radiation protection programs; and providing advisory services and instruction on the physical aspects of radiology and radiation protection. In high-complexity services, the medical physicist is indispensable; in services of low and medium complexity, at the least, a medical physicist should be available to provide periodic advisory services (*26, 28, 29*).

Education

Medical physicists should receive comprehensive training in the physical aspects of the production of radiological images, the operation of radiology equipment, diagnostic ultrasound, nuclear magnetic resonance imaging, and the essential aspects of the techniques of obtaining and processing images, including digital techniques. The should also have knowledge of dosimetry, radiation biology, and radiation protection (*30*). In addition, they should gain practical experience in the application of ***quality control*** programs.

The practical training of the medical physicist is of considerable importance. It should last at least a year and be performed in a recognized center (*31*).

5.3.2.4 Radiological Technologist

The main responsibility of the radiological technologist is to perform radiological studies under the supervision of the radiologist. These technologists have considerable influence on the ***dose*** the patient receives

because it is they who position the patient, adjust the controls of the equipment and select the appropriate accessories.

Education

The education of the radiological technologist should include instruction in radiation physics, dosimetric quantities and units, radiation biology, and radiation protection. The technologist should acquire knowledge and experience in the use of radiology equipment of various degrees of complexity, as well as knowledge of anatomy, physiology, pathology, and radiological and image-processing techniques. Appendix III-D provides an example of the curriculum for the training of diagnostic imaging technologists in Spain, and Appendix III-E contains a draft curriculum proposed by the Spanish Association of Radiology Technologists for the professional training of radiological technologists.

It should be taken into account that services do not always have qualified radiological technologists. Some low-complexity services can manage with an equipment operator. In such cases, it is important to organize the practical training of operators so that they acquire the necessary skills and the essential knowledge of radiation protection.

5.3.2.5 Nursing Personnel

Nursing personnel participates in preparing and positioning the patient, especially in interventional radiological procedures, such as heart catheterization and angioplasty.

Education

The education of nursing personnel should include instruction in basic concepts of radiology and radiation protection.

5.3.3 Radiation Therapy

The personnel involved in radiation therapy include radiation oncologists, medical physicists, radiation therapy technologists[2], dosimetrists and nursing personnel.

[2] Called radiation therapists in some countries.

5.3.3.1 Radiation Oncologist

The radiation oncologist specializes in the use of ***ionizing radiation*** for the treatment of cancer. He/she must not only have thorough knowledge of his or her own specialty, but must also be knowledgeable about other alternatives for the treatment of cancer (surgery, chemotherapy, hormonal therapy, etc.). An essential aspect of the radiation oncologist's job is to decide which of the possible curative or palliative therapeutic procedures should be used for each patient.

Education

The radiation oncologist should possess a good general medical education and thorough knowledge of oncology. He/she should also have general knowledge of physics, radiation physics, dosimetry, radiation biology, radiation protection, and clinical dosimetry and elements of computation. In addition, the radiation oncologist should be familiar with the concepts of ***quality assurance***. Appendix III-B shows an example of a curriculum for this specialty.

It is generally agreed that the radiation oncologist should have acquired at least three years of experience in a recognized center before taking on the responsibilities of chief of a radiation therapy service.

5.3.3.2 Radiation Therapy Physicist

The radiation therapy physicist is responsible for advising on the selection of appropriate equipment to meet treatment needs; performance of acceptance testing; calibration of all ***sources*** of radiation and of dosimetric equipment; design and supervision of construction of treatment accessories such as bolus, compensators, wedges, and immobilizers; supervision of clinical dosimetry and treatment planning; establishment and supervision of a ***quality control*** program; education and training of service personnel, residents, and technologists in his/her area of expertise; advising the radiation oncologist on the appropriate treatment of patients; periodic revision of patient treatment plans; and establishment and supervision of radiation protection monitoring (*32*).

Education

The radiation therapy physicist should have a university degree in physical sciences and have special training in radiological physics applied to radiation therapy. He/she should have thorough knowledge of the physical aspects of the equipment utilized in radiation therapy and should be well versed in physical

and clinical dosimetry, radiation biology, radiation protection, instrumentation, and computation. He/she should also have knowledge of anatomy, physiology, and oncology and should have experience with ***quality control*** programs.

Practical training for radiation physicists is extremely important. It should last at least a year and be completed in a recognized center (*31*).

5.3.3.3 Radiation Therapy Technologist (radiation therapist)

The radiation therapy technologist or radiation therapist is responsible for operating the equipment and for routine positioning of the patient. He/she assists the radiation oncologist and the radiation therapy physicist in carrying out the treatment planned by them.

Education

The radiation therapy technologist or radiation therapist should have basic training in radiology similar to that of the general radiation technologist but with an orientation toward treatment with radiation ***sources***. He/she should have a good knowledge of radiological physics and the principal concepts of dosimetry, knowledge of radiation biology and of radiation protection, and a basic understanding of anatomy and oncology. An example of a proposed curriculum for this specialty is shown in Appendix III-E.

5.3.3.4 Dosimetrist

Within the field of radiation therapy, there is an increasing trend toward specialization in dosimetry.

The dosimetrist, under the supervision of the radiation therapy physicist, calculates the ***dose***, plans the treatment, and constructs treatment accessories. It is often the dosimetrist who periodically measures the ***absorbed dose*** rate from external ***sources*** and carries out other ***quality control*** tests designed by the medical physicist.

Education

The dosimetrist may be a radiation therapy technologist or a university graduate with an undergraduate degree in physics, biology, or engineering who has pursued a special course of study, which normally takes one year.

5.3.3.5 Nursing Personnel

Nursing personnel collaborate in care of patients during the different phases of treatment. In brachytherapy cases, they should assist the physician during the implant procedure and care for patients during the time they are hospitalized with implanted ***sources***.

Education

The nursing personnel who work in radiation therapy services should have knowledge of radiation protection and be trained to work in ***controlled areas***, especially when they care for patients in brachytherapy areas.

5.3.4 Nuclear Medicine

Medical specialists, medical physicists, radiochemists or radiopharmacists, nuclear medicine technologists, and nursing personnel are the personnel involved in nuclear medicine.

5.3.4.1 Nuclear Medicine Specialist

The nuclear medicine specialist is the physician responsible for utilizing in vitro or in vivo ***radionuclides*** for diagnosis or therapy, depending on the objectives of the intervention. He/she decides the course to be followed in the case of each patient in order to best meet the needs specified by the referring physician, taking into account the possibilities associated with the various techniques of diagnosis and treatment with radiopharmaceuticals and the ***doses*** of radiation involved.

Education

Nuclear medicine is a specialization which requires a solid foundation in general clinical medicine, including in particular endocrinology, mathematics, statistics, computation, physics, radiological physics, radiation biology, radiation protection, and instrumentation. The nuclear medicine specialist must have thorough knowledge of the variety of equipment available, its characteristics, its capabilities and limitations, and the radiological ***risks*** of using ***unsealed*** radioactive ***sources***. He/she should also understand the concepts of ***quality assurance***. Appendix III-C shows an example of a curriculum for this specialty.

Before taking on primary responsibility for a nuclear medicine service, the specialist should have acquired at least two years of documented experience in diagnosis and three years in treatment using nuclear medicine techniques in a recognized center.

5.3.4.2 Nuclear Medicine Physicist

The nuclear medicine physicist is responsible for the technical and dosimetric aspects of procedures carried out, ***quality control*** of the equipment and radiopharmaceuticals used, and the radiation protection in the service. He/she is also responsible for the data analysis and computational aspects of nuclear medicine.

Education

The nuclear medicine physicist should hold a university degree in physical sciences and have special training in radiological physics and nuclear medicine. He/she should have thorough knowledge of radiation dosimetry, radiation biology, radiation protection, instrumentation, statistical analysis, computation, ***quality control***, radiopharmacy, and operational aspects of radiation protection when working with ***unsealed sources***.

Practical training for nuclear medicine physicists is of considerable importance. It should last at least a year and be completed in a recognized center (*31*).

5.3.4.3 Radiochemist or Radiopharmacist

The radiochemist or radiopharmacist is responsible for the development, production, and ***quality control*** of radiopharmaceuticals used in a nuclear medicine service. The radiopharmacist is an indispensable staff member in services that have radioimmunoassay capabilities.

Education

The radiochemist or radiopharmacist should possess a university degree in chemistry or pharmacy. He/she should have completed specialized course work and practical training in handling radioactive material. He/she should also possess good knowledge of dosimetry, radiation biology, and radiation protection.

5.3.4.4 Nuclear Medicine Technologist

The role of the nuclear medicine technologist is to execute, under proper medical supervision, the preparation, administration, and measurement of radiopharmaceuticals; to perform basic maintenance of the equipment, and to help to ensure radiation protection.

Under the supervision of the medical physicist, he/she carries out dosimetric calculations and ***quality control*** tests.

Education

The nuclear medicine technologist should be a secondary school graduate with subsequent training in radiological physics and nuclear medicine. He/she should have basic knowledge of anatomy, physiology, pathology, radiation biology, radiation protection (in particular ***contamination***), statistical data analysis, and computation. Appendix III-E shows an example of a proposed curriculum for this specialty.

5.3.4.5 Nursing Personnel

The nursing personnel who work in nuclear medicine services assist physicians in the care of patients during the various stages of procedures, especially regarding inpatient care. Their contribution is especially important in the case of patients treated with radioactive materials.

Education

The nursing personnel should have good basic knowledge of radiation protection and be trained in operational aspects relating to the utilization of ***unsealed*** radiation ***sources***.

5.3.5 Maintenance

Equipment maintenance is essential to the proper function of imaging, radiation therapy, and nuclear medicine services. Correct and safe operation of the equipment is indispensable in order to ensure that the value of medical procedures using radiation ***sources*** is not undermined by errors in the procedures or uncontrolled radiological ***risks*** that can harm patients or service personnel. The greatest damage can occur when errors or flaws are not detected in time, in which case the information yielded by a diagnostic

procedure may be useless or, worse still, erroneous. The situation can be even more serious if, due to equipment failures or defects, ***doses*** different from those planned are administered to patients.

In view of these considerations, maintenance should be not only corrective but principally preventive and should be linked to ***quality control*** programs.

5.3.5.1 Maintenance Staff

The maintenance staff is responsible for keeping the equipment of the service in good working order, performing preventive maintenance and, when required, corrective maintenance. Maintenance personnel should work in collaboration with medical physicists in order to ensure that the necessary calibration or testing is performed after equipment has been worked on by the maintenance staff.

Education

Technical and professional (engineers) maintenance personnel should have completed a technical course of study or a university program in electromechanics and electricity or electronics. They should also have completed specialization courses and practical training in maintenance of the equipment for which they will be responsible. Preferably, they should be certified or accredited by the manufacturer of the equipment. They should know the basic concepts of radiological physics and radiation protection and should have a thorough understanding of the equipment's function with regard to the health of patients. With the advent of modern computerized equipment, it has become essential for maintenance personnel to also be well versed in computer technology.

6. Equipment Purchasing for Imaging and Radiation Therapy: Specifications, Acceptance Testing, and Maintenance

6.1 Overview

The acquisition of equipment for an imaging or radiation therapy service is fundamental for achieving the objectives of ***local health systems***. The degree of success achieved in the procurement process will significantly influence the quality of the procedures as well as the costs, and a professional approach must therefore be taken to purchasing. It is important to point out that the purchase of this type of equipment consumes a major share of the budget of a medical institution. The procurement process is part of an overall plan that comprises the following stages:

- Analysis of equipment needs, clearly defining the intended use of the system.
- Equipment specifications, outlining the general requirements and detailing specific functional parameters and image quality factors in the case of imaging and nuclear medicine equipment.
- Vendor bid analysis, with emphasis on meeting the specifications.
- Finalization of the contract, which should include all relevant terms and conditions.
- Equipment installation, followed by acceptance testing and on-site training.
- Implementation of a program of preventive maintenance to detect and correct any equipment malfunctions.

- Establishment of a ***quality control*** program to assure constancy of performance and to detect and correct any tendencies toward system malfunction.

6.2 Analysis of Equipment Needs

The equipment requirements for each ***local health system*** were discussed in Chapter 4. Once a ***local health system*** has decided on the type of equipment to be purchased, it must carefully select the particular model and brand, since this is an area of rapid progress in which technology becomes obsolete very quickly. The model should be selected according to the following criteria: effectiveness, safety, infrastructure, maintenance, and cost.

To determine effectiveness, it is necessary first to compare the technical specifications of various types of equipment and analyze their impact on the clinical application for which the equipment is being selected. Next, it is necessary to assess what kind of ancillary equipment is required for the main equipment to be effective. For example, if a high-energy radiotherapy machine is to be purchased, it is essential to also have a dosimetry system to calibrate the beam. In addition, there must be provisions for making beam modifiers, such as blocks, bolus, and compensators, as well as some kind of treatment planning unit.

Safety implies knowledge of mechanical, electrical, and radiological ***risks***. It is necessary to know what radiation levels are emitted by the equipment (if any) and to design the necessary protection (for example, structural ***shielding***) in accordance with the radiation protection laws of the country.

With regard to infrastructure considerations, it is necessary to determine what type of specialized personnel will be required to operate a particular model. For example, the expertise of software technicians may be needed for trouble-shooting and maintenance in the case of computerized linear ***accelerators*** but not in that of manually controlled ***accelerators***.

Among the factors to consider in estimating costs are the following: the initial purchase of the main and ancillary equipment; its installation, including ***shielding*** and ***contamination*** prevention; the maintenance program, including spare parts; accessories (films, screens, dosimeters, supplies in general); the cost of operator training and continuing education; and the cost of final disposal of equipment if it contains radioactive ***sources***.

6.3 Purchase Specifications

Written system specifications should start with an objective statement summarizing the clinical procedures to be performed and outlining any specific needs beyond the normal clinical procedures. In addition, an estimate of the number of procedures per day should be given; the expected location of the equipment, with the room dimensions, should be specified; and any particular site problems should be noted (*33*).

The specifications should not indicate any particular product or be vendor-specific. This will make it possible for vendors to propose products that the end user may not be familiar with.

As part of the required specifications, it should be stipulated that any equipment that is imported must comply with the sale and/or certification regulations of the country of origin as well as with any other national norms, if there are any. In the case of non-imported equipment, it must be decided which international standards are to be followed (e.g., those of the International Electrotechnical Commission, the International Standards Organization, etc.) *(26)*.

In order to ensure smooth post-installation transfer of equipment from vendor to purchaser, it is advisable, early in the process, to clearly define the standards for equipment acceptance. Hence, purchase specifications should identify the equipment features that are to be tested as part of the acceptance testing process.

In some institutions and medical centers, a third party is recruited to handle equipment acquisition in order to free the hospital staff from the tedious and time-consuming task of writing specifications and carrying out the required follow-up. Third-party consultants may also have more experience and information than hospital personnel because they have been involved in a larger number of similar equipment purchasing transactions. Nevertheless, third-party involvement may distance the future user from the vendor, increasing the likelihood that the equipment received will not meet the user's needs.

In preparing the final contract, care should be taken to ensure that it contains no unreasonable, impractical, or unfair terms or provisions. If accepted by the vendor, such terms may increase the cost indicated in the original bidding process and complicate the future relationship between vendor and purchaser.

In addition to equipment specifications, site planning issues such as equipment location, room size, construction plans, and ***shielding*** requirements should be considered early in the process. This will minimize the possibility of future construction problems, such as lack of sufficient space when equipment and accessories are installed, an inadequate or noisy power source for the equipment, or insufficient air conditioning to protect computer systems and other delicate parts.

One common way of purchasing radiological equipment is to establish generic bid specifications in order to take advantage of the competition generated through the process. The bid structure and style will vary from one medical institution to another. There are, however, similarities in certain elements of the bid format—for example, descriptions of the type of equipment desired and key performance requirements. In the case of diagnostic radiology equipment these similarities might include:

- General requirements, clearly identifying the desired equipment (general radiography, trauma, computed tomography, radiography/fluoroscopy, dental, etc.) and the department acquiring it (radiology, emergency, surgery, oncology, etc.).

- Major equipment components, including the main system configuration (***source*** assembly, table system, ***generator***, console, etc.). For example, components of radiographic equipment intended for trauma work in an emergency department would include the following: a WHO radiographic unit (WHIS-RAD) or alternatively a ceiling-suspended ***x-ray*** tube and collimator, ***x-ray generator*** and console, patient table and wall bucky assembly, and other options, such as linear tomography.

- Equipment functional requirements, which should cover the desired system capabilities, including possible projections (views) and image acquisition parameters. For example, functional requirements for general radiography equipment might include the following possible patient positions, views, and parameters:
  - Standing patient, view from shoulders to knee joints with a horizontal ***x-ray*** beam
  - Sitting patient with a horizontal ***x-ray*** beam (dorsal spine, cervical pine, paranasal sinuses)
  - Sitting patient with a vertical ***x-ray*** beam (arm, elbow, wrist)
  - Recumbent patient with horizontal, vertical, or angled ***x-ray*** beam

In the past, the above-mentioned examinations were performed using either a vertical cassette holder or a bucky table. However, with the WHIS-RAD, the design was optimized by combining a single examination stand with a simple examination table to make it possible to perform all the required examinations.

A further example of functional requirements for a combination radiographic/fluoroscopic unit, might include the following:

- Performing general radiography, fluoroscopy, and spot filming
- Auto-***exposure*** control on spot filming, bucky table and bucky radiography modes
- Capacity to obtain cross-table radiographs without patient movement
- Capacity to produce TV fluoro between spot film rapid sequence exposures

- Specific equipment requirements, including a detailed description of the specifications for system hardware components. An example from a bid for an ***x-ray CT*** system would include:
  - Required minimum ***gantry*** aperture size
  - ***Gantry*** tilt angle
  - External or internal beam alignment lights
  - Tube housing anode heat capacity/maximum cooling rates
  - Table capability to accommodate heavy patients

- Computer capabilities should be clearly specified when a computer is to be part of the imaging system, as with CT, digital imaging, and MRI. The requirements may vary depending on the imaging modality under consideration. However, for all modalities image acquisition parameters must be defined, including the number of images per unit time, matrix size, reconstruction time, and ***pixel*** depth. Short- and long-term-storage memory devices and their storage limits will have to be specified taking into consideration the storage capacity needed per image and the institutional policy on long-term storage of medical images.

- Expected system performance and, for imaging equipment, the desired image quality should be specified in quantitative terms, whenever possible. In fluoroscopy, for example, the required contrast and spatial resolutions obtained from the imaging chain should be defined. Patient radiation ***dose*** under various operating conditions should also be documented.

- Other requirements:

  In addition to the technical requirements, other operational, training, and maintenance requirements must be met. The vendor, for instance, should provide copies of the operation and service manuals in a language acceptable to the user (*26*). Arrangements should also be made for the provision of adequate applications training. For some staff, specialized training at a designated training site might be needed.

As an illustration of the type of specifications that might be developed for the purchase of equipment, Appendix IV presents bid specifications for a ***CT scanner*** taken from the American Association of Physicists in Medicine (AAPM) Report 39: *Specification and Acceptance Testing of Computed Tomography Scanners* (*34*).

6.4 Bid Analysis and Vendor Selection

The decision to award a contract to a particular vendor is a critical aspect of the purchasing process. This decision should be based not just on the amount of the bid but also on the company's reliability as demonstrated through all the documentation it has submitted in the bidding process.

The degree to which the specifications are met, the guarantees that a vendor offers, and its ability to provide maintenance service for the equipment and training of personnel, as well as to assure the availability of spare parts during the entire useful life of the equipment, are also very important factors to take into account.

6.5 Service and Warranty

The supplier should assume the responsibility for delivery and installation of the equipment and for training of personnel prior its use. Competing vendors should be asked to submit, as a supplement to their bids, a service statement describing their maintenance and service response policy. The statement should indicate the firm's minimum and maximum response time for emergency and routine calls; the availability of service on weekends, after hours, and on holidays; and the availability of critical parts that would take more than one day to receive. The vendor should guarantee that parts will be available for a period of at least seven years after the equipment is purchased. It is important to have

a clear idea of the initial investment costs and the operating costs over the life of the equipment, as well as its period of obsolescence.

All system components should be covered under a comprehensive one-year warranty. The vendor should specify the warranty period for any components not covered for one year.

The final contract with the selected vendor should include a service agreement of at least two years' duration, which should enter into force upon expiration of the warranty period. The cost of any services rendered under the agreement should not change during the two-year period.

6.6 Acceptance Testing

Acceptance testing is a crucial part of the purchasing process. Through these tests it is possible to verify that the equipment complies with the specifications provided by the vendor in the bid and it should also be possible to detect any non-compliance or defect.

Final payment for the equipment should not be made until acceptance testing is complete.

Acceptance testing entails verification of the following parameters:

- Manufacturer's technical specifications
- Performance standards of the country of origin, national standards or adherence to international standards, as appropriate
- For equipment emitting ***ionizing radiation***: radiation ***doses*** and compliance with the country's radiation protection laws and regulations

Should the facility not have the required instrumentation and/or personnel to perform the tests, there should be a clause in the sales contract under which the vendor is required to lend the required equipment and/or personnel. For instance, acceptance testing of a cobalt unit requires verification of the symmetry of the radiation beam. Should the facility not have a radiation beam scanner, the installer should be able perform the test with his own equipment. The information acquired during acceptance testing should be used as a baseline for future ***quality control*** testing, for which the owner of the radiologic equipment must have the necessary testing instrumentation.

The design of acceptance testing protocols should incorporate methods and means for testing all parameters selected. To minimize subjective evaluation of equipment performance, it is important to use ***phantoms*** and test tools which can provide quantitative and reproducible data. The additional use of anatomical ***phantoms*** will bring the system setup closer to clinical requirements.

Installation of newly acquired systems should be considered provisional until acceptance testing has been completed. As mentioned earlier, it is advisable to have a written statement in the sales contract detailing the nature and specifications of acceptance testing. If such a statement is not included, it should be decided in advance whether the acceptance testing will be performed according to the manufacturer's procedures or the user's ordinary testing methods. In any case, the testing should include non-invasive measurements of the output of the system.

In the case of diagnostic equipment, measurements should be made of image quality and patient ***dose***. In the case of radiotherapy equipment, the measurements should include radiation beam characteristics such as field flatness and symmetry, and ***penetration quality***, as well as accurate ***absorbed dose*** determinations. All types of machines need to be tested for mechanical integrity and safety, mechanical alignment, and proper collimation.

The number and nature of the problems found through acceptance testing time will vary depending on the complexity of the system. Radiologic equipment, such as angiography units used in special procedures, linear ***accelerators*** and ***SPECT*** systems, generally have the highest number of major problems.

Appendices V and VI give suggested testing parameters and tolerances—which may be used if none are specified by the manufacturer—for all types of diagnostic and radiotherapy equipment.

6.7 Preventive Maintenance

The preventive maintenance program consists of periodic procedures and interventions performed on equipment to reduce the possibilities of a malfunction and ensure its continuous, safe, and economical operation.

Preventive maintenance also ensures that the equipment operates according to the manufacturer's technical specifications and in compliance with safety standards. The functional parameters of the equipment should be checked initially during the acceptance testing performed before the machine is put into service and subsequently following any repairs or modifications (*35, 36*).

The frequency with which maintenance is performed will be determined by the manufacturer's recommendations, the workload and how often the equipment is used, the physical and environmental conditions in which it is operated, and the turnover of the personnel who operate it.

Depending on the technical capabilities of the maintenance personnel and the availability of instruments, calibration equipment, and technical information, as well as the technological complexity and amount of equipment, maintenance may be carried out by:

- Staff of the institution;
- External maintenance personnel contracted through the manufacturer, distributor, or a maintenance firm;
- Both internal and external personnel (a combination of the first two modalities).

Regardless of who carries out maintenance activities, a logbook should be kept in which all maintenance procedures and their costs are recorded. In addition, within the institution there should be personnel capable of exercising technical supervision of maintenance services provided by both internal and external personnel.

The person or persons responsible for operating the equipment are also responsible for its upkeep and should promptly report any malfunctions in order to avoid major damage.

6.8 Coordination of Preventive Maintenance and *Quality Control* Programs

Preventive maintenance and ***quality control*** involve concepts and activities that are different but complementary. The quality of diagnostic and therapeutic procedures cannot be adequate if the equipment used is not functioning properly due to lack of maintenance (*37*). Both programs are essential to the

continuous improvement of quality, and they are also key factors in the process of health establishment accreditation (*38*).

7. *Quality Assurance (QA)* and *Quality Control (QC)*

7.1 Definitions

Quality assurance (QA) is a management tool which, through the development of policies and the establishment of review procedures, aims to ensure that every exam or treatment in a radiology department is necessary and appropriate to the medical problem and that it is performed:

- According to previously accepted clinical protocols
- By adequately trained personnel
- With properly selected and functioning equipment
- To the satisfaction of patients and referring physicians
- In safe conditions
- At minimum cost

Thus, a ***QA*** program should include periodic reviews of referral patterns, clinical protocols, continuing education opportunities for staff, facility inspections, equipment testing, and administrative procedures related to the purchase of supplies and billing. The ultimate goal of ***QA*** is to improve patient care. The ***QA*** procedures to be implemented and the frequency of the reviews may be dictated by a national authority or recommended by a professional organization. In our Region mandatory ***QA*** programs for mammography have been instituted in Argentina (see Appendix II-A) and the United States (see Appendix II-B) and for radiation therapy in Argentina and Cuba.

Clinical protocols need to be developed for each ***local health system*** by imaging physicians or radiation oncologists (depending on the type of protocol) with the consensus of referring physicians and medical specialists. It is suggested that the standards developed by the American College of Radiology (ACR) (*38*) be consulted and adapted to local circumstances whenever there are

no national standards. The ACR standards available in 1997 are listed in Appendix VII. Administrative procedures regarding patient management are dealt with extensively in other PAHO/WHO publications, including *Quality Assessment: Hospital Accreditation for Latin America and the Caribbean* (*39*), and they will therefore not be repeated here. Continuing education requirements for professional and technical staff were addressed in Chapter 5 and radiation safety issues are discussed in Chapter 8; this chapter will deal mainly with the specific tests required to ensure effective and safe equipment performance. These tests are usually referred to as ***quality control (QC)***.

7.2 Responsibilities

Regardless whether the ***QA*** and ***QC*** procedures are mandatory or are recommended by a professional body, responsibility for their implementation in any radiology department lies with the management of the medical facility. Depending on the complexity of the department, the task may be assigned to one or several persons, but at least one individual should be made responsible and accountable for its success or failure.

For teletherapy, brachytherapy, and ***radionuclide*** therapy uses of radiation, the calibration, dosimetry, and ***quality assurance*** requirements must be conducted by or under the supervision of a ***qualified expert*** in radiotherapy physics. For diagnostic uses of radiation, the imaging and ***quality assurance*** requirements should be fulfilled with the guidance of a ***qualified expert*** in the physics of diagnostic radiology, nuclear medicine, ultrasound, or magnetic resonance, as appropriate (*26*).

The role of medical physicists is mainly a supervisory one; routine testing, in which the goal is to check reproducibility, should be performed by adequately trained technicians using simple equipment. In very small imaging departments having one or two ***x-ray*** machines, the tests can be done by the ***x-ray*** operator.

7.3 Implementation of QC Programs

QC programs must be initiated at the time of acceptance testing. The main difference between acceptance tests and ***QC*** tests is that the former are intended to verify the manufacturer's specifications, using the methodology and the instrumentation indicated by the manufacturer, while ***QC*** tests check the

performance of the equipment under routine clinical conditions. For example, a ***CT scanner*** manufacturer may state the spatial resolution of the unit in terms of the modulation transfer function (MTF), specifying a particular ***phantom*** and a computer program, and the manufacturer will demonstrate compliance during acceptance testing by bringing the ***phantom*** and the software to the facility. At this time the user should scan his own ***phantom*** under clinical conditions and establish baseline values for future reference. ***QC*** programs also need to be coordinated with maintenance programs. The maintenance department should contact the person responsible for ***QC*** after performing any service on the equipment that may affect its imaging and/or radiation characteristics. Service records should always be consulted before initiating any test in order to properly assess the extent and impact of possible changes.

7.3.1 *QC* Equipment Requirements

QC programs require not only trained individuals to check technical parameters, but also equipment for performing the tests. Equipment needs range from simple tools, such as measuring tapes and rulers to measure the accuracy of scales, to three-dimensional scanners to measure isodose distributions in high-energy beams. The equipment required may be classified in four categories:

- Equipment to check the electromechanical performance of the unit, for example, ***gantry*** isocentricity
- Equipment to verify the accuracy of the radiation control settings, for example, a kVp meter to measure the ***x-ray*** tube potential
- ***Ionization chambers*** and ***electrometers*** to measure ***absorbed dose*** or ***activity***
- Spatial resolution ***phantoms*** to measure image quality

Some instruments in use today may be associated with software programs, which are run on the diagnostic or treatment machine itself or independently on a PC; an example would be software designed to determine MTF, an objective measure of spatial resolution.

Appendices V and VI list the equipment required for ***QC*** programs in diagnostic imaging and radiation therapy, respectively. Appendix V is taken from the United States National Council on Radiation Protection and

Measurements (NCRP) Report 99: *Quality Assurance for Diagnostic Imaging* (*40*). Appendix VI is taken from *Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group* (*41*).

7.3.2 General Features of QC Protocols

QC protocols should address facilities, equipment, and procedures. The first area in which to institute a ***QC*** program in imaging departments is the darkroom, since any type of radiology department will use film for image recording. For film processors, whether manual or automatic, it is essential to maintain a daily log of developer and water temperatures, replenishment rate, waterflow, and cleaning and maintenance procedures. The screens require regular inspection and cleaning and periodic testing for screen-film contact.

A very effective method for testing the quality of the films produced is to implement a film reject analysis program, in which the reasons for discarding films are periodically explained. Consistently overexposed films coming from the same unit may point to an improperly calibrated ***generator***. Improper patient positioning or anatomical misses in films taken by the same technologist may indicate deficiencies in his/her training. In such cases, corrective actions can be easily implemented and can lead to significant reductions in repeat rates, with the consequential economic savings (*5*). More sophisticated film analysis involves periodic measurement with a densitometer of optical densities in typical radiographs.

In radiation therapy departments, the most important ***QC*** test is the redundant and independent confirmation of the ***source*** calibration on a periodic basis (*26*).

In regard to imaging and/or therapy equipment, before performance parameters are tested and radiation characteristics are measured, the units should be checked for mechanical integrity, mechanical stability, electrical integrity, and electrical safety, in accordance with manufacturer's specifications and national and/or local safety codes. Regrettably, fatal ***accidents*** have occurred as a result of equipment parts falling on patients, which could have been avoided had the necessary safety checks been performed (*42*). The initial testing should verify the accuracy of readouts (scales, meters, and digital displays) and the proper functioning of collision detection devices, emergency shut-off switches, and interlocks. Mechanical and optical tests should verify ***gantry*** motions, including those of all moving parts, such as the collimator and detachable accessory trays, as well as motions of the patient support assembly. In the case of radiation-emitting machines, the next step is to verify the

alignment and limitation of the radiation beam, checking the congruence with optical indicators if available. For this type of unit, measurement of radiation characteristics involves the verification of ***generator*** settings, including tube potential, tube current, and irradiation time. Beam quality determinations involve the measurement of ***half-value layers*** for low- and medium-energy ***x-ray*** machines and beam ***penetration ratios*** at two different depths for high-energy machines (*43*). ***Absorbed dose*** determinations require the ***dose*** to be measured with calibrated dosimeters in air (diagnostic radiology) or in appropriate ***phantoms*** (radiation therapy) for each beam quality at the distances, field sizes, and depths in clinical use. Protocols for external radiotherapy measurements were published by the IAEA in *Absorbed Dose Determination in **Photon** and **Electron** Beams—An International Code of Practice* (*43*). For brachytherapy there is a code of practice published by the AAPM in 1997 (*44*).

Rather than developing their own methodologies, institutions within each ***local health system*** should adopt these recommendations, thus ensuring the uniformity of measurements. The dosimeters with which the measurements are to be made need to be calibrated periodically. This calibration should be done at a standards dosimetry laboratory (SDL) or at an accredited dosimetry calibration laboratory (ADCL). There are 73 IAEA/WHO secondary standards dosimetry laboratories (SSDL) in 56 countries, 43 of them in the developing world. In the Region of the Americas, such laboratories are located in Argentina, Bolivia, Brazil, Colombia, Chile, Cuba, Guatemala, Mexico, Peru, and Venezuela. *In vivo* dosimetry of patients is accomplished using thermoluminescent dosimeters, the accuracy of which should also be tested periodically. Devices containing ***sealed*** radioactive ***sources***—such as lexiscopes with iodine-125 used for imaging, cobalt-60 units used for teletherapy, and high-***dose***-rate remote afterloaders with iridium-192 used for brachytherapy—require special testing to detect possible radioactive ***contamination*** and radiation leakage with the ***source*** in the "on" and "off" positions.

Quality control should include the testing of all peripherals, including computer software, especially in the case of computer-controlled devices.

7.3.3 Specific *QC* Protocols in Imaging

The goal of a *QC* program in imaging is to ensure the accuracy of the diagnosis or the intervention. When the imaging method uses ***ionizing radiation***, this goal is to be accomplished using the minimum radiation ***dose***

required to achieve the objective of the diagnostic or interventional procedure. The most important parameter to be measured in imaging is image quality. The whole imaging chain needs to be tested, starting with the ***x-ray*** tube—in case of radiology—or with the preparation of the ***radionuclide*** (*45*)—in case of nuclear medicine—to the hard copy device (*40*). Often institutions with sophisticated equipment such as cinefluorographic units used in cardiac catheterization and angioplasty develop the cine film in outdated processors with chemicals that are infrequently changed and developing processes that are rarely monitored. The same applies to the projector, the viewing conditions of which should be periodically tested. The radiographic procedure in which image quality assessment on a periodic basis is absolutely essential is mammography (*46*).

Image quality is a subjective concept that imaging physicists have "quantitized" in terms of several parameters, namely: spatial resolution, which measures the ability of a system to discriminate high-contrast patterns; noise, which is affected by the granularity of the receptor, the quantum fluctuations of the radiation, and statistical sampling, if the image is digitally created; and contrast, which reflects the different responses of objects to the imaging process. These parameters may be quantitatively determined through the measurement of MTFs, Wiener spectra, and contrast-detail diagrams (*47, 48*). They require special ***phantoms*** and software programs.

Spatial resolution, noise, and contrast may be qualitatively assessed by the use of suitable ***phantoms*** that either mimic the tissue to be imaged or contain periodic patterns of different contrasts and/or spatial frequencies. Examples of the first type are ultrasound ***QC phantoms*** that test the Doppler effect by using flow rigs in a gel that mimics the acoustic properties of tissue (*49*). Examples of the second type are lead bar patterns ranging from 1 to 10 pair lines/mm, which are used to test the resolution of screen/film systems or blood vessel patterns in an acrylic ***phantom*** filled with iodinated epoxy of different concentrations, which are used to test DSA systems (*50*).

A trained observer may reproduce his/her assessment of an imaging system by analyzing the image of a particular ***phantom*** and discerning all clearly visible ("resolved") patterns. In order to ensure more objectivity, several observers may be required to evaluate the resulting image. The results are graphed as curves referred to as receptor-operator-characteristics (ROC) (*47, 48*).

Because image quality is affected by the imaging device and the image receptor, both have to be tested. In radiography the ***x-ray*** tube parameters to be tested are: beam quality (tube potential and filtration), focal spot size,

source-image receptor distance, and tube current and time. The reproducibility of the factors selected for each radiographic projection need to be periodically verified to minimize exam repetitions due to ***generator*** or ***x-ray*** tube inconsistencies. This is particularly important when the system uses automatic ***exposure*** controls. The tests to be performed on the image receptors used in radiography involve the determination of the screen/film characteristics: fog, contrast, latitude, and speed. The variation of these factors *vis-à-vis* radiation ***exposure*** is called the Hunter and Driffith (H&D) curve, and needs to be drawn for each type of screen/film combination during acceptance testing procedures. On a daily basis it may be sufficient to measure the optical density of the film at one ***exposure*** level. In fluoroscopic systems the characteristics of the imaging chain—input phosphor, image intensifier, mirror, TV camera, output phosphor, and TV monitor—as well as analog-to-digital converters and other electronic recording devices, if available, need periodic testing. The automatic ***exposure*** control circuit also needs to be checked periodically to verify range and saturation. ***Absorbed dose*** rates at the input phosphor level (*51*) and at the patient entrance surface, together with the corresponding spatial resolution values, need to be assessed under all clinical conditions. Other imaging parameters to be tested in fluoroscopic systems are image distortion, lag, flare, and the relative conversion factors of image intensifiers. Contrast resolution and linearity (*50*), vignetting, and logarithmic processing fidelity need periodic testing in DSA systems.

Digital systems such as ***CT*** (*34*) and MRI (*52*) require careful validations of field uniformity and noise. Spatial uniformity is also a stringent requirement in ***gamma cameras*** (*53, 54*). The complete list of parameters to be tested for all systems, including ultrasound, MRI and nuclear medicine, is given in Appendix V (*40*).

7.3.4 Specific *QC* Protocols in Radiation Therapy

The goal of a ***QC*** program in radiation therapy is to ensure accurate delivery of the prescribed ***dose*** to the tumor in the patient and to minimize the ***dose*** to other tissues.

For all external beam patients, a prescription, dated and signed by the radiation oncologist, must be obtained prior to treatment. It should contain the following information: total dose, dose per fraction, treatment site, fractionation and overall treatment period. In addition, the maximum doses to critical organs in the irradiated volume should be stated. Specification of

various volumes, e.g., ***treatment planning volume***, tumor volume, etc., should follow the recommendations of ICRU Report No. 50 (*55*).

For all brachytherapy patients, a prescription, dated and signed by the radiation oncologist, must also obtained, prior to treatment. It should contain the following information: total ***dose*** to a reference point, the number of ***sources*** and their distribution, the ***radioisotope***, and ***source*** strength or ***activity*** at a reference date. Specification of the treatment volume and ***dose*** specification points should follow the recommendations of ICRU Report No. 38 (*56*).

Patients treated with radiopharmaceuticals require a prescription on the total ***activity*** to be administered; the ***activity*** being determined and recorded at the time of administration (*26*).

The ***QC*** tests required for the imaging equipment involved in tumor localization are slightly different from the ones listed in the preceding section. In general, reduction of radiation ***dose*** is not critical, whereas accuracy of display scales and quantitative information is. For example, distortion of an MRI brain image due to magnetic field inhomogeneities is not significant if the information is used to diagnose a brain tumor, but it becomes crucial if it is to be used in setting radiation treatment fields (*52*). Furthermore, it is essential that patient positioning be identical during tumor localization, simulation, and treatment. To achieve this special requirement, it is important to have imaging protocols specifically tailored to radiotherapy treatments. These protocols may require the construction of special accessories.

In teletherapy, after the tumor is localized, the treatment needs to be simulated using either the same treatment machine or special imaging devices called simulators (*57*). When economically feasible, the latter option is definitely recommended, as the image quality obtained with high-energy beams is very poor, and the time available in any treatment machine is very valuable. ***QC*** testing protocols for simulators are listed in Appendix VI (*41*).

Once the volume to be treated is identified and the treatment planned, the ***QC*** program needs to ensure accurate ***dose*** delivery. It has been estimated that this accuracy must be between +7% and -5% of the prescribed ***dose*** (*43, 44*).

All the parameters to be tested in teletherapy and brachytherapy, the respective tolerances, and the testing frequency are listed in Appendix VI (*41*). It is important to note that some parameters should be tested both by technicians and by physicists. For example, a technician may check the percentage depth ***dose*** of a radiation beam daily for one particular depth and field, while the physicist will do so quarterly for all fields and depths. The

daily check of ***absorbed dose*** in linear ***accelerators*** is crucial. Had it been done in the "Hospital Clínico de Zaragoza," Spain, in December 1991 (*58*), the change in beam energy that occurred would have been immediately detected and the overexposure of 27 patients prevented. The AAPM has recently published a specific ***QC*** protocol for linear ***accelerators*** (*59*).

To restrict the prescribed ***dose*** to the ***treatment planning volume*** it is necessary to develop a treatment plan. Treatment optimization may be done manually or using a computer. In the latter case, the associated hardware and software should also be tested periodically. A suggested ***QC*** protocol is shown in Appendix VI (*41*). Execution of the treatment plan may require the construction of accessories, such as patient immobilizers, and beam modifiers, such as bolus, blocks, wedges, and compensators. Testing their adequacy is part of the overall ***QC*** program.

7.4 *QC* Program Monitoring

In order to monitor the success of any program it is necessary to develop indicators. For the ***QC*** program, the indicators may be related to the efficacy of the exam or treatment, to safety, or to economics. Examples of the indicators of efficacy are local control of the tumor or absence of side effects in radiotherapy patients; examples of the second type include decreases in radiation levels for patients and staff; examples of the third type of indicator would be reductions in requirements for spare parts, such as ***x-ray*** tube inserts, and supplies, such as films and screens. For the program to be effective, the costs incurred in its development and implementation need to be offset by the benefits it will produce. Sometimes these benefits may be difficult to measure—for example it may be difficult to assess whether improvements in diagnostic accuracy are due to improvements in image quality. In making such determinations, the facility must rely on internationally acknowledged criteria (*60, 61, 62*).

7.5 PAHO/WHO Commitment to *QA* in Radiology

With a view to improving diagnostic imaging as a means of ensuring more accurate diagnoses and better-informed decisions concerning treatment, the Institute of Radiation Hygiene of the Federal Health Office and the Society for Radiation and Environmental Research of the then Federal Republic of

Germany, in collaboration with WHO, organized a workshop on ***quality assurance***, which was held in Neuherberg, Germany, in October 1980 (*63*). The organizers, who believed that it was time for a concerted international effort towards a systematic approach to ***QA***, and specialists from various countries and different backgrounds (diagnostic radiology, medical physics, and public health administration) were brought together to exchange views and provide solid recommendations for routine application in diagnostic radiology departments. The implementation of national ***quality assurance*** programs was recognized as necessary in order to achieve three main objectives: the improvement of medical diagnostic imaging, cost containment, and reduction of radiation ***exposure***.

The participants at this meeting identified four specific areas in which the efforts of international organizations such as PAHO and WHO would be effective: collection and publication of comparative information, development of recommendations for quality protocols, training, and the establishment of internationally accepted guidelines and criteria for image quality.

Similar guidance concerning ***quality assurance*** in nuclear medicine was published in 1982 following a workshop held in Heidelberg, Germany, which was organized by the Institute of Radiation Hygiene of the Federal Health Office, the Society for Radiation and Environmental Research, the Institute of Nuclear Medicine of the German Cancer Research Center of Heidelberg, and WHO (*64*).

In the area of radiation therapy, a guide, *Quality Assurance in Radiotherapy*, was published by WHO following a workshop held in Germany in December 1984, organized jointly by WHO and the Institute of Radiation Hygiene, Federal Health Office, Heidelberg, then Federal Republic of Germany (*65*). PAHO organized the First International Symposium on Quality Assessment in Radiation Oncology in Washington, D.C., in June 1983, jointly sponsored by the three United States agencies: the Center for Devices and Radiological Health of the Food and Drug Administration (FDA), the National Cancer Institute, and the ACR, and by PAHO. The proceedings are contained in the publication *Quality Assurance in Radiation Therapy: Clinical and Physical Aspects* (*66*).

8. Basic Principles and Practical Aspects of Radiation Protection

8.1 Overview

Ionizing radiation poses a physical ***risk*** to people, who may be exposed by natural and artificial means. The interaction of radiation with matter produces ***ionization*** phenomena capable of modifying the chemical behavior of molecules. If this occurs in live cells, biological effects of varying degrees of severity can result.

People who work with ***sources*** of ***ionizing radiation***, some ***members of the public***, and patients who undergo radiological procedures are exposed to the ***risks*** of ***ionizing radiation***. It is not possible to totally eliminate these ***risks***, but it is feasible to control them and keep them within acceptable ***limits*** through application of the principles of radiation protection.

Radiology services should be designed and operated on the basis of these principles in order to adequately protect ***workers***, patients, and the general public. In order to achieve systematic application of the principles, it is necessary for the countries to adopt radiation protection standards and establish a regulatory agency to enforce them. It is also important to ensure adequate training of the human resources involved in radiology services (see Appendix III).

8.2 Characteristics and Interactions of *Ionizing Radiation*

Forms of ***ionizing radiation*** include ***x rays***, ***radiation*** produced by radioactive substances and nuclear reactions, radiation generated in particle ***accelerators***, and radiation of cosmic origin (***cosmic rays***). The various types of ***ionizing radiation*** differ in mass, electric charge, and the energy of their

particles. These properties determine how radiation will behave when it interacts with matter.

Radiation composed of electrically charged particles, such as ***alpha*** and ***beta particles***, are capable of directly ionizing the atoms of a material with which they interact. This type of radiation is called "direct ***ionizing radiation***". ***Gamma rays*** and ***neutrons***, which are not electrically charged, emit charged particles when they interact with matter. It is these particles which ionize the atoms of the material. This type of radiation is called "indirect ***ionizing radiation.***"

When a radiation beam interacts with matter, it releases some of its energy in each ***ionization*** process, and the radiation thus diminishes in intensity along the beam's path. This phenomenon is exploited in the design of ***shielding*** materials.

8.3 Microscopic Distribution of Ions

The microdistribution of ions generated by ***ionizing radiation*** can be highly diverse and depends on the mean quantity of energy that its particles give off per unit of distance traveled (linear energy transfer, LET). Some particles, such as ***alpha particles*** and ***protons***, concentrate the ions that they generate in small volumes, whereas ***electrons*** scatter the ions in much greater volumes. The degree of ion concentration in the matter influences the biological effects that may be produced when biological material is irradiated.

8.4 Types of Radiation *Exposure*

People can be exposed to ***ionizing radiation*** produced by external ***sources*** such as ***x-ray*** machines or cobalt therapy units. This type of ***exposure*** is known as external irradiation.

A person's tissues may be also be exposed as a consequence of the intake of radioactive material into the body through inhalation, ingestion, or wounds. ***Radioisotopes*** are absorbed selectively by certain tissues according to the metabolism associated with the chemical characteristics of the molecules of which they are a part. This is known as internal irradiation or ***contamination***.

This distinction between types of ***exposure*** is important for determining which radiation protection techniques will be most appropriate in each case.

8.5 Quantities and Units Used in Radiation Protection

In radiation protection, appropriate quantities and units are defined to assess radiation ***exposure*** and correlate it with biological effects. The quantities and units most frequently utilized in radiation protection are defined in the glossary.

The fundamental dosimetric quantity is called the ***absorbed dose***, which is defined as the energy that an irradiated material absorbs per unit of mass. In ***practice***, for radiation protection purposes, in procedures involving the irradiation of people it is more useful to know the value of the organ or tissue ***dose***, which is the mean energy that the organ or tissue receives per mass unit. In the scientific literature, the letter D is used to denote ***absorbed dose***.

The unit of ***absorbed dose*** is the joule per kilogram ($J{\cdot}kg^{-1}$), termed the gray (Gy).

Because the ***absorbed dose*** is a strictly physical quantity, it is not always possible to establish an appropriate correlation between it and the biological effects of radiation. At the same ***dose*** level, different types of radiation can produce different effects, owing to the diverse ways in which the ions are distributed microscopically. In order to take account of this phenomenon, the ***absorbed dose*** is weighted by a factor that depends on the type of radiation (see Appendix VIII-A), which yields a value called the ***equivalent dose***. The unit of ***equivalent dose*** is also $J{\cdot}kg^{-1}$, but in this case it is termed the sievert (Sv). It is identified by the letter H. Different tissues and organs have differing degrees of radiosensitivity, or susceptibility to biological effects as a result of radiation, which can be taken into account by using a specific ***tissue weighting factor*** (see Appendix VIII-A). The quantity that results from the summation of the ***equivalent doses*** to all tissues and organs, each multiplied by the appropriate tissue weighting factor, is called the ***effective dose***. It is also expressed in sievert (Sv) and is represented by the letter E.

These units can have multiples and submultiples, such as kilo (10^3), mega (10^6), milli (10^{-3}), micro (10^{-6}), etc.

8.6 Natural and Artificial *Sources* of Radiation

People are exposed to ***ionizing radiation*** from both natural and artificial ***sources***. Natural ***exposure*** comes from radioactive substances existing in the earth's cortex and in radiation from cosmic space. Artificial ***exposure*** results from the use of radiation-emitting equipment and radioactive materials for medical, industrial, research, and energy-generation purposes.

Every inhabitant of the planet receives an average ***dose*** of 2.4 mSv per year. The most important ***source*** of natural ***exposure*** is ***Radon***-222 and its decay products. ***Radon*** is a gas found abundantly in nature, especially in construction materials. Potassium-40, an element found in the human body, also contributes to natural ***exposure***.

The most important ***source*** of artificial ***exposure*** is the use of radiation in the medical field. More than 80% of the artificial radiation ***dose*** to people comes from medical radiodiagnostic procedures (*5*).

Appendix VIII-B lists the annual average ***doses*** of radiation from various ***sources***.

The concept of radiation ***source*** includes radioactive substances and equipment that contains radioactive substances or produces radiation, including consumer products, ***sealed sources***, and ***unsealed sources***.

8.7 Biological Effects of *Ionizing Radiation*

The interaction of ***ionizing radiation*** with a biological medium can give rise to biological effects. The ***ionization*** of atoms modifies the chemical behavior of the molecules of which they are a part, inducing reactions that cause morphological or functional changes in cells.

The molecules of deoxyribonucleic acid (DNA) are the most vulnerable targets within cells. One significant effect of ***exposure*** to ***ionizing radiation*** can be the inability of the cell to reproduce. ***Ionizing radiation*** can also produce changes in the genetic information of the cell without affecting its reproductive capability.

The biological ***effects*** of radiation are classified as ***deterministic*** and ***stochastic***.

8.7.1 *Deterministic Effects*

Deterministic effects are produced when a sufficiently large quantity of cells die or lose their reproductive capability due to radiation. The severity of the effect increases as the ***dose*** received increases over a certain threshold level, which varies depending on the tissue or organ in question. (See Appendix VIII-C.)

The symptoms that are manifested when the entire body is exposed to acute radiation, that is, radiation of brief duration, constitute the acute radiation syndrome. If the whole body ***dose*** is on the order of 3.5 Gy, there is a 50% probability of death, which may occur 30-60 days after the time of irradiation.

8.7.2 *Stochastic Effects*

When ***ionizing radiation*** produces changes in the genetic information of the DNA molecules in cells without affecting their reproductive capability, ***exposure*** to radiation can induce cancer in the long term. This type of effect is ***stochastic***, which means that it can only be predicted statistically. There is no threshold ***dose***. The probability that such effects will occur is proportional to the ***dose*** received.

The ***risk*** of death from cancer is estimated at 5% per Sv for the public and 4% per Sv for those exposed occupationally (since the latter group does not include young people under 18 years of age) (*67*).

When irradiation occurs during gestation, the possibility of mental retardation is the most important effect. The ***risk*** is highest during the period between weeks 8 and 16 of pregnancy.

8.8 Radiation Protection Concepts

The International Commission on Radiation Protection (ICRP) issued its most recent basic recommendations on radiation protection in 1991, in ICRP Publication No. 60 (*67*). These recommendations led to the joint publication of the *International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (BSS)* by the Food and Agriculture Organization of the United Nations (FAO), the IAEA, the International Labor Organization (ILO), the Nuclear Energy Agency of the

Organization for Economic Cooperation and Development (NEA/OECD), PAHO and WHO (*26*). These documents establish the basic principles of radiation protection and provide practical guidance for their implementation. The main principles are summarized below.

Sources of radiation are utilized in various ***practices*** that result in the ***exposure*** of people. Depending on the group of people involved, radiation ***exposure*** is classified as ***occupational exposure***, in the case of ***workers***; ***public exposure***, in the case of ***exposures*** incurred by ***members of the public***, and ***medical exposure***, in the case of patients, support personnel who are not occupationally exposed, and volunteers in research programs.

The decision to accept the initiation of a ***practice*** involving ***sources*** of radiation makes it necessary to analyze the ***risks*** that the ***practice*** may entail, both during the execution of planned operations ***(normal exposures)*** and in the event of radiological ***accidents*** that might result in higher-than-expected ***doses (potential exposures)***.

Sometimes ***exposures*** occur and it is not possible to act on their causes, as in the case of ***accidents*** or natural radiation in certain circumstances. In such cases, whenever feasible, appropriate measures should be taken to prevent unacceptably high radiation ***doses***. Such situations are called situations that require ***intervention***.

The objective of radiation protection is to prevent ***sources*** of radiation from causing ***deterministic effects*** on people and to reduce the likelihood of ***stochastic effects*** as much as possible taking into account economic and social considerations. There are three basic principles that sum up the philosophy of radiation protection:

8.8.1 Justification

No ***practice*** involving ***ionizing radiation*** should be accepted unless there is evidence that it will produce, for individuals or society, benefits that outweigh the possible ***detriment*** it may cause. The application of this principle helps to prevent the utilization of radiation ***sources*** for nonessential purposes.

8.8.2 *Dose* Limitation

In order to reduce the magnitude of the ***risks*** associated with a justified ***practice***, ***limits*** on individual ***doses*** are established to prevent the occurrence of ***deterministic effects*** and minimize the likelihood of ***stochastic effects***. Monitoring of the application of these ***limits*** should take account of ***doses*** generated by external ***sources*** and those produced by the intake of ***radionuclides*** into the body. Appendix VIII-D lists the ***dose limits*** applicable to ***workers*** and to ***members of the public***.

8.8.3 Optimization of Protection

Dose limits do not constitute ***risk*** thresholds; they represent the maximum tolerable levels of ***risk***. In most applications of radiation ***sources***, it is feasible to adopt measures to ensure that the radiation ***doses*** people will receive are significantly lower than ***dose limits***. Optimization is the process in which an analysis is undertaken and decisions are made regarding the magnitude of resources that can reasonably be devoted to radiation protection in order to minimize radiation ***doses*** to the extent possible, taking into account economic and social factors.

8.8.4 *Potential Exposures*

Potential exposures are those that may result from possible radiological ***accidents***. It is not possible to rule out their occurrence from accidental events. In an ***accident*** situation, control over the ***source*** or people is lost, and radiation ***doses*** may be considerably larger than planned for the normal operation of a facility.

Past experience with ***accidents*** and knowledge of the characteristics of radiology facilities makes it possible to anticipate the various ***accidents*** that could occur and to design safety systems to prevent sequences of events that might lead to ***accident*** situations.

The criterion to be applied in this regard is the following: the more serious the potential consequences of an ***accident*** are (i.e., the higher the ***dose*** that it could entail), the lower the probability of its occurrence should be.

8.8.5 Situations Requiring *Intervention*

Typical situations that may require ***intervention*** include:

- Emergency ***exposure*** situations requiring protective action to reduce or avert temporary ***exposures***, such as radiological ***accidents***.

- Chronic ***exposure*** situations requiring remedial action to reduce or avert chronic ***exposure***, such as certain cases of natural ***exposure***.

The criteria for justification and optimization are also applicable to ***intervention*** actions. Justification in this case means that the ***intervention*** should be undertaken only if its benefits (avoidance of radiation ***doses***) are greater than the ***detriment*** it might cause. Optimization, in the case of ***interventions***, is the analysis carried out to decide on the most appropriate means of ***intervention*** (and that which will yield the greatest net benefit).

The ***dose limits*** foreseen for planned ***practices*** are not applicable in ***intervention*** situations. However, application of the concept of ***intervention levels*** provides a useful guide for rapidly deciding on the most appropriate course of action. These levels indicate the type of action needed in ***accident*** situations, depending on the severity and characteristics of the situation. The *BSS* establish guidelines for these ***levels*** (*26*).

8.8.6 Special Considerations Relating to *Medical Exposures*

The concepts discussed above are applicable to both ***occupational*** and ***public exposures***. In the case of ***medical exposures***, there are some special considerations in relation to the three aforementioned principles.

It is not possible to establish ***dose limits*** for the ***exposure*** of patients, since in each case the balance between ***risk*** and benefit will be different. In the final analysis it is the responsibility of the physician to determine whether or not a radiological procedure is justified, and it is the responsibility of the respective specialists (radiological technologists, medical physicists, etc.) to determine the conditions under which the procedure should be performed.

Diagnostic procedures should be carried out using all available means to reduce patient ***exposure*** without affecting the necessary image quality; this what is meant by optimization. The *BSS* (*26*) recommend the adoption of ***guidance levels*** for the various ***practices***.

In radiation therapy, patients should be irradiated with a high degree of accuracy, both in the value of the ***dose*** and in its location. Every effort should be made to minimize ***exposure*** of healthy tissues. This is what is meant by optimization, and this implies maintaining strict ***quality control*** procedures.

The prevention of ***potential exposures*** is particularly important in the case of radiation ***sources*** used for medical purposes. Worthy of mention in this regard are several ***accidents*** that have occurred, including one with a linear ***accelerator*** in Zaragoza, Spain, which over-irradiated 27 patients (*58*), resulting in several deaths among them; one with a caesium-137 teletherapy ***source*** in Goiania, Brazil, which resulted in the death of four members of the general public (*68*), and one with a cobalt-60 teletherapy ***source*** in Ciudad Juarez, Mexico, which led to the overexposure of numerous ***members of the public*** and caused significant material damages (*69*).

8.9 Implementation of Radiation Protection and Safety Measures

The only way to control the ***risks*** associated with ***ionizing radiation*** is to restrict and monitor the radiation ***doses*** that individuals receive under normal conditions and to adopt safety measures to reduce the probability of ***accidents***.

Reduction of radiation ***doses*** from external ***sources*** can be achieved by increasing the distance from ***sources***, interposing ***shielding***, or diminishing ***exposure*** time. In the case of internal irradiation, it is only possible to reduce ***doses*** by controlling people's intake of radioactive materials. For each ***radioisotope*** it is possible to calculate the annual maximum intake (***annual limit on intake***) that will yield a ***dose*** over a period of time (***committed dose***) that does not exceed the ***dose limit***. The *BSS* (*26*) gives the values of the ***committed effective doses*** per unit of ***activity*** for every ***radioisotope***.

8.9.1 Distance

Generally speaking—assuming that the ***source*** is a point ***source***—the ***dose*** depends inversely on the square of the distance. Doubling the distance reduces the ***dose*** to one fourth. Increasing the distance tenfold decreases the ***dose*** one hundredfold.

Example: An ***x-ray*** machine is placed in the center of a room. If the distance of the equipment to one of the walls is 1 meter and the ***dose*** rate at this point is 1 mSv/hr; by increasing the distance to 2 meters, the ***dose*** rate would diminish approximately to 0.25 mSv/hr.

8.9.2 *Shielding*

The interposition of material between radiation ***sources*** and people is an important means of reducing the ***dose*** of radiation. The intensity of the radiation beam is attenuated exponentially.

The ***half-value layer*** is defined as the thickness of the ***shielding*** material which reduces the beam intensity by one half. The ***half-value layer*** is a characteristic of each type of material and of the radiation energy utilized.

The ***shielding*** material most commonly used in diagnostic radiology is lead and in radiation therapy, concrete.

Example of equivalent ***shielding*** (*70*):

Material	***X Rays* (70 kVp)**	**Co-60**
Concrete	8.4 mm	62 mm
Lead	0.17 mm	12 mm

8.9.3 Time

There is a linear correlation between ***dose*** and ***exposure*** time. ***Exposure*** time refers to the length of time during which a person is in proximity to ***sources*** when they are being used for irradiation; it does not bear any relation to the length of the work day.

8.9.4 Control of *Contamination*

The use of ***unsealed sources*** creates the potential for radioactive material to spread to work surfaces and materials, floors, and walls, thereby contaminating them and the air in the surrounding area. Control of such ***contamination*** is achieved by keeping work surfaces and materials clean and using a forced ventilation system, equipped with filters, in environments in which ***unsealed sources*** are used.

8.9.5 Safety Systems

Accident prevention should be envisaged in the planning and operation of all radiology services.

The aim in designing safety systems is to reduce the likelihood of ***accidents*** to acceptable levels. To this end, safety systems should be redundant and independent.

The experience gained from past ***radiological accidents*** has shown that the most important factor is the human factor. The influence of the human factor should be minimized, since it is one of the least reliable elements in routine circumstances. For those functions in which ***intervention*** is necessary, the individuals carrying out the ***intervention*** must have adequate training and be in an appropriate psychophysical state. ***Intervention*** procedures should be described in codes of ***practice***.

8.10 Application of Radiation Protection in Radiology Services

In radiology services, as in any other installation, both ***occupational exposure*** and ***public exposure*** should be taken into account. In addition, ***medical exposure*** must be considered.

Outlined below are the most important recommendations that should be borne in mind in the design and operation of radiology services. For each ***level of care***, there may be specific additional requirements, depending on the complexity of the services provided.

In order to provide adequate radiation protection, every radiology service should be appropriately planned and installed, the equipment should comply with certain essential design requirements, and maintenance and ***quality control*** should be ensured. The staff should possess appropriate knowledge and training in their particular specialties and in radiation protection.

8.10.1 General Design Requirements (*36, 68*)

The structural design of each radiology service should be in accord with its functional characteristics and the need for interrelationship with other medical

care services. ***Shielding*** considerations may influence the location and arrangement of irradiation rooms. In the design of the rooms, several factors should be considered, among them:

- Type of ***sources***, their location, and the characteristics of the radiation beam
- Workload and use factors
- Purpose for which adjacent areas are used and occupancy factors
- ***Dose limits*** for the design
- ***Shielding*** materials

Shielding fulfills an essential function in every radiology service. Radiation ***sources*** have their own ***shielding***, which should meet mandatory design requirements for ***sources*** and be guaranteed by the manufacturer. Structural ***shielding*** needs should be calculated for each installation. Mobile ***shielding*** and leaded aprons play an important protective role in certain applications, such as fluoroscopy.

8.10.1.1 *Controlled Areas*

Access to areas in which radiation ***sources*** are used or stored should be limited to those personnel who are strictly necessary and are authorized to conduct ***practices*** in these areas. Appropriate safety and signaling systems should be utilized to restrict access. These areas are called ***controlled areas***. Access is restricted not only to avoid unnecessary ***exposures*** but also to prevent ***accidents*** that could be caused by people who lack the necessary expertise.

Safety devices (interlocks) should be installed when it is necessary to prevent anyone from entering a ***controlled area*** while patients are being irradiated.

8.10.1.2 *Supervised Areas*

Supervised areas are areas that have not been designated as ***controlled areas*** but for which ***occupational exposure*** conditions are kept under review. Specific protective measures and safety provisions are normally not necessary.

8.10.2 Specific Requirements

8.10.2.1 Diagnostic Radiology Services

Structural ***shielding*** should be adequate to protect the public and staff. ***X-ray*** machines should be equipped with appropriate accessories to reduce unnecessary ***doses*** of radiation to patients. The recommended radiological techniques for reducing patient ***doses*** should be used to obtain and process films.

In order to protect the operator, the equipment controls should be located within a shielded booth or area so that the operator is obliged to operate the machine from within this area. The booth should have a shielded window to allow the operator to easily see the patient. Oral communication between them must also be ensured. When the operator's presence in the radiation room is imperative, he/she should use personal protection elements such as leaded aprons and leaded gloves. Should a patient need to be physically supported or held during a radiological examination, this function should be performed by someone accompanying the patient who is not occupationally exposed and who is not pregnant. The ***exposure*** of this person should considered a ***medical exposure*** and should be constrained to 5 mSv per application (*26*). In such cases, all available protective resources, such as a leaded apron, should be utilized.

Mobile equipment is often moved into rooms in which people other than the patient may be present. As a result, special care should be taken in the collimation of this equipment, and it should be placed at a sufficient distance from other people who cannot be removed from the room while radiographic images are being taken. The operator should be positioned outside the direct radiation beam at a distance of not less than 2 m from the patient and should wear a leaded apron (*71*).

The procedures that expose radiologists and patients to the largest ***doses*** of radiation are fluoroscopic procedures, especially in interventional radiology, in which the physician utilizes fluoroscopic procedures and/or cinefluorography as a guide during surgery.

Dentists should take precautions with regard to their location at the time radiographic films are taken. They should not hold films in place with their hands, but rather should use special devices for this purpose or should ask the patient to hold the film.

With respect to patient protection, ICRP Publication No. 34 (*72*) contains abundant information on equipment and appropriate techniques to reduce unnecessary ***doses*** of radiation. WHO has also published guidelines for the rational use of radiation in medicine, which include methods for reducing unnecessary ***doses*** to patients (*7, 8*).

The most important features for this purpose are (*26, 70*):

- Radiation beam collimators and/or ***shielding*** for organs
- Beam filters
- Highly sensitive films and intensifying screens
- Non-absorbent structural materials between the ***x-ray*** tube and the patient (carbon fiber)
- High-voltage techniques
- Appropriate film processing techniques

8.10.2.2 Radiation Therapy Services

The ***sources*** used in external radiation therapy are high-***activity sources*** in the case of cobalt therapy units or high-intensity ***sources*** in the case of ***accelerators***. These ***sources*** produce high ***dose*** rates, which necessitates careful design of the installation and, especially, of the structural ***shielding***. Appropriate placement of radiation room helps to reduce the investments needed for structural ***shielding*** (for example, location of the room so that the surrounding areas have a very low occupancy factor and are inaccessible to the public).

Safety systems should be designed to prevent irradiation from accidental entry by ***workers*** or the ***public***. The doors to the room should be equipped with interlocks that function automatically during irradiation.

The equipment control booth should be positioned so that the operator can control the access to the room and see the patient who is undergoing treatment. It is advisable to have two visual monitoring systems—for example, a viewing window with leaded glass and a closed-circuit television system.

Another important aspect of radiation protection is the correct disposal of spent ***sources***, which is essential in order to prevent serious ***accidents*** like those

that have occurred as a result of improper disposal of ***sources*** (*68, 69*). ***Sources*** which are no longer to be used should be disposed of in facilities equipped to handle this type of ***radioactive waste*** and in accordance with existing standards in each country.

Equipment should be kept in good working order and should be properly calibrated. Each treatment should be planned by personnel with specialized training in medical physics, and the service should have the variety of equipment necessary to ensure the most appropriate selection for each case. ***Quality control*** of the mechanical and radiant characteristics of the equipment should also be ensured (*65, 66*).

Correct application and continual updating of the computer programs used with the equipment and in treatment planning are equally important.

In brachytherapy services, appropriate design and ***shielding*** of patient rooms is of utmost importance, as is appropriate storage and transport of radioactive ***sources***. The insertion of radioactive ***sources*** into patients should be carried out by manual or automatic afterloading systems, which make it possible to considerably reduce the ***doses*** to operators.

Radiation therapy services need to have radiation detection instruments for radiation protection and precision instruments for dosimetry.

In addition to specialized medical personnel (radiation oncologists, radiation therapy technologists), radiation therapy installations should have the services of a medical physicist with experience in dosimetric calibration techniques, treatment planning, equipment ***quality control***, and radiation protection (*26*).

ICRP Publication No.44 contains important recommendations on the most effective means of approaching treatments so as to achieve better health results for the patient (*73*).

8.10.2.3 Nuclear Medicine Services

In the design of nuclear medicine services, independent rooms should be provided for the preparation of radiopharmaceuticals, storage of radioactive material, inoculation of patients, use of instruments, waiting room for patients, and meeting room. Special bathrooms may also be provided for patients. In order to prevent ***contamination***, the work surfaces, floors, and walls should not be porous or absorbent and should be easily cleanable. Exhaust hoods should be installed in the rooms in which radiopharmaceuticals are prepared. ***Radioactive waste*** should be disposed correctly.

Equipment such as ***radionuclide calibrators*** should be available to accurately determine the ***activity*** of radiopharmaceuticals to be administered to patients, and ***quality control*** programs should be implemented (*26*).

ICRP Publication No. 52 contains important recommendations for the protection of patients in nuclear medicine (*74*).

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.

10. Coordination of the Agencies Involved in the Organization and Delivery of Radiology Services

10.1 The Role of the Central Government

While the actual planning and operation of health services, including radiology services, should take place at the local level, in accordance with the criteria of ***local health system*** management, it should be the responsibility of the central government, within the context of public sector reform, to provide guidance regarding how radiology services should be organized and operated. This function should be independent from, but consistent with, the government's regulatory activities in the area of radiation protection and safety at radiological installations. As the previous chapters have illustrated, the provision of guidance requires a certain level of scientific and technological expertise in order to address both technical issues relating to the radiological equipment itself and the ***risks*** posed by ***ionizing radiations***, if the equipment emits them. This expertise is required not only for the development of standards and norms, but also for the day-to-day operation of radiological facilities which, like those in ministry of health and social security hospitals, which used to come under the direct jurisdiction of the central government, but have now been privatized or depend on a municipal government..

The key professionals who are able to provide this level of expertise in both normative and service-related activities are medical physicists. However, the availability of these professionals is limited, particularly in the area of imaging. The estimated number of medical physicists in the Region of the Americas is shown in Table 10.1.

Given this situation, it will be difficult for many governments to hire well-qualified medical physicists, as the United States did in 1994 to implement the Mammography Quality Standard Act (see Appendix II-B), which require that government-approved medical physicists survey all existing mammography units to ensure optimal equipment performance and minimal radiation ***dose***. Another obstacle which may prevent governments from hiring medical physicists is the high salary that these professionals generally command. (Well-trained medical physicists in the United States make over US$100,000 a year.)

Unless physicists, like many government-employed physicians, can find a secondary source of income—for example, in private practice—the probability of their remaining in government service is low. Although the government may have invested considerable money and time in their training, it is likely that many will emigrate to the United States or Europe, or they will join an international organization such as the IAEA in Vienna, or they will leave the field altogether. A different solution must be found.

Table 10.1
Estimated Number of Medical Physicists in Countries of the Region of the Americas, 1994

Country	Medical Physicists
Argentina	108
Barbados	1
Bolivia	3
Brazil	700
Chile	5
Colombia	17
Costa Rica	3
Cuba	20
Ecuador	4
Honduras	1
Jamaica	1
Mexico	30
Panama	2
Paraguay	1
Peru	6
Trinidad & Tobago	4
Uruguay	2
Venezuela	14

A similar problem occurs with regard to availability of testing equipment, for example, the equipment required to evaluate diagnostic units. In some cases, the SSDLs will have survey-type instruments, and an agreement to share equipment between two governmental institutions may be reached. However, in most cases the needs will exceed the inventory of available equipment. The government must own a minimum set of equipment for inspections, although more sophisticated items, such as thermoluminescent dosimetry systems, may be leased from outside suppliers.

10.2 The Role of Universities

It would appear that the first place to seek physicists is the physics department of a university. Although there are very few medical physicists working in universities in Latin America and the Caribbean, they may be approached to provide guidance regarding the development of standards, but it will be difficult to engage them in providing direct services such as equipment surveys. However, physics graduate students may be willing to provide such services in order to broaden their professional experience and increase their income.

Even when a university does not have any medical physicists on staff, it may be possible to arrange for some contractual services, as long as some needed training and equipment are provided. Examples of such services might be thermoluminescent dosimetry, as mentioned before, and structural ***shielding*** calculations.

The most important role universities can play is educational. They should assist the medical management of ***local health systems*** in providing training, including continuing education courses, to physicians, physicists, engineers, and technologists.

In no case should a university itself assume a regulatory role.

10.3 The Role of Scientific and Professional Organizations

Although medical physics societies exist only in Argentina, Brazil, Canada, Colombia, Cuba, Mexico, Panama, Trinidad and Tobago, the United States and Venezuela, almost all the countries of the Region have associations of radiologists and radiological technologists. The cooperation of these organizations is essential in the development of clinical protocols, and it may also prove invaluable in equipment assessment and the application of ***quality assurance*** criteria. Their assistance should be enlisted through the creation of radiology and radiological health advisory committees to the government, which would provide guidance to governments on technical issues. In the area of medical physics, the government might consider engaging qualified medical physicists individually as "state inspectors" on an *ad hoc* basis. The government might also consider requesting the assistance of a foreign expert panel to evaluate the qualifications of physicists.

10.4 The Role of Industry

Manufacturing and service corporations might also help in providing experts and equipment on a loan basis. In some countries these firms may have knowledge of the latest technological developments and they will be able to provide technical assistance. They should not be asked to give information on the performance of a competitor's product. In many countries major equipment manufacturers are a good source of grants and fellowships for clinicians, technologists, physicists, and maintenance engineers, and they often provide support in the organization of refresher courses and other continuing education activities.

10.5 The Role of International Organizations

The role of international organizations is to provide advisory services to governments and institutions in the areas of radiation medicine and radiation protection and safety, to visit the countries to assess existing policies and resources in health services and radiation protection programs, to develop standards and guidelines, to promote ***quality assurance*** and training programs, to produce relevant publications, to coordinate interregional activities, to distribute bibliography and equipment, to promote the marketing of national products to be used in radiology services and to provide direct technical assistance in radiological emergencies.

Examples of consultations in radiation medicine:

- Planning of radiological services
- Specification, selection, acceptance testing, maintenance, and repair of equipment
- Review of imaging and radiotherapy procedures
- Calibration of radiation ***sources***
- Physical and clinical dosimetry

Examples of consultations in radiation protection:

- Implementation of the *BSS* (*26*)

- Determination of environmental radiation levels
- Assessment of ***occupational***, ***medical***, and ***public exposures***
- ***Shielding*** specifications
- Evaluation of ***contamination*** problems
- ***Radioactive waste*** management
- Recommendations on ***dose limits*** and constraints
- Determination of non-***ionizing radiation risks***

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APPENDIX I

Basic Radiological Equipment Specifications

Appendix I-A

*Specifications for the WHIS-RAD Radiographic Unit**

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* Taken from: World Health Organization. *Report from the Consultation Meeting on the WHO Basic Radiological Systems held at the WHO Collaborating Centre for General and Continuing Radiological Education, University Hospital, Lund Sweden, 7-11 June 1993, including the Technical Specifications for the World Health Imaging System for Radiography, the WHIS-RAD*. Geneva: WHO; 1994. (RAD/94.1).

Technical Specifications for the Radiation *Source* of the WHIS-RAD

HT *Generator* and *X-ray* Tube

1. High-tension *Generator*

1.1 *Mains connection*

A wall outlet or a separate 50/60 Hz AC generator, which can deliver 2.3 kW within 10%, is required. This corresponds to nominal values of 10 A at 230 V or 20 A at 115 V.

Note: Solutions without mains connection, using a battery with other type of charging, e.g. solar cells or a small AC ***generator***, are also acceptable.

1.2 *Energy storage*

The power rating of the ***x-ray generator*** will be much higher than the instantaneous power (2.3 kW) available from the AC source described above. The high tension ***generator*** therefore must have an integrated energy storage unit. An individual ***exposure*** of a very dense object may in rare occasions require close to 30 kWs (kilowatt-seconds) at 90 kV. ***Generators*** without energy storage, intended to operate directly from the mains, are not recommended. Peak power loads in the range of 12-30 kW for 0.1 s and 12-15 kW for 2 s may be expected.

Note: The energy storage unit shall be maintenance-free and carry a 5 year *pro rata temporis* warranty. It is preferable to use a battery for energy storage but other methods may also be acceptable, such as a large capacitor on the primary side of the high-tension transformer or a fly-wheel.

1.3 *High-tension transformer frequency*

Only high-tension ***generators*** using multipulse inverter technology are acceptable. Frequencies from a few kHz to 100 kHz are used with satisfactory results. The high-tension voltage ripple shall be no larger than 4%, measured at 100 kV (kVp) and 100 mA.

1.4 ***Generator*** *control panel*

Only the following switches or controls shall be available: ON/OFF, kV-selector, mAs-selector, anode rotation, and ***exposure***. The ***exposure*** switch should be mounted on the control panel, so that the operator must stand behind a protective screen or wall during ***exposures***. The selected values for kV and mAs shall be shown before and after the ***exposure***. A light signal shall indicate if the ***generator*** is READY for the selected tube loading. The actual tube loading (***exposure***) shall be indicated with a sound and/or a light signal.

1.5 *Nominal* ***x-ray*** *tube voltage*

The nominal ***x-ray*** tube voltage (highest available kV) shall be at least 120 kV.

Note: The high-tension ***generator*** must have circuits which automatically protect the ***x-ray*** tube from overload (tension and temperature) and the high-tension circuit from damage by flash-over.

1.6 *Available **x-ray** tube current*

The tube current shall be or exceed 100 mA.

1.7 *Electric power rating*

The nominal electric power rating (kW) shall be stated as the highest constant electric power in kilowatts, which the high-tension ***generator*** can deliver for a loading time of 0.1 s in the voltage range of 90-100 kV. The minimum acceptable power rating for a WHIS-RAD ***generator*** is 12 kW at 100 kV.

1.8 *Electric energy rating*

The nominal electric energy (total available energy for one single ***exposure***), measured at 90 kV and a tube loading time not exceeding 2.5 s, shall be in the range of 23-30 kWs (kilowatt-seconds). (See below and note under item 1.9 d.)

The measurement at 90 kV (instead of 100 kV, which is customary) depends on the fixed selection of kV-values used in the WHIS-RAD philosophy. Typical peak load situations, using current and ***exposure*** time values available in the Renard-10 series (see item 1.9 d), are: 90 kV + 160 mA + 2 s, resulting in 28.8 kWs or 90 kV + 100 mA + 2.5 s, resulting in 22.5 kWs.

Note: This type of electric energy rating (not yet applied by the International Electrotechnical Commission—IEC) is necessary if the ***generator*** uses power storage or falling tube current during the tube loading (***exposure***).

Exception: The electric energy rating specified above, presumes that the image recording medium (screen-film combination) used has a nominal speed of at least 200 in the 70-120 kV range, corresponding to an ***exposure*** requirement of 0.5 mR (air ***kerma*** of close to 5 μGy) at the input side of the film cassette. When a recording medium is used, which has a nominal speed of 500, requiring 0.2 mR/***exposure*** (air ***kerma*** close to 2 μGy) at 90 kV (retaining acceptable image quality), the nominal electric energy, measured as above, may be as small as 12 kWs.

For the time being this requires the use of green-emitting intensifying screens and green-sensitive x-ray film. The use of such film requires special attention to the darkroom lighting and the film development. Free access to green-sensitive (orthochromatic) x-ray film is also required, which may be a problem in some remote areas.

1.9 *Selection of loading factors*

The selection of loading (***exposure***) factors is optimized in the WHIS-RAD Unit and limited to kV- and mAs-values. ***Exposure*** times and mA-values shall not be set separately, but only selected as current-time products (mAs-values). The shortest possible ***exposure*** time and the highest possible mA-value shall be automatically selected for each mAs-value used.

Adequate information shall be available to the operator before, during and after the loading of the ***x-ray*** tube about which loading factors (kV and mAs) that are used.

a) Values of ***x-ray*** tube voltage shall be measured as kVp but indicated as kilovolts (kV) because the voltage ripple is no more that 4%. The concept of kVp shall not be used in the manual or on the control panel.
For didactic reasons the choice of kV-values is limited to a small number of fixed steps, which do not limit the practical use of different radiation qualities in radiography.

*Recommended values of **x-ray** tube tension:*
46 - 53 - (60) - 70 - 80 - 90 - (100) - 120 kV

Note: 60 kV and 100 kV are required for testing purposes, but not needed for clinical use. A larger number of kV-steps or continuously variable tube tension are not acceptable.
The selected kV-value must not fall more than 5% from the initial value during the ***exposure*** (corresponding to about 10% in air ***kerma*** loss).

b) Values of ***x-ray*** tube current shall be selected automatically and not displayed. If the tube current is constant during the ***exposure***, its minimum value shall be 100 mA. If the tube current is falling during the ***exposure***, the initial value should be in the range of 200-320 mA.
Note: If ***exposure*** times and mA-values are selected from ranges of fixed values, these must be taken from the Renard-10 series, thus resulting in mAs-values according to item 1.9 d below.

c) Values of loading time (***exposure*** time) need not be displayed.
Shortest reproducible ***exposure*** time (measured as the time during which the kV is 75% of the selected value) shall be 5 ms or shorter. ***Exposure*** times longer than 2.5 seconds are not permitted.

d) Values for current-time product shall be indicated in milliampere-seconds (mAs) and shall be chosen as decimal multiples and submultiples from the rounded values of the Renard-10 series (R'10) shown below (ISO Standard 497/1973).

R'10 = the Renard-10 Series

1	1.25	1.6	2	2.5	3.2	4	5	6.3	8
1.0000	1.2589	1.5849	1.9953	2.5119	3.1623	3.9811	5.0119	6.3096	7.9433

The minimum range of fixed mAs-values to be used in the WHIS-RAD is:

							0.5	0.63	0.8
1	1.25	1.6	2	2.5	3.2	4	5	6.3	8
10	12.5	16	20	25	32	40	50	63	80
100	125	160	200	250	(320)				

Note: It is not required that the entire range of mAs-values is available at all tube tensions. Thus it is acceptable that only 20 kWs is reached at 80 kV (with 250 mAs) and that only 12 kWs is reached at 120 kV (with 100 mAs). The combination of 250 mAs and 90 kV (= 22.5 kWs) is usually enough as the peak output. The combination of 320 mAs and 90 kV (= 28.8 kWs) is needed extremely seldom in a population with an average weight of individuals around 80 kg and never in a population with an average weight of 70 kg.

e) Precalculated current-time products shall be shown by the control panel. The lowest mAs-value should be stated, which is within the specified ranges of compliance for linearity and constancy (see below).
Note: This information is very important. The energy loss in the high-tension circuit may be in the order of magnitude of 0.06 kWs at each ***exposure***, which corresponds to 0.5 mAs at 120 kV (= the lowest possible combination of loading factors used in chest radiography).

1.10 *Reproducibility, linearity and constancy of radiation output*

Multipulse ***x-ray generators*** with energy storage inherently have much better reproducibility and linearity than required in the IEC Standard 601-2-7/1987 (Medical electrical equipment, part 2: Particular requirements for the safety of high voltage ***generators*** of diagnostic ***x-ray generators***). This standard does not apply to battery-operated ***generators***.

a) Reproducibility of air ***kerma***: The coefficient of variation of measured values of air ***kerma*** shall not be greater than 0.1 (10%) for any combination of loading factors within the available range.

b) Linearity of air ***kerma***: Within the available ***x-ray*** tube voltage range (46-120 kV) the quotient of the measured values of air ***kerma*** divided by the indicated precalculated value of current-time product (μGy/mAs) shall not differ from the quotient of the measured value of air ***kerma*** and indicated current-time product at 10 mAs by more than 0.1 (10%) of that latter quotient.
Comments: Measurements of air ***kerma*** shall be made with a minimum added filtration on the ***x-ray*** tube of 20 mm Al or equivalent.
Measurements of mAs inside the ***x-ray*** tube are not made and measurements in the grounded centerpoint of the high-tension transformer are of no value.
The linearity requirement is only related to the magnitude of the steps in the precalculated mAs-scale, representing 26% increments of air ***kerma***.
The linearity requirement is more strict than the corresponding IEC requirement for mains-connected ***x-ray generators***. Practical experience at the WHO Collaborating Centre for General and Continuing Radiological Education in Lund, Sweden, has shown, however, that multipulse ***x-ray generators*** using energy storage can easily be modified to give a μGy/mAs quotient, which does not differ more than 2-5% from the reference value (at 10 mAs) over the entire mAs-range.

c) Agreement between indicated and measured values of loading factors:
At a given measurement date, using the same measuring instrument, the permissible average error of the indicated value of ***x-ray*** tube voltages shall

not be greater than 0.025 (2.5%), approximately corresponding to the requirements of air ***kerma*** given above.

Under the same conditions the permissible average error of current-time products shall not exceed the value 0.05 (5%) or 0.1 mAs, whichever is larger.

2. The *X-ray* Tube

Due to the long time usually required to change an ***x-ray*** tube at a remote location and the very high tube replacement costs, longevity of the ***x-ray*** tube is a very important characteristic. An ***x-ray*** tube for a WHIS-RAD unit benefits from design features which promote a long tube life such as a large anode diameter and renium/tungsten alloy in the anode surface.

2.1 *Expected lifetime*

An ***x-ray*** tube for a WHIS-RAD installation should have an expected lifetime of 10 years or more with the types and mixture of examinations to be found in an x-ray department at primary-care or first referral level (see below). This may correspond to a total of about 50,000 ***exposures*** in normal use.

Distribution of examinations to be expected in primary care or at first referral level:

35-40% chest
8-10% abdomen
38-42% extremities
10-15% spine and pelvis
3-4% head and neck

The anode of an ***x-ray*** tube develops small cracks in the target surface due to heat variations. These cracks lead to reduction in the output of the ***x-ray*** tube. When the output reduction reaches 20%, corresponding to one ***exposure*** step in the Renard-10 series, the demand on the ***x-ray generator*** power output has increased with 25%, which may prove critical for some examinations.

The average tube load at this type of work is around 3 kWs/***exposure***, corresponding to 10% of the permitted maximum load. However, the actual tube load varies within a very wide range: from 0.25 kWs for a normal PA chest to 30 kWs for a lateral view of the lumbo-sacral junction of a heavy person.

2.2 *Focal spot*

A rotating anode must be used. The focal spot of the ***x-ray*** tube shall have a nominal size no larger than 1 mm, measured according to IEC 336.

Note: A new IEC standard for focal spot measurements is anticipated. In this the nominal figure for focal spot size is dimensionless and specified in terms of detail resolution in lines/mm at a specified geometric magnification. This practice, however, is not yet in general use by manufacturers, users or purchasing agents and its introduction is beyond the scope of this publication. For practical purposes the nominal values may still be interpreted as representing millimeters.

2.3 *Anode angle*

The anode angle should be in the range of 12-15°. No special recommendations are given about anode diameter or rotation speed.

Note: An anode angle in the range of 12-15° is compatible with a nominal focal spot size of 0.8-1.0 (mm) and a tube rating of 23-30 kW (at 0.1 s).

An anode angle of 12° easily permits an ***x-ray*** field of 45 x 45 cm without visible heel effect at the expected working conditions.

Comments: The aging of the anode is very dependent on how it can withstand heat. Anodes made of pure tungsten may not live up to the requirements stated in this paragraph. Reliable figures for the drop in anode output with normal clinical use are not available. The output from a tungsten target containing 10% renium and 90% tungsten drops at a rate which is about 25% of the rate for a pure tungsten target. The overall lifetime of a 90/10% tungsten/renium target is about 4 times longer than that of a pure tungsten target.

2.4 *Tube rating*

The high-tension rating of the ***x-ray*** tube shall be 125 kV (from a low-ripple HT ***generator***).

The nominal power rating shall be in the range of 23-30 kW at an ***exposure*** time of 0.1 s.

The long time power rating shall be in the range of 12-15 kW at an ***exposure*** time of 2 s, corresponding to a total energy load of 24-30 kWs.

2.5 Tube filtration

The total filtration (inherent + added) shall be within the range of 3-4 mm Al. The filtration shall be determined by ***half-value layer*** (HVL) measurements of the emerging radiation, which may be performed with a penetrameter.

2.6 *X-ray beam collimator*

It is recommended to use a standard, multilevel light-beam collimator. Special attention should be paid to the following features:

- The controls should have reliable format indicators (e.g. for 12, 18, 24, 35 and 43 cm) for a focus-film distance of 140 cm, so that the collimator can be used also in case of mains power failure or a light-bulb blow-out.
- It is advantageous if the collimator controls are no more than 110 cm away from the front wall of the cassette holder, enabling a person not taller than 155 cm to reach them, when the ***x-ray*** tube is in normal position for examination of a recumbent patient on a 70 cm high patient trolley.
- The collimator should be designed in such a way that the light bulb can be replaced with retained exact position without the use of special tools. The position of the centre of the light field shall not vary more than 14 mm (1% of the FFD) from the point, where the central ***x-ray*** beam reaches the cassette holder. The limits of the light field may not vary more than 1% of the FFD from the limits of the ***x-ray*** field.
- Spare collimator bulbs, sufficient for an estimated 10 year's consumption, should be provided.

Specification for the WHIS-RAD Examination Unit

1. *General Description of the Examination Unit*

The examination unit consists of a support for the ***x-ray*** tube and the cassette holder, usually called the stand, and a patient trolley, which can be used as a floating-top table.

The examination unit combines the functions of a chest unit, a vertical bucky, and a floating-top table with an ***x-ray*** tube stand. It must permit the use of horizontal, vertical and angulated ***x-ray*** beam on lying, sitting and standing patients, also in emergency situations.

2. *The Support for **X-ray** Tube and Cassette Holder*

It is necessary to use a design of the stand which will ensure that the ***x-ray*** tube can always be connected to the cassette holder in a rigid and stable way, providing precise and simple centering of the ***x-ray*** beam.

The focus-film distance (FFD) shall be fixed at 140 cm. The ***x-ray*** tube and the cassette holder shall be mounted in such a way that also a recumbent patient can be examined with a horizontal ***x-ray*** beam. The arm assembly shall be perfectly balanced (with a 24 x 30 cm cassette in place) in two basic positions: horizontal and vertical.

It must be possible to angulate the arm $\pm 30^{\circ}$ from both these positions, retaining the balance, and to use a horizontal central ***x-ray*** beam in the minimum range of 50-170 cm above the floor. No individual tube angulation is acceptable in a standard installation.

Comments: If a WHIS-RAD unit is extensively used in traumatology, e.g. in an emergency room, it should be possible to create a horizontal ***x-ray*** beam, which is not directed towards the cassette holder. It should also be possible to tilt the ***x-ray*** beam 90° downwards, when the tube arm is horizontal, for radiography of patients which cannot be moved from the bed or stretcher, on which they have arrived. This use implies taking away the radiation protection included in the cassette holder and should be applied only under the supervision of a qualified radiographer.

3. *Cassette Holder*

The cassette holder shall be fixed at right angles to the central ***x-ray*** beam and shall accept any standard cassette format in longitudinal and transversal position. Critical dimensions are given in Table 6.

Note: The largest format may be different in different parts of the world, depending on the size and constitution of the individuals to be radiographed. In many parts of the world the 35.6 x 35.6 cm format ("35 x 35") is satisfactory for PA chest, abdomen and pelvis due to the advantageous imaging geometry of the WHIS-RAD (the FFD is 140 cm and the skin-film distance is 2.5 cm in chest radiography). However, the 35 x 43 cm format is required in large parts of Africa and in most parts of Australia, Europe, and North America.

It must be possible to change cassettes with minimal difficulty also when the ***x-ray*** beam is used in the vertical direction, with the trolley in place above the cassette holder.

The cassette holder may be used as a small horizontal examination table without using the trolley. It must permit a load of at least 15 kg without unwanted downward movement or disalingment of the focused grid.

The centre of the ***x-ray*** beam and vertical film format dimensions for the four most used film formats shall be indicated on the front wall of the cassette holder. If the 35 x 43 cm format is anticipated to be used also in the transverse position, this must be indicated on the cassette holder.

The front wall of the cassette holder shall contain a fixed anti-scatter grid (see below).

The back wall of the cassette holder shall contain a protective screen with a density equivalent to 0.8 mm of lead and outer dimensions not smaller than 49 x 49 cm.

4. *Anti-Scatter Grid*

The anti-scatter grid must be focused at a distance of 135-140 cm. The grid ratio shall be 10:1 with a line density of 40-60 lines/cm. The grid shall be large enough to cover a vertical film format of 35 x 43 cm. If the 35 x 43 cm format will be used in transversal position, the grid must be 43 x 43 cm.

Note: Practical experience has shown that a grid with 40 lines/cm is satisfactory and practically invisible, when correctly focused and when the resulting film is viewed at a distance longer than 30 cm. Lead with interspacing aluminum is advantageous in the 90-120 kV-range and acceptable in the 70-80 kV-range.

Grids using carbon fiber as interspacing material usually come with at least 60 lines/cm. They are advantageous in the 53-70 kV range but not equally effective (resulting in lower contrast) in the 90-120 kV range.

5. *Examination Table*

The examination table shall be a trolley, which can be used as a floating-top table. The table top shall be rigid and be able to support a patient weighing 110 kg, sitting on the middle of the table, without appreciable distortion. The equivalent density of the table top should not be more than 1 mm Al.

The design of the trolley must permit the use of the cassette holder in horizontal position under the trolley in such a way that the distance between the table top and the film plane does not exceed 8 cm. In this position it must be possible to use the trolley as a floating-top table, so that the longitudinal midline of the trolley can be offset no less than $\pm$12cm from the midline of the cassette holder.

The trolley shall have large wheels, with locks on at least two of them. A central lock for the wheels is preferred. The table surface should be flat. Dimensions are given on the following section 6: Summary of critical dimensions of the examination unit.

6. Summary of Critical Dimensions of the Examination Unit

Focus-film distance (fixed, not variable) Distance between arm pivot and x-ray film	140 cm 80-100 cm	
Space available for trolley with patient: a. minimum trolley clearance at a level 8 cm below the central horizontal ***x-ray*** beam: b. minimum possible lateral movement of the patient trolley with vertical ***x-ray*** beam: c. space under cassette holder arm for patient lying in lateral decubitus position:	 trolley width + 5 cm (min 70 cm) ± 12 cm from central *x-ray* beam minimum 25 cm from arm to central ***x-ray*** beam	
Tube/cassette-holder arm angulation from vertical and horizontal position: - Brake for arm rotation - Brake for height adjustment (additional option) - Distance from pivot to central ***x-ray*** beam	±30° mechanical mechanical (electro-magnetic brake) 0 (or very short)	
Height above floor for horizontal beam:	variable: min 50-170 cm	
Optional tube angulation of horizontal arm for use in traumatology by qualified operator:	30° down and 90° down	
Cassette holder - Cassette holder height (=length): - Distance between front wall and film: - Largest distance between front wall and floor at vertical ***x-ray*** beam:	 maximum 50 cm 2-3 cm 90-100 cm	
- Film cassette formats: small format intermediate format long format large format	recommended 18 x 24 cm 24 x 30 cm 18 x 43 cm 35 x 43 cm	alternate - - 15/20 x 40 cm 35 x 35 cm
Patient trolley: table width table length table height table top density equivalence dimension of wheels *Distance from table top to film with no angulation of the x-ray beam*:	 65-70 cm 200-210 cm 70 cm ± 1 cm 1 mm Al or less diameter 10-15 cm maximum 8 cm	

Protective Devices

It is recommended that the control panel is installed behind a protective screen or wall, separating an area from the x-ray room, large enough for two people (e.g. operator and interpreter or parent). The lead equivalence of the wall should be no less than 0.5 mm Pb.

The screen or wall must have a lead glass window, adjusted to the average height of a standing radiographer, thus providing a good view of the patient being examined. The lead glass window may be as small as 30 x 30 cm in a thin screen but should be at least 40 x 50 cm in a brick wall.

The back wall of the cassette holder contains 0.8 mm lead (or equivalent), which usually will make regular solid 12 cm thick brick or concrete walls satisfactory as general radiation protection around the x-ray room, if the room is at least 18 square meters in size and no more than 2.000 examinations are made per year.

At least two full length (shoulder to knee, adjusted to the size of a normal person) radiation protection aprons and two pairs of radiation protection gloves with 0.25 mm Pb equivalence should be offered with the ***x-ray*** equipment.

Appendix I-B

*Specifications for a General-Purpose Ultrasound Scanner**

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* Taken from: World Health Organization. *Future use of new imaging technologies in developing countries: report of a WHO scientific group*. Geneva: WHO; 1985. (Technical report series 723).

Specifications for a General-Purpose Ultrasound Scanner

1) *Transducer*
Standard unit: 3.5 MHz center frequency.
Optional unit: 5.0 MHz center frequency.
Fixed in-slice focusing on both units desirable but not essential.
Sector angle 40° (sector scanner) or better.
Array length: 5-8 cm (linear array scanner).

2) *Controls*
To be simple and clearly arranged.
Gain control is required.
Time gain compensation to be by choice of preset and variable conditions.

3) *Frame rate*
5-10 Hz (sector scanner), 15-30 Hz (linear array scanner).

4) *Frame freeze and display*
512 x 512 x 4 bits (to provide 16 "gray" levels).

5) *Omnidirectional calipers*
One pair to be provided, with facility for quantitative read-out and recording.

6) *Patient identification*
Facilities to be provided for manually entering and recording data-patient identification, date, etc. —on the image screen.

7) *Permanent recording*
Provision must be made for the economical preparation of good-quality permanent image records.

8) *Construction*
The unit should be portable (not more than 8 kg), drip-proof, and dust-proof. Proper and continuous operation should be possible under the following conditions:

Temperature: 0°C to +40°C
Humidity: up to 95%

Prolonged storage should be possible under the following conditions:

Temperature: -30°C to +50°C
Humidity: up to 100%.

The unit should be rugged and capable of withstanding the vibration likely to occur during rough, cross-country transport. Special care should be taken to avoid failure of the transducer, its cable, and its connector under the above conditions. The mechanical design of the transducer should include:

a) Maximum protection against damage by dropping;

b) Tolerance of the use of a variety of coupling media, particularly local vegetable oils.

9) *Electrical and mechanical safety*
The equipment should conform to the standards set out by the International Electrotechnical Commission for Medical Electrical Equipment. Where interventional use is intended, particular care must be taken to ensure that the relevant standards of equipment earthing (grounding) and leakage of current are met.

10) *Power supply*
The equipment must be capable of working from any of the following types of supply:
Direct current: standard batteries, preferably rechargeable
Alternating current:
- 50 and 60 Hz
- 100, 110, 117, 125 and 200, 220, 240 V
- line voltage variation $\pm 15\%$
Surge protection to be provided.

11) *Servicing and **quality control***
Although modern equipment should be reliable and stable in performance, both failures and degradation should be anticipated; the following ***quality control*** procedures are highly recommended:
a) At regular intervals (at least every 3 months and preferably every week) the resolution and sensitivity performance of the unit should be checked using a suitable ***phantom***. Corrections should be made if there is any appreciable change in performance over a period of time.
b) Arrangements should be made (with the manufacturer or otherwise) for a centralized repair and maintenance service to be provided, to cover a number of units in a country or region.
c) Provision must be made for a supply of spare parts to be rapidly available. These parts must include spares for the transducer, the display monitors, and the principal electronic assemblies.

12) *Space*
Ultrasound examinations may be made at the bedside, but it is preferable to set aside a room that will provide both privacy (if necessary by curtains) and a suitable horizontal support for the patient. It is helpful if the room illumination can be reduced. A toilet should be provided close to this room. In busy departments the provision of several changing cubicles will increase the number of patient examinations that can be carried out. No added structural protection is required.

Appendix I-C

Design Requirements for Megavoltage

*X-Ray Machines for Cancer Treatment in Developing Countries**

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* Taken from: Borrás C, Stovall J, eds. *Design Requirements for Megavoltage X-Ray Machines for Cancer Treatment in Developing Countries: Report of an Advisory Group Consultation. Washington, D.C., 6-10 December 1993.* Los Álamos: Los Alamos National Laboratory; 1995. (LA-UR-95-4528).

Executive Summary

An Advisory Group Consultation on the Design Requirements for Megavoltage ***X-Ray*** Machines for Cancer Treatment in Developing Countries was organized by PAHO in Washington, D.C., 6-10 December 1993, with the collaboration of WHO Headquarters, the IAEA, and UNIDO. It was attended by 40 participants including radiation oncologists, physicists, technologists, and representatives from radiotherapy equipment manufacturers. The goal of this Consultation was to propose design alternatives for megavoltage ***x-ray*** units that have the potential of lower manufacturing cost, simpler design, and less frequent and costly maintenance than current ***electron accelerators***.

As the populations age, the availability of equipment, facilities, and staff for cancer treatment is emerging as a major problem in developing countries since they have only a very small percentage of the world's cancer therapy resources. According to estimates by WHO there are currently 9 million new cancer cases per year worldwide. This number is expected to increase to about 15 million new cases by the year 2015, with about two-thirds of these cases occurring in developing countries. It is likely that radiotherapy will, for years to come, remain one of the most important treatment modalities, for both cure and palliation.

The dimensions and radiation characteristics of high-energy ***x-ray*** machines required to meet the needs of developing countries were defined and found to be very similar to those of high-quality low-voltage machines presently used in the developed countries. The Consultation concurred that such a machine would be equally suited for use in both developing and developed countries.

Major performance characteristics agreed upon

Two-thirds of patients in developing countries are treated with simple parallel-opposed fields. It is desirable to avoid the more complex treatment planning required when using more than two fields. Therefore, the ***photon*** beam energy should be selected to limit hot spots and the consequent ***risk*** of fibrosis at the depth of maximum ***dose*** in thick patient sections when using parallel-opposed fields. The ***dose*** buildup should provide an adequate ***dose*** at 5 mm depth for superficial lymph node irradiation, while minimizing the skin ***dose*** to avoid telangiectasia. The beam quality should therefore be selected so that for a 25 cm thick patient the maximum ***dose*** in a 10 cm x 10 cm field will be less than 115% (preferably less than 110%) of the ***dose*** delivered to a central tumor in an equally weighted parallel-opposed beam configuration. In addition the superficial 90% isodose should occur at a depth of less than 5 mm. In practice this implies that the ***photon*** beam should provide deeper penetration than a ^{60}Co beam. In general a ***photon*** beam in the 5-6 MV range or a highly filtered 4 MV beam with low ***electron*** contamination is needed to meet these requirements. There was a strong feeling that if the machine is to be an ***accelerator***, it must provide significantly greater beam penetration than ^{60}Co.

The proposed ***x-ray*** machine should have the following dimensions:

1. Low isocenter height. No higher than 130 cm, with 115 cm preferred. A small depression in the couch turntable is permissible but generally not desirable for safety reasons.
2. A 100 cm ***source***-to-axis distance (SAD) is preferred; a SAD of 80 cm is acceptable if adequate field sizes and patient clearance in isocentric treatments are provided. An isocentric clearance of at least 35 cm from the front flange of the collimator head is required when accessories are attached.
3. The vertical travel of the couch should be at least 65 cm below isocenter. The couch rotation should be at least 90 degrees from the isocentric axis. The field size at isocenter should be at least 30 cm x 30 cm (at least 42 cm x 42 cm on the surface of a 25 cm thick patient with the couch fully lowered).

The following ***accelerator*** technologies were considered as Category A - meriting further exploration or Category B - probably usable to reach the goal

A-1. Low-energy linac, in-line ***accelerator*** design.
A-2. Low-energy linac, bent beam design.
A-3. Integrated pulsed ***klystron*** and low-energy linac combined in same vacuum envelope.
A-4. Low-energy microtron mounted in line with the radiation head.
A-5. Low-energy ***accelerator*** built of replaceable, standardized modules for ease of maintenance.
A-6. Miniaturization via shorter microwave wavelength (e.g., 3 cm instead of present 10 cm) with possible improvement of ***magnetron*** reliability.
A-7. Replacing the high-voltage modulator with a pulsed ***magnetron*** magnet.
B-1. Low-energy betatron mounted in the radiation head, with its magnet driven at about 10 kHz to achieve adequate ***x-ray*** intensity at 6 MV.
B-2. Low-energy rhodotron, a continuous-wave (cw) ***electron accelerator*** using a half-wave coaxial cavity to accelerate the beam on multiple passes.
B-3. cw microwave ***accelerator*** (no modulator, simple ***magnetron***) with reflected beam to increase accelerating potential to 4 or 6 MV.
B-4. A 2 or 2.5 MV direct current (dc) ***accelerator*** with power supplies cascaded, transformer-coupled, nested, or of an electrostatic type (i.e., Laddertron or Pelletron). ***X-ray*** beam filtered to 3 MV penetration.
B-5. ^{60}Co unit with a 100 cm SAD at 1.6-1.8 Gy/min (~3 MV equivalent penetration).

The following descriptions summarize some of these systems

1. ***Electron Linear Accelerators (Linac)***. There are approximately 2,500 linacs operating in the U.S. and perhaps double that number worldwide. Linacs are the most widely used device for the production of ***x-rays*** in the range of 4-20 MV. However, their complexity results in frequent breakdowns that can cause unacceptably long delays in patient treatments. In the U.S. these machines cost between $500,000 and $1.2 million excluding installation. To be a serious contender for developing countries, linacs would have to be

simplified to reduce their cost, and their reliability would have to be markedly improved.

2. Cobalt-60. The ^{60}Co radioactive ***source***, having a 5.3 year ***half-life***, provides a level of reliability not yet achieved by electrically powered devices. However, mechanical problems do arise that can pose serious radiation ***exposure risks*** for both the patient and medical staff because the radiation ***source*** cannot be turned "off." Because of their relatively simple mechanical construction and few electrical components, the cost of ^{60}Co units is typically less than that of ***electron accelerators***. The main problems with ^{60}Co units are their relatively low ***dose*** rates, which reduce patient throughput, a steadily decreasing ***dose*** rate over time, which dictates that the ***source*** be changed every 3-4 years, ***dose*** distributions in the patient that are inferior to those provided by high-energy ***x-ray*** machines, and disposal of spent ***sources*** which, in the past, has created public health problems in developing countries.
3. *Microtron*. There are about 40 commercially produced microtrons operating worldwide. Microtrons are inherently simpler than linacs and, with a comparable level of development, might achieve greater reliability. The production of 4-8 MV ***x-rays*** is easily achieved in a microtron 30-50 cm in diameter (depending on the injection method), which can be mounted at the treatment head of a rotating ***gantry***.
4. *Direct-coupled-**klystron**linac*. This device, under development at Los Alamos National Laboratory, is similar to the standard linac in the way it accelerates ***electrons***. However, it differs in that the ***klystron*** that is directly coupled to the ***accelerator*** is used as a radiofrequency (rf) oscillator as well as an rf amplifier. Some of the most fault-prone components of the standard linac are eliminated, simplifying both the electronic and mechanical aspects of the ***x-ray*** system.
5. *Modular-rf-supply linac*. In this proposed linac design, the rf power supply (***magnetron***-or ***klystron***-based) and the ***accelerator*** would be constructed as an integral unit, which would be replaced in its entirety should any component fail. To increase the lifetime of the ***magnetrons***, their magnets would be pulsed by a dc supply, thereby eliminating thyratrons which have a high failure rate.
6. *High-frequency linac*. The operating frequency of a standard linac is 3 GHz. Frequencies higher than 10 GHz are being investigated. Such an increase in operating frequency would result in a more compact machine with a reduction in both weight and cost.
7. *High-frequency betatron*. The first betatrons were operating in the 1940s with ***electron*** beam energies of 20-50 MeV at frequencies of 60-180 Hz. A betatron operating a 10 kHz could produce 6 MV ***x-ray*** beams having clinically acceptable ***dose*** rates. The main advantage of the betatron is its high degree of reliability that derives from its simple, low-frequency electronic components.
8. *Rhodotron*. Designed in France for food sterilization, this nonlinear ***electron accelerator*** utilizes a cw, 300 MHz rf ***source***. This lower frequency permits the use of reliable vacuum tubes, and its cw operation eliminates the need for

a high-voltage pulse modulator, hopefully improving its reliability compared with the standard linac.

9. *dc **Accelerators***. In both clinical and research laboratories, these machines have proven to be highly reliable and, because of advances in technology, can now be mounted in a compact ***gantry***. However, the 2-3 MeV maximum energy achievable was considered too low by most users. Heavy filtration would allow beam characteristics similar to a conventional 3 or 4 MeV ***accelerator***. With heavy filtration low beam currents may continue to be a problem.

Additional aspects considered and recommendations made

Many interruptions in the use of modern medical ***electron accelerators*** are caused by failures of relatively simple electrical, hydraulic, or mechanical components. Difficulties in providing satisfactory maintenance are compounded by administrative problems and delays in addition to inadequate organization, infrastructure, and funding which often lie beyond the control of the individual radiotherapy facility. Some of the problems could be avoided at the equipment design stage by incorporating components of high reliability that are already available for industrial use, and by using a modular design with easily replaceable components. It would be of additional benefit if the modules were compatible in machines from different manufacturers.

Suggestions were made for training programs and for a suitable organization to provide maintenance and to stock spare parts. It was recognized that the term "Developing Countries" has been applied to an economically very heterogeneous group of nations. In many of these nations the economy is now expanding so rapidly that the term "Developing Countries" has been changed to "Emerging Markets" by investors. In these nations, the funding situation for radiation therapy can be expected to improve markedly. This situation will affect the types and numbers of ***x-ray*** equipment that will be put into service over the next 25 years, as well as the staffing for their operation and maintenance. It is hoped that this change will spread to all developing countries.

The current manufacturers of ***electron*** linear ***accelerators*** and microtrons should be encouraged to design and prototype a super-reliable ***x-ray*** system operating in the 4-6 MV range and meeting the established performance specifications. This encouragement should come from the ***accelerator*** designers who might cooperate with the manufacturers as well as representatives of the developing nations who can best make the case for their needs.

APPENDIX II

Mammography Legislation

Appendix II-A

*Argentine Mammography Law**

* Taken from: Argentina, Ministerio de Salud y Acción Social. *Normas relativas a la instalación y funcionamiento de equipos generadores de rayos X.* Buenos Aires: MSAS; 1991. (Free translation).

Argentine Republic

National Executive Branch
Ministry of Health and Social Action

Standards regarding the installation and operation of x-ray generating equipment

Law N° 17.557/67
Decree N° 6.320/68
Decree N° 1.648/70
(Modification of Decree N° 6.320/68)
Resolution N° 2.680/68
Resolution N° 273/86
(Modification of Resolution 2680/68)
Directive N° 30/91
Resolution N° 631/90
Directive N° 259/91
Directive N° 560/91
Resolution N° 61/92

Buenos Aires
1993

Directive (SASPS) N° 560. 26 March 1991.

Having examined File 1-2020-24832/90-2, and
Considering

that mammography is a recognized method for the diagnosis of preclinical breast cancer;

that the survival rate depends on the stage at which the disease is diagnosed, the 5-year survival rate being more than 90% for stage I;

that the induction of breast cancer by ***ionizing radiation*** is probably a linear function of the ***absorbed dose***;

that it is essential that all ***exposures*** to ***ionizing radiation*** be kept as low as is reasonably achievable;

that the present action is taken in accordance with Article 19 of Decree N° 6320/68, a regulation under Law N° 17,557;

The Under Secretary of Health Services and Programs Administration therefore directs that:

Article 1 --- Mammographies shall be carried out in installations ***licensed*** to this end, in accordance with the provisions of Law N° 17,557, and they shall meet the technical specifications described in Annexes I and II, which are part of the present directive.

Article 2 --- The ***practices*** alluded to in the foregoing article shall always be conducted by a medical professional who possesses the required individual ***authorization*** (Article 17 of Decree N° 6320/68).

Article 3 --- Mammograms shall be interpreted by medical professionals who have received specialized training in this area in establishments recognized by the Ministry of Health and Social Action. Auxiliary personnel shall also have received training in mammography techniques in similar establishments.

Article 4 --- Mammographies shall be performed only with dedicated radiological equipment specially designed for this purpose; the equipment shall have a target material, focal spot, and filtration suited to the image receptor utilized.

Article 5 --- Radiographic films with intensifying screens especially designed for mammography or Xerox systems shall be used as image receptors. In no case shall radiographic films without intensifying screens be utilized.

Article 6 --- Mammography equipment shall have a suitable breast compressor.

Article 7 --- The quality of the radiological images produced shall be verified periodically through the establishment of ***quality assurance*** programs. The programs shall monitor each phase of the operations of mammography installations and shall include quality management inspection techniques and procedures. The

inspection techniques shall include monitoring, evaluation, and maintenance in optimum condition of all performance characteristics that can be defined, measured, and controlled. Administrative management procedures shall be aimed at ensuring that the techniques are implemented, that they are evaluated correctly, and that the necessary corrective measures are taken.

Article 8 --- The ***doses*** produced by techniques used in mammography shall be measured. The entrance values measured shall be converted to ***average mammary glandular doses*** using the conversion table in Annex II. It is recommended that the ***average glandular dose*** for breast tissue 4.5 cm thick not exceed 1 mGy for film-screen systems without antiscatter grids and 4 mGy for film-screen systems with antiscatter grids or Xerox systems. ***Doses*** exceeding these values are not justified.

Article 9 --- The Advisory Commission on Mammography is hereby created; the Commission shall be made up of representatives of the technical areas of medical radiation physics at the national and provincial levels and representatives of the Argentine Societies of Mastology, Gynecology, Radiology, Diagnostic Imaging, and Radiation Therapy.

Article 10 --- The Commission shall be chaired by the Under Secretary for Health Services and Programs Administration or an official designated by him and shall be coordinated by the representative of the corresponding technical area at the national level.

Article 11 --- The Commission's functions shall be to advise the authorities and institutions concerned with mammography on matters relating to the subject and to promote further study with a view to updating the present standards.

Article 12 --- This directive shall be recorded, disseminated, published, transmitted to the National Bureau of Records, and filed.

Annex I

	Target Material	Focal Spot	Total Filtration
Mammography with film-screen	molybdenum	0.3-0.6 mm	0.03 mm Mo
Magnification technique*	molybdenum	0.1-0.3 mm	0.03 mm Mo
Xerox system	molybdenum	0.5-1.0 mm	1-1.5 mm Al

* requires low-ripple *generator* (triphase rectification or high frequency).

Annex II

Average mammary glandular dose, D_{gN}, per unit of *exposure* in air (rad/R) (cGy/ 2.58 x 10^{-4} C kg^{-1})

Breast Thickness (cm)	Mo Target Half-Value Layer (mm Al)		W Target Half-Value Layer (mm Al)				
-	0.31	0.30	0.8	1.0	1.2	1.4	1.6
3.0	0.22	0.22	0.47	0.535	0.595	0.645	0.71
3.5	0.195	0.20	0.43	0.49	0.55	0.605	0.665
4.0	0.175	0.185	0.395	0.455	0.515	0.57	0.63
4.5	0.155	0.17	0.365	0.425	0.48	0.54	0.595
5.0	0.14	0.15	0.335	0.395	0.45	0.51	0.565
5.5	0.125	0.14	0.315	0.375	0.425	0.485	0.54
6.0	0.115	0.125	0.295	0.35	0.40	0.46	0.515
6.5	0.105	0.11	0.275	0.33	0.38	0.435	0.49
7.0	0.095	0.10	0.26	0.31	0.36	0.415	0.47
7.5	-	-	0.245	0.29	0.34	0.395	0.445
8.0	-	-	0.23	0.275	0.325	0.375	0.425

Appendix II-B

United States Mammography Law

Summary Review (1995) of the 1992

*Mammography Quality Standards Act (MQSA)**

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* Taken from: United States, Food and Drug Administration, Division of Mammography Quality and Radiation Programs. *What a mammography facility should do to prepare for the MQSA inspection.* Rockville: FDA; 1995.

What a Mammography Facility should Do to Prepare for the MQSA Inspection

The Mammography Quality Standards Act (MQSA) of 1992 requires that, starting October 1, 1994, each facility conducting mammography in the United States (except those of the Department of Veterans Affairs) be certified by the Food and Drug Administration (FDA) and undergo an annual MQSA inspection.

This document gives an overview of the inspection procedures that will be followed. It also describes facility responsibilities and recommends actions that the facility may take prior to the inspection to minimize disruption and inspection time.

Each inspection will be scheduled with the facility in advance (at least 5 working days notice), will include equipment tests and records review, and will be followed by a summary report. The exception to advance scheduling will be in certain cases where FDA has reason to believe that conditions at the facility may present a threat to public health.

INTRODUCTION

MQSA requires that all mammography facilities:

- Meet quality standards for personnel, equipment, maximum allowable radiation ***dose***, ***quality assurance***, medical audit (system to track positive mammographic findings) and outcome analysis, and record keeping and reporting.
- Apply for and become accredited by an FDA-approved accreditation body. Currently, the American College of Radiology (ACR) and the States of Iowa, California, and Arkansas are FDA-approved accreditation bodies.

When a facility is accredited, the accreditation body notifies the FDA and the FDA issues an MQSA certificate to the facility. The facility must display the certificate where it can be viewed by mammography examinees (patients).

Since October 1, 1994, only certified mammography facilities may lawfully conduct mammography. Once certified, each facility must maintain its certified status by:

- Having an annual survey performed by a qualified medical physicist,
- Undergoing periodic audits and/or clinical image reviews by the accreditation body,
- Permitting an annual inspection conducted by an FDA-certified MQSA inspector,
- Paying an inspection fee (and re-inspection fee, where applicable), and
- Correcting any deficiencies found during inspections.

Since October 1, 1994, the Health Care Financing Administration (HCFA) has been accepting MQSA certification as evidence of compliance with mammography quality standards. Only MQSA certified facilities will receive Medicare/Medicaid payment for screening and diagnostic mammography.

FACILITY INSPECTION

Certified MQSA inspectors will check the facility's compliance with MQSA quality standards during each inspection, and any deficiencies found must be corrected. The quality standards were published as federal regulations in the December 21, 1993 issue of the *Federal Register* and amended in the September 30, 1994 issue, and were previously mailed to all mammography facilities. The required records listed in this document are based on these standards. Items and issues in the required records that are not specifically addressed in the standards, are based on FDA policy and interpretative guidelines.

To keep inspection costs to a minimum without compromising the quality required by MQSA, the scope of the MQSA inspection will be limited to items that have the most direct bearing on facility performance and mammographic quality. However, in order to eliminate the need for a separate and additional State mammography inspection, some States may add to the MQSA inspection some elements that are required by their State laws. Facilities should be aware of their State radiation control program requirements.

MQSA inspection procedures are designed to cover the following areas:

- Equipment performance (including image quality and ***dose***)
- ***Quality Assurance (QA)*** records
- ***Quality Control (QC)*** records and tests
  - Technologist tests
  - Medical physicist's annual survey report
- Medical audit and outcome analysis records
- Medical records (mammography reports and films)
- Personnel qualification records

Based on the scope of the tests and records review outlined below and our experience with MQSA inspections to date, the average on-site inspection time for a facility with a single ***x-ray*** unit is estimated to be about six hours.

We estimate that the inspector will require one hour to test each mammography ***x-ray*** unit and darkroom/film processor combination. The remainder of the inspector's time will be spent reviewing facility records. We recommend that you schedule a block of time for the testing of each ***x-ray*** unit and film processor combination to help minimize any inconvenience to patient care from the inspection process. For the remainder to the inspection time, staff may conduct their usual duties but should be available during the records review portion, should the inspector have questions or need assistance.

PRIOR NOTIFICATION

A facility normally will receive at least five business days advance notice before an inspection. The inspector will schedule a mutually agreeable inspection date. FDA recommends that the facility prepare for the inspection in advance, primarily by assembling in one location the records the inspector will need to review, such as ***QA/QC*** records, medical audit and outcome analysis records, the physicist's report and personnel qualification records. These records are described more fully below. Organizing these records before the inspector arrives will minimize disruption to services and avoid searching for documents during the

inspection. Whenever possible, certified MQSA inspectors have been advised to hold off any questions they have until the end of the inspection, in order to allow facility personnel to attend to their normal duties for most of the day.

SCOPE OF THE INSPECTION

At the outset of the inspection, the inspector will meet briefly with a facility representative(s) who is referred to in our program as the "Facility Contact," such as the radiology administrator, radiologist, chief technologist or ***QC*** technologist, to verify preliminary facility information. The inspector will then briefly review the inspection agenda with that person(s). When the inspection is completed, the inspector will again meet with the facility representative(s) to review inspection results.

INSPECTION DATA COLLECTED

The inspection will cover the tests and records review outlined below and will use a laptop computer and an inspection software program to input inspection data. The order in which the tests and records review are performed may be varied to minimize interruption of the facility's normal schedule.[1]

Equipment tests

These tests should take about one hour per ***x-ray*** unit/processor. For most of the tests, the inspector will use the facility's film and cassettes with technique factors that the facility normally uses for their average breast examination. The inspector will request assistance from one of the facility's technologists in setting-up technique factors, operating the equipment, and any other preparatory work needed for each of the following tests:

1. Collimation Assessment (***x-ray*** field/image receptor and image receptor/compression device alignments).
2. Entrance Skin ***Exposure*** and ***Exposure*** Reproducibility.
3. Beam Quality (***half-value layer*** [HVL]) Measurement (this test and the previous one are used for ***dose*** calculation).
4. ***Phantom*** Image Quality Evaluation (including ***phantom*** scoring).
5. Processor Evaluation and Darkroom Fog.

Records

Quality Assurance (QA) *Program.* The ***QA*** program should include the following information (Ref. 1992 and 1994 ACR *Mammography Quality Control [MQC] Manual*, radiologist's section):

1. Personnel responsibilities and procedures for ***QA/QC*** testing (procedures used may be the same as those contained in the ACR MQC Manual).
2. Procedures for equipment use and maintenance (equip. owner/operator's manual) for both the ***x-ray*** units(s) and processor(s).

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[1] Contents of the data entry screens used by the inspector are shown at the end of the document where this appendix was taken from, but are not reproduced here.

3. Equipment service records (***x-ray*** unit(s) and processor(s)).
4. Mammographic technique charts, including information pertinent to optimizing mammographic quality, such as positioning and compression.
5. Any other ***QA***-related written policies, procedures, and records.

Quality Control (QC) *Tests*. Records of the 11 tests/tasks listed below should be available (Ref. 1992 & 1994 ACR *MQC Manual*, technologist's section). We expect facilities not to take clinical images when any critical parameter that monitors the daily performance of the processor, exceeds action ***limits***. Also, the repeat analysis test should be conducted quarterly and should include all the films taken in the quarter regardless of how many patients were examined in the quarter. In general, the facility's ***QC*** records should show that all tests were:

- conducted at the appropriate frequencies,
- conducted properly (using parameter values as recommended in the ACR manuals),
- followed by documented corrective actions when necessary.

The inspector will review past records (1) over the indicated period listed for each, or (2) back to the date of the original accreditation, whichever is the shortest:

- The previous 12 months records for each of the following:
  1. Darkroom Cleanliness
  2. Processor ***Quality Control***
  3. Screen Cleanliness
  4. Viewboxes and Viewing Conditions
  5. ***Phantom*** Images
  6. Visual Check List
  7. Repeat Analysis
  8. Analysis of Fixer Retention in Film
  9. Darkroom Fog
  10. Screen-Film Contact
  11. Compression
- Actual sensitometric film strips for the previous 30 days of mammographic film processing and charting of the strips for the previous 12 months.
- ***Phantom*** images and charting for the previous 12 months.
- Images from screen-film contact and darkroom fog tests for the previous 12 months.

Mobile Mammography. The requirements for mobile radiographic units are the same as for fixed units. This means that the ***exposure*** and development of a ***phantom*** image after each relocation of a mobile unit and prior to patient ***exposure***, which was previously required for Medicare and Medicaid payment under the Health Care Financing Administration (HCFA), is no longer required under the MQSA interim final regulations.

Although the 1992 version of the ACR *MQC Manual* includes the recommendation that a ***phantom*** image be exposed after each relocation of a mobile unit, there was no suggestion that the image be processed and scored prior

to patient imaging. The 1994 version of the ACR manual does not include any recommendations on ***phantom*** images specific to mobile units. Therefore, the only ***phantom*** images required are those exposed monthly. Certified MQSA inspectors will simply ask to see records of the monthly ***phantom*** images for a mobile unit, just as for a fixed unit.

Medical Physicist's Survey Report. The most recent annual report covering an evaluation of the 11 technologist's ***QC*** program tests and the 10 physicist's ***QC*** tests (Ref. 1992 & 1994 ACR *MQC Manual*, medical physicist's section) for each ***x-ray*** unit.

Personnel Qualifications. The required records for each personnel category are listed below and must be available for the inspector to review (please refer to the Note following each professional category):

Interpreting Physician

1. License to practice medicine in the State, and
2. certificate in radiology or diagnostic radiology from any of the following boards:
   - The American Board of Radiology (ABR)
   - The American Osteopathic Board of Radiology (AOBR)
   - The Royal College of Physicians and Surgeons of Canada (RCPSC), or:

   Documented 2 months full-time training in mammography interpretation, including radiation physics, radiation effects, and radiation protection, and
3. Documents showing 40 hours of continuing medical education (CME) in mammography (time spent in residency specifically devoted to mammography can be included), and
4. Documents showing initial experience in reading/interpretation of mammograms from 240 patients during any 6 month period preceding October 1, 1994. Any such experience acquired after October 1, 1994, must be under the supervision of a qualified interpreting physician, and
5. Documents showing continuing experience in reading and interpreting mammograms from the examinations of an average of at least 40 patients per month over 24 months, and
6. Documents showing an average of five CME credits per year in mammography.

Note 1: Double reading/interpreting of mammograms, or summing of reading/interpreting from different facilities is permitted in calculating the total mammographic examinations for items 4 and 5 above.

Note 2: If documentation is not available for interpreting physicians, attestation will be acceptable for items 3 and 4 for CME and experience acquired prior to October 1, 1994.

Note 3: The starting date for meeting the requirements in items 5 and 6 above is the later of October 1, 1994 or the date the physician met the requirements in items 1-4 above.

Note 4: Failure to meet the continuing experience requirement in item 5 above will not be considered a noncompliance until at least 2 years after the physician's starting date (as defined in note 3). Likewise, failure to meet the CME requirement in item 6 above will not be considered a noncompliance until 3 years after the physician's starting date. However, in order to be prepared for the future, the facility should begin keeping records on progress towards meeting the starting date requirements for each physician.

Radiologic Technologist

1. General/full ***license*** to perform radiographic procedures in a State, or Certificate from either one of the following two boards:
   - The American Registry of Radiologic Technologists (ARRT)
   - The American Registry of Clinical Radiography Technologists (ARCRT), (only general radiologic technology certification, not advanced certification in mammography, is required), and
2. Documents showing either:
   - training specific to mammography (40 credit hours or equivalent), or
   - one year experience in performing mammography (or 100 exams), and
3. Documents showing an average of five continuing education units (CEUs) per year in mammography.

Note 1: If documentation is not available for radiologic technologists, attestation will be acceptable for item 2 above for training or experience acquired prior to October 1, 1994.

Note 2: The starting date for meeting the CEU requirements in item 3 above is the later of October 1, 1994 or the date the technologist met the requirements in items 1 and 2 above.

Note 3: Failure to meet the requirements in item 3 above will not be considered a noncompliance until 3 years after the technologist's starting date. However, in order to be prepared for the future, the facility should begin keeping records on progress towards meeting the starting date requirements for each technologist.

Medical Physicist

1. a. State License, or:
   b. State Approval, or:
   c. Certificate in diagnostic radiological physics or radiological physics from either one of the following boards:
      - The American Board of Radiology (ABR)
      - The American Board of Medical Physics (ABMP), or:
   d. i. M.S. degree or higher in one of the following fields: physics, medical physics, applied physics, biophysics, health physics, engineering, radiation science, or in public health with a BA/BS in physical science, and
      ii. Documents showing one year training in diagnostic radiologic physics, and

iii. Documents showing two years experience in mammography surveys (or 20 surveys), and

2. Documents showing an average of five (CMEs per year in mammography.

Note 1: If documentation is not available for medical physicists, attestation will be acceptable for items 1d.ii and 1d.iii for training and experience acquired prior to October 1, 1994.

Note 2: The starting date for meeting the CME requirements in item 2 above is the later of October 1, 1994 or the date the physicist met the requirement in item 1 above.

Note 3: Failure to meet the requirement in item 2 above will not be considered a noncompliance until 3 years after the physicist's starting date. However, in order to be prepared for the future, the facility should begin keeping records on progress towards meeting the starting date requirements for each physicist.

Medical Records

These are the examinee (patient) permanent records of mammography reports and films (mammograms).

Examinee (patient) Permanent Records (reports and films)

The inspector will randomly select records dated after October 1, 1994, to ensure that both films and reports are being retained at the facility or at another identifiable location.

Mammography Reports

The inspector will ask for a sample of a report that the facility sent (or would send) to a referring health care provider and a sample of a lay summary of positive mammographic findings that the facility sent (or would send) to a self-referred examinee (if the facility provides services to self-referred examinees). Additionally, the inspector will randomly select reports that were done after October 1, 1994, to verify that these reports have an interpreting physician identified (signed) and that they contain the results of the examination. The facility should also be prepared to explain its procedure for communicating test results to referring physicians and self-referred examinees.

Medical Audit and Outcome Analysis

Each facility must have a system to track positive mammographic findings and a process to correlate such findings with the biopsy results the facility has obtained. The audit system need not be computerized. "Positive" mammograms refer to mammograms interpreted as suspicious for cancer or highly suggestive of cancer or where biopsy is recommended. The minimum biopsy data, when obtained, should indicate if the specimen was benign or malignant. The inspector will examine the facility's tracking system and inquire as to how the facility obtains biopsy results. The inspector will also request to see examples of biopsy results that the facility has obtained or, if no biopsies were obtained, documentation of attempts to get this information.

AFTER THE INSPECTION

The inspector will review the results of the inspection with the facility representative(s) and either leave a summary of the inspector's findings with him/her, or mail this summary to the facility within two weeks. In some cases, the facility will be requested to respond to the FDA within 30 days after receiving the summary regarding its plans for correcting identified deficiencies. In other cases, the facility will be expected to correct the deficiencies, but will not be required to follow with a written response.

If major deficiencies are found, the facility will receive a letter from the FDA addressed to the facility's "Responsible Person." This should be a person who has the authority to make vital operational and financial decisions concerning corrective actions that are required to bring the facility into compliance. The letter will describe the deficiencies that need to be corrected. All deficiencies are expected to be corrected as soon as possible. When it is determined that the deficiencies found could affect mammographic quality directly, the facility should correct the deficiencies before conducting further mammography examinations. Facilities that continue to operate under deficient conditions are subject to certificate suspension and other sanctions.

FDA will bill each facility after the inspection. The bill is addressed to the facility's billing name (if different) and to the attention of the person responsible for paying the bills such as the accountant or financial officer. The bill is due 30 days after it is received by the facility. Certain "governmental entities" are exempt from the inspection fee. The inspection fee for fiscal year 1995 is $1,178 for a facility with one mammography unit, $152 for each additional unit and $670 for any follow-up inspections needed.[2] Facilities will receive information on inspection fees and governmental entity exemption criteria in a separate mailing. FDA is committed to improving nationwide mammography services. To this end, the FDA's objective is to ensure that all facilities achieve the minimum quality standards set by MQSA so that all women will receive quality mammography services.

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[2] Fees still in effect in 1997.

APPENDIX III

Spanish Guide for the Training of Medical and Technical Specialists

Appendix III-A

Spanish Guide for the Training of Medical Specialists

*Diagnostic Imaging**

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* Taken from: España, Ministerio de Sanidad y Consumo, Consejo Nacional de Epecialidades Médicas y Consejo Nacional de Especialidades Farmacéuticas. *Guía de formación de especialistas*. Madrid: Ministerio de Sanidad y Consumo; 1986. (Free translation). (An updated version of this Guide was published in 1996.)

A) Definition of the Specialty

The specialty of diagnostic imaging is the branch of medicine that deals with diagnostic morphology, i.e., the study of images obtained through the use of ***ionizing radiation*** and other energy sources, as well as certain other diagnostic and therapeutic processes, the execution and control of which requires the use of such energy sources.

B) Sphere of Action, Nature of the Specialty, and Possible Areas for Specific Training

Through the program presented by this Commission, current specialists in diagnostic imaging will be trained to perform, interpret, and explain all diagnostic imaging techniques, as well as the diagnostic and therapeutic procedures generally carried out with the aid of radiological images.

Specific training areas considered are neuroradiology and pediatric radiology.

C) Content and Duration of the Training Program

The duration of the training program for diagnostic imaging residents will be four calendar years.

The theoretical component of the program will be imparted over the four-year period and will include courses in the basic sciences related to diagnostic imaging and subjects specific to the specialty.

The resident will receive instruction in radiation physics, radiation biology, and radiation protection, if possible during the first year. The teaching hospital will be responsible for ensuring that its residents obtain certification as supervisors of installations utilizing radioactive materials.

During the fourth year, the resident will receive instruction in the organization of diagnostic imaging departments.

The diagnostic imaging service will conduct a minimum number of sessions in radiology and clinical radiology, which will be indicated in the criteria for accreditation. Residents will attend all the such sessions and will collaborate actively in the preparation and execution thereof.

Residents' attendance at congresses, scientific meetings, courses, and conferences relating to the specialty will be facilitated.

Residents will take part in research from the beginning of their training. The diagnostic imaging service will encourage and facilitate the involvement of residents in research and will make it possible for them to complete their doctoral dissertations during their residency.

The specialization program will comprise rotations in the different sections of the service, according to the attached timetable.

Residents will complete one six-month rotation that will include internal medicine, surgery (five months) and radiological technique (one month). The latter is absolutely mandatory. The rotation in internal medicine and surgery is also considered mandatory, unless the resident can demonstrate to the local

education commission that during his/her education he/she has acquired the minimum necessary clinical training.

	3 Months	3 Months	3 Months	3 Months
1st year	Internal Medicine Surgery Radiological Technique		Chest	Bone
2nd year	Urology	Digestive System	Ultra-sonography	CT
3rd year	Neuro-radiology	Vascular Radiology	Mammography Gynecological Radiology OB/GYN Ultra-sonography	Pediatric Radiology
4th year	Ultrasonography Chest Bone Digestive System		Elective Pathological Anatomy Nuclear Medicine	
	8 Months		4 Months	

During the next eighteen months, residents will complete rotations in the areas that constitute basic radiology: radiography of the chest, bones, urology, and digestive system, ultrasonography, and computed tomography. Each rotation will last three months.

The third year will include rotations in those sections that require greater technical sophistication: neuroradiology; vascular radiology; mammography coupled with gynecological radiology, gynecological ultrasonography, and gynecological and obstetric ultrasonography; and pediatric radiology. Each of these rotations will also last three months.

In the fourth year, residents will spend the first eight months in another rotation devoted to ultrasonography and radiography of the chest, bones, and digestive system. In the final four months they will have the option of choosing a rotation in pathological anatomy, nuclear medicine, or an elective rotation.

All the techniques of interventional radiology, both diagnostic and therapeutic, will be covered in the corresponding rotations in the various sections.

Residents will be included on the on-call roster of the diagnostic imaging service; fourth-year residents, at the discretion of this Commission, may be given full responsibility both in their hospital on-call work and their daily duties.

D) Quantitative Requirements for the Program

It is difficult to present detailed quantitative requirements for the diagnostic imaging program. The requirements are closely linked to the criteria for accreditation of diagnostic imaging teaching centers and include the following:

1. Teaching hospitals should possess the necessary capabilities to practice all the techniques currently in use in our country. In some cases accreditation may be granted to a hospital that lacks two of the following four radiology

sections: pediatric radiology, neuroradiology, gynecological-obstetric radiology, and therapeutic interventional radiology. Single-specialty hospitals will not be accredited as teaching hospitals.

2. The accreditation documentation should clearly describe the purposes and objectives of the unit; its organization and administration; its management and staff; its physical facilities and equipment; programs, planning, and activities of the personnel; and a detailed training and ***quality control*** program.
3. No fewer than two, but no more than four, residents should be trained per year.
4. The service must carry out a minimum of 10,000 radiological studies per resident per year. Hence, with two residents per year, the total numbers of studies would be:
   10,000 studies x 2 residents x 4 years = 80,000 studies/year
   With four residents:
   10,000 studies x 4 residents x 4 years = 160,000 studies/year
   With three residents:
   10,000 studies x 3 residents x 4 years = 120,000 studies/year
5. The approximate percentage distribution of these studies would be as follows:

	%
Chest	40
Bones	30
Digestive system	8
Urography	5
CT	6
Ultrasonography	9
Vascular system	1
Other	1

   Each section must be actively practicing the various techniques of diagnostic and therapeutic interventional radiology.
6. With respect to the curriculum, the guide presented by the previous Commission is considered appropriate. That guide is contained in the "Guide for the Training of Medical Specialists: Section 36, Diagnostic Imaging Service."

Appendix III-B

Spanish Guide for the Training of Medical Specialists

*Radiation Oncology**

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* Taken from: España, Ministerio de Sanidad y Consumo, Consejo Nacional de Especialidades Médicas y Consejo Nacional de Especialidades Farmacéuticas. *Guía de formación de especialistas*. Madrid: Ministerio de Sanidad y Consumo; 1986. (Free translation). (An updated version of this Guide was published in 1996.)

Radiation Oncology

1. Definition of the Specialty

Radiation oncology is a medical specialty concerned with the diagnosis, clinical care, and treatment of the oncological patient. It is primarily oriented toward the use of radiation treatments, as well as the use and assessment of the relative value of alternative or associated treatments, and research and education.

2. Sphere of Action, Nature of the Specialty, and Possible Areas for Specific Training

Radiation oncology as a medical specialty is concerned with the following:

2.1 Study of the natural epidemiological aspects, diagnosis, treatment, and follow up of all patients—whether or not they are oncological patients—for whom treatment with radiation may be indicated.

2.2 Study and application of the concepts of radiation physics to research, radiometry, clinical dosimetry, and the protection of personnel exposed to radiation.

2.3 Study and application of the concepts of radiation biology, both in the experimental and clinical fields.

2.4 Study and application of the physical agents used in the specific diagnostic techniques employed in radiation oncology (localization, centering, simulation).

2.5 Planning, execution, and control of radiation treatments.

2.6 Knowledge and application of treatments involving interstitial radiation therapy, the ***practice*** of which requires appropriate training.

2.7 Planning of treatment simulations and utilization of alternative and associated treatments in order to develop an integrated treatment strategy.

2.8 Early detection and prompt treatment of disease-related or iatrogenic complications.

2.9 Utilization of all available biological, physical, and technical resources in research and teaching programs in the field of radiation oncology.

Content and Duration of the Training Program

First year

The entire first year is devoted to general clinical training. The radiation oncology residents will be included on the on-call roster of the hospital and will work under the same conditions as residents in internal medicine.

During this year, optionally and in accordance with the directives of the education committee of each center, residents may participate in rotations in services related indirectly to radiation oncology.

In any case, residents must complete at least 6 months' training in internal medicine.

Second year

Residents will complete a rotation of four months in radiation physics and dosimetry; the remaining months in the second year will be spent in the external radiation therapy section.

The education committees of the centers are authorized to distribute this time among these areas and other basic areas, if any are available (radiation biology, radiation protection, etc.), following the timetable that is most appropriate for each center.

During this period, residents should achieve the cognitive objectives in the basic sciences and radiation therapy.

Residents will be expected to attend the clinical and clinical anatomy sessions of the service at least once a week; general bibliography sessions and in-depth, single-topic seminars twice monthly, and at least four graduate lectures a year on subjects relating to the specialty.

Third year

In the third year residents will complete rotations in all teletherapy units and their complementary services and spend no fewer than four months in the brachytherapy unit.

During this period, residents should achieve all the cognitive objectives of the program.

Residents will be expected to participate actively in the clinical, clinical anatomy, bibliographic, and single-topic sessions.

Fourth year

In the last year, residents will perfect their skills by working, with increasing responsibility, in all sections of the service.

During this period, residents should achieve the psychomotor and affective objectives of the program.

Residents will participate in all the scientific and instructional activities of the service.

It is advisable that residents obtain certification as supervisors of installations utilizing radioactive materials.

Definition of Objectives for the Training of Specialists in Radiation Oncology

1. Cognitive objectives in the basic sciences of radiation therapy and oncology.
2. Cognitive objectives in external radiation therapy.
3. Cognitive objectives in brachytherapy.
4. Cognitive objectives in cancer chemotherapy.
5. Psychomotor objectives.
6. Affective objectives.

1. Cognitive objectives

1.00 *Basic Sciences*[1]

1.01 *Radiation Physics*. After completing the training program, the specialist will be able to:

- 1.01.1 Describe the atomic models that explain the phenomenon of the interaction of radiation with matter.
- 1.01.2 Describe the phenomena of natural and artificial ***radioactivity***, as well as the physical laws that govern them.
- 1.01.3 Identify the differences between electromagnetic and corpuscular, ***ionizing*** and non-***ionizing radiation***.
- 1.01.4 Describe the origin, nature, classification, and mechanism for the production of radiation used in radiation therapy (RT).
- 1.01.5 Describe the physical and physicochemical phenomena involved in the interaction of the radiation used in RT with matter.
- 1.01.6 Define the physical quantities and units used in RT, as well as their equivalencies.
- 1.01.7 Describe the methods used to detect and measure the radiation used in RT, as well as the equipment utilized.
- 1.01.8 Describe, qualitatively and quantitatively, the values that define the ***dose*** distribution in an irradiated material.
- 1.01.9 Describe the way in which the equipment used in the production and application of radiation in RT works.
- 1.01.10 Name the ***isotopes*** used in radiation oncology, identifying their specific physical characteristics.
- 1.01.11 Describe the mechanisms through which heat is produced in the body, as well as the generating apparatus and their dosage.

1.02 *Statistics*. After completing the training program, the specialist will be able to:

- 1.02.1 Define basic statistical concepts, as well as the statistical and biometric methods used in research and ***quality control*** in radiation therapy and oncology (RTO).
- 1.02.2 Give mathematic descriptions of linear, exponential, and logarithmic functions.
- 1.02.3 Explain the basic concepts of compartmental analysis and name its most important clinical applications.

1.03 *Information Science*. After completing the training, the specialist will be able to:

- 1.03.1 Describe the basic electronic components that perform logical-binary operations.
- 1.03.2 Explain the basic components of the hardware of a computer.
- 1.03.3 Describe the input/output units (peripherals) of a computer.

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[1] Objectives are numbered according to the following system: first digit—type of objective; second and third digits—specific subject matter; fourth and fifth digits—objectives.

1.03.4 Illustrate, using a block diagram, the sequence that links ordinary language with machine language.

1.03.5 Name the most common applications of data processing in RTO.

1.03.6 Describe the methods for developing and utilizing a database and file registry of clinical documents in RTO.

1.04 *History of Radiology*. After completing the training program, the specialist will be able to:

1.04.1 Explain how the concept of radiation therapy is applied in the various medical disciplines and describe the historical evolution of its application in these areas.

1.04.2 Describe the principal international and national schools of thought in radiation therapy.

1.04.3 Name the principal national and international radiation oncologists.

1.04.4 Describe the historical origins and principal milestones in the evolution of radiation therapy.

1.04.5 Identify the changes that have occurred in the application of radiation therapy, the dates when they occurred, and the reasons that prompted them.

1.05 *Radiation biology*. After completing the training program, the specialist will be able to:

1.05.1 Describe chronoradiobiology.

1.05.2 Describe the action of the physical agents (***ionizing*** and non-***ionizing***) used in radiation therapy, distinguishing between ***stochastic*** and ***deterministic effects***.

1.05.3 Describe the action of these physical agents on healthy or normal cells, tissues, organs, and whole bodies.

1.05.4 Describe the action of these physical agents on morbid cells, tissues, organs, and bodies.

1.05.5 Define the terms "latency," "fractionation," and "protection."

1.05.6 Define the terms "radiosensitivity," "radiocurability," and "radiation resistance," as well as the general principles of their clinical application and management.

1.05.7 Define postirradiation syndrome and disease, as well as the general principles of their clinical treatment.

1.05.8 Define iatrogenesis and the various types of iatrogenic effects (involuntary, deliberate, negligent), with assessment of the ***risk*** factors.

1.06 *Basic Oncology*. After completing the training program, the specialist will be able to:

1.06.1 Describe the differential characteristics of tumor cells and normal cells.

1.06.2 Describe tumor biology at the cell and tissue level, both *in vivo* and *in vitro*.

1.06.3 Describe the mechanisms and causes of neoplastic cellular transformation.

1.06.4 Define the epidemiological methods used in research and clinical ***practice*** in oncology and radiation therapy.

1.06.5 Describe the characteristics and histological varieties of malignant neoplasms.

1.06.6 Describe the immune mechanisms and other aspects of the tumor-host relationship.

1.06.7 Explain the basic principles of treatment with hormonal and immunological chemotherapy agents.

1.06.8 List and describe the various chemotherapy agents.

1.06.9 List and describe the ways in which the various chemotherapy agents work.

1.06.10 Explain the pharmacodynamics and pharmacokinetics of the various chemotherapy agents.

1.06.11 Explain the results of hormone determination tests.

1.06.12 Describe therapeutic procedures, indicating route of administration, specific treatment modalities, maximum ***doses***, ***dose*** modification factors, etc.

1.06.13 Describe the adverse effects of the various chemotherapy agents.

1.06.14 Describe the indications and contraindications for use of the various chemotherapy agents in the treatment of solid tumors and hematological cancers.

1.07 *Clinical Management of Diseases Susceptible to Treatment with Radiation Therapy*. After completing the training program, the specialist will be able to:

1.07.1 Describe the diseases susceptible to treatment with radiation therapy, including their etiology, pathogenesis, symptomatology, staging, pathological anatomy, differential diagnosis.

1.07.2 Name and describe the principal disease classification systems (the International Classification of Diseases [ICD] of WHO, the TNM [tumor staging] system of the International Union Against Cancer [IUAC], FIGO, etc.).

1.07.3 Describe and classify the principal pharmacological agents (not chemotherapy agents) utilized in the treatment of diseases susceptible to radiation therapy (radiosensitizers, radioprotectors, anti-inflammatory drugs, symptomatic medication, etc.).

1.08 *Radiation Therapy Technique*. After completing the training program, the specialist will be able to:

1.08.1 Describe the various techniques used in the treatment of diseases susceptible to radiation therapy.

1.08.1.1 Delimit the field of RT within RTO, as well as its interrelationships with the other medical-surgical specialties.

1.08.1.2 Define the concept of external radiation (ER) therapy and its significance within radiation therapy and oncology (RTO).

1.08.1.3 Define the concepts of curietherapy and brachytherapy and their significance within the field of RTO.

1.08.2 Classify the various techniques used in treating diseases susceptible to radiation therapy in terms of:

1.08.2.1 Energy.

1.08.2.2 Proximity of the ***source*** to the irradiated object.

1.08.2.3 Movement or non-movement of the ***source***.

1.08.3 Determine the indications and contraindications for ER and for curietherapy and brachytherapy, used alone or in combination.

1.08.4 Describe the various RT techniques used for each disease susceptible to treatment with radiation therapy.

1.08.5 Describe the theoretical basis underlying the particular characteristics of curietherapy and brachytherapy.

1.08.6 List the indications for external radiation therapy and for curietherapy and brachytherapy, according to nosological entities and their localization.

1.08.7 Analyze the therapeutic outcomes that can be achieved through exclusive treatment with radiation therapy in any of its modalities, according to pathological anatomy, localization, and energy.

1.08.8 Analyze the therapeutic outcomes that can be achieved through the combination of RT with other medical and surgical methods of treatment.

1.08.9 Describe the treatment of iatrogenic complications.

1.09 *Radiation Protection and Legislation*. After completing the training program, the specialist will be able to:

1.09.1 Define the effects of ***risk***, harm, detriment, and justification (ALARA index) and ***dose limit*** in the use of radiation ***sources*** in radiation therapy.

1.09.2 Specify the ***dose limits*** for those exposed occupationally and for the general public.

1.09.3 Describe the various operational methods and techniques for reducing ***exposure*** to the lowest possible level, or in any case keeping it below permissible levels.

1.09.4 Distinguish between individual and collective protection and describe personal dosimetry methods.

1.09.5 Identify the critical organs for the various radiotherapeutic techniques, as well as their respective tolerance ***doses***.

2. Psychomotor objectives

(Note: Although it is recognized that there is currently a trend toward teamwork within this specialty, which is practiced almost exclusively in tertiary-level hospitals, the educational objectives described here are presented as skills to be learned by individual practitioners. Nevertheless, the expression "will be able to..." does not necessarily mean that the practitioner will actually use each skill in his/her professional activities.)

2.00 *Basic Sciences*

2.01 *Radiation Physics*. After completing the training program, the specialist will be able to:

2.01.1 Use the dosimetry instruments for the radiation ***sources*** used in radiation therapy.

2.01.2 Measure and calibrate the radiological installations for which he/she is responsible, or delegate this responsibility to the physicist or other authorized specialist.

2.02 *Statistics*. After completing the training program, the specialist will be able to:

2.02.1 Apply the basic concepts of statistics (probability, mean, standard deviation, Gaussian and Poisson distributions) and correlation techniques, assessing the significance of the results.

2.02.2 Calculate and interpret data curves of various biological events.

2.03 *Information Science*. After completing the training program, the specialist will be able to:

2.03.1 Analyze and program basic problems that arise in his/her daily practice.

2.03.2 Use a computer (dedicated microcomputer for general use or for use in ***CT***) for treatment planning and calculation of optimal isodosis in radiation therapy.

2.07 *Clinical Management of Diseases Susceptible to Treatment with Radiation Therapy*. After completing the training program, the specialist will be able to:

2.07.1 Personally take patients' medical histories.

2.07.2 Personally collect the data from clinical examinations for diseases susceptible to treatment with radiation therapy.

2.07.3 Request and assess complementary examinations related to diseases susceptible to treatment with radiation therapy.

2.07.4 Diagnose diseases susceptible to treatment with radiation therapy, and especially in the case of neoplasms:

2.07.4.1 Determine the extent to which they have metastasized.

2.07.4.2 Stage the neoplasm according to the TNM system or another system specific to certain neoplastic localizations (e.g., FIGO).

2.07.5 Determine the indications and contraindications for the various treatment techniques and assess what combinations of techniques will be most appropriate in the case of the various diseases susceptible to treatment with radiation therapy.

2.07.6 Prescribe treatment for patients with diseases susceptible to treatment with radiation therapy, specifying:

2.07.6.1 In the case of radiological treatment: the technical data in the broadest sense.

2.07.6.2 In the case of chemotherapy: the treatment plan.

2.07.6.3 In the case of surgical treatment: why surgery is recommended.

2.07.6.4 In the case of combination treatment: in addition to the foregoing, the sequence for the use of the various treatment modalities.

2.07.7 Prescribe support therapy (psychological, rehabilitative, pain relief, medical, etc.) appropriate to each case.

2.07.8 Manually calculate the iso***dose*** distribution prior to the commencement of external radiological treatment.

2.07.9 Assess patient response to treatments and recommend modifications in the treatment plan if necessary.

2.07.10 Plan follow-up for each patient with a disease susceptible to treatment with radiation therapy, setting the appropriate dates in each case for successive follow-up periods, individually and in combination with an interdisciplinary unit.

2.07.11 Determine the most likely prognosis prior to the administration of the first treatment and make modifications based on the results of the treatment.

2.08 *Radiotherapeutic Technique.* After completing the training program, the specialist will be able to:

2.08.1 Carry out external irradiation treatments by him/herself, or delegate this responsibility to a technician/technologist.

2.08.2 Carry out by him/herself, with the necessary collaboration, interstitial and intracavitary treatments, determining the ***radionuclide*** to be used, ***activity***, mode of application, etc.

2.08.3 Collaborate with the surgeon in interstitial applications that require major surgery, especially in those in which insertion of a ***source*** into a cavity is necessary.

2.09 *Protection in Radiation Therapy.* After completing the training program, the specialist will be able to:

2.09.1 Put in place the radiation protection measures provided for in current legislation on RT services.

2.09.2 Establish special protective measures in each case for the management of physical agents used in radiation therapy.

2.09.3 Assess protective measures for ***radioactive waste***.

2.09.4 Implement radiation protection and safety measures in the daily operations of RT services.

2.09.5 Plan radiation protection and safety measures at work for potentially ***exposed*** persons of ***members of the public*** and the general population.

2.09.6 Establish and carry out ***emergency plans*** in case of ***accidents*** that might occur in the handling of radiation ***sources***.

2.10 *Diagnostic Imaging.* After completing the training program, the specialist will be able to:

2.10.1 Correctly use a simulator for radiological treatment.

2.10.2 Obtain the information needed from diagnostic equipment to make dosimetric calculations for radiological treatments.

2.11 *Nuclear Medicine.* After completing the training program, the specialist will be able to:

2.11.1 Utilize by him/herself, with the necessary collaboration, the techniques of nuclear radiation therapy.

2.12 *Physical Medicine.* After completing the training program, the specialist will be able to:

2.12.1 Operate equipment that generates non-***ionizing radiation***, used alone or in conjunction with radiological treatment.

3. Affective objectives

After completing the training program, the specialist will be able to:

3.03.1 Collect, organize, and transmit data on treatments, following the most appropriate method to contribute to scientific progress.

3.03.2 Systematize the sources necessary for periodic review of the data acquired from patients.

3.08.1 Adequately inform patients and their family members of the characteristics of radiological studies, their ***risks***, and the potential benefits that justify them.

3.08.2 Adequately inform patients and their family members about the various possible treatments, assessing the ***risks*** and benefits of each.

3.08.4 Participate actively in the preparation of patient follow-up plans.

3.08.5 Critically evaluate treatment outcomes, employing all available scientific means of verification, and complete the information acquired, using all the resources available to him/her professionally, without waiting for it to be requested.

3.09.1 Inform the public about the type and magnitude of the potential ***risks*** associated with radiation therapy activities.

3.09.2 Assess the ***risk***-benefit ratio in choosing among possible treatment options.

3.09.3 Monitor the application of radiation protection measures and measures taken to prevent the ***contamination*** of people, installations, and the environment.

3.13.1 Train the personnel assigned to the various functional units within the service.

3.13.2 Identify opportunities for utilizing applied research in his/her work.

3.13.3 Promote scientific meetings and participate actively in them.

3.13.4 Update his/her knowledge and skills, utilizing the necessary sources.

3.13.5 Organize a primary-care-level radiation therapy service.

4. Required achievement levels

After completing the training program, the specialist will have mastered:

4.01 Ninety percent of the objectives and contents established for the licentiate period at the end of the first year of the specialization program.

4.02 Eighty percent of the objectives and contents established for the specialization period by the end of that period.

Appendix III-C

Spanish Guide for the Training of Medical Specialists

*Nuclear Medicine**

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* Taken from: España, Ministerio de Sanidad y Consumo, Consejo Nacional de Especialidades Médicas y Consejo Nacional de Especialidades Farmacéuticas. *Guía de formación de especialistas*. Madrid: Ministerio de Sanidad y Consumo; 1986. (Free translation). (An updated version of this Guide was published in 1996.)

Nuclear Medicine

1. Definition of the Specialty

Nuclear medicine is the medical specialty that uses radioactive ***isotopes***, nuclear radiation, the electromagnetic variations of the components of the nucleus and related biophysical techniques for the prevention, diagnosis, and treatment of disease and for medical research.

2. Nature of the Specialty

2.1 Scientific basis

Nuclear medicine utilizes knowledge from other basic sciences, such as physics, chemistry, mathematics, and biology, for medical purposes.

2.2 Areas of activity

Prevention: In the area of prevention, nuclear medicine applies knowledge and techniques from the specialty to hygiene and to prophylactic and preventive medicine.

Research: Nuclear medicine is used in basic and applied research using radioactive ***isotopes*** and related biophysical techniques.

Diagnosis: Diagnostic nuclear medicine consists basically of functional, morphological, dynamic, morphodynamic, and radioanalytical tests performed in order to gain a better understanding of the function and structure of the human body, based on biological and physiopathological principles.

Treatment: Nuclear medicine is used in the treatment of various specific human pathologies (e.g., metabolic, endolymphatic, and intracavitary therapy).

2.3 Professional responsibility of the specialist

The specialist in nuclear medicine should be trained to carry out his/her professional functions in accordance with accepted practices in the specialty. He/she is expected to prescribe, execute, interpret, apply, and explain diagnostic and therapeutic procedures of the specialty in general, encompassing all its different areas. The objective of the training program is to produce a self-reliant medical specialist capable of independently practicing all facets of nuclear medicine at any medical care level, and, given the rapidly changing nature of the specialty, applying future developments in the field.

2.4 Specific areas of competence

Given the nature of the specialty, it is agreed that it should not be divided into subspecialties devoted to the application of the conceptual principles to specific organs or systems.

2.5 Relationship of Nuclear Medicine to the Basic Sciences

Because the collaboration of a multidisciplinary team of professionals is necessary in order to achieve superior development at the various care levels,

the specialist in nuclear medicine should collaborate with professional colleagues in the areas of biology, physics, chemistry, pharmacy, and information science applied to nuclear medicine.
The qualifications of these professionals will be defined subsequently.

3. Contents and duration of the training program

3.1 Overall duration of the program

The training of specialists in nuclear medicine should be completed over a four-year period and should include a balance between theoretical and practical instruction carried out simultaneously.

3.2 Stages of training

a) Generic Training Stage:
Learn the fundamentals of mathematics, physics, chemistry, pharmacy, instrumentation, hygiene, and radiation protection and their practical applications in nuclear medicine.
Understand the physiological, physiopathological, and pathological mechanisms studied.

b) Specific training stage:
Learn to assume all professional responsibilities:
- Monitoring of patients and supervision of the laboratory
- Selecting appropriate tests, radiopharmaceuticals, instrumentation, reporting of results
- Maintaining bibliographic information
- Initiating and carrying out research projects

With regard to theoretical instruction, given the nature of teaching in the specialty and the small number of graduates undergoing training, it is preferable that theoretical instruction be imparted in tutorials to small groups.

Activities to be undertaken in each training stage

General overview of the program

a) First-year residents:
- Basic concepts: mathematics, radiation physics, radiation biology, radiation chemistry, radiopharmacy, hygiene, and radiation protection

b) Second-year residents:
- In vivo methodology
- In vitro methodology
- Instrumentation
- Participation in a program of radiation protection in order to obtain the ***license*** as a supervisor of installations utilizing radioactive materials. This will be done during the early years of residency.

c) Third- and fourth-year residents
- Clinical course (clinical nuclear medicine)

During the four years of their training, residents will have the option of participating in a six-month rotation in other services.

Objectives

General objective

The objective of the training is to produce a physician specialized in nuclear medicine (PSNM): A physician who contributes to diagnosis by means of techniques in which spontaneous or induced radiation associated with nuclear processes is used and who is trained to carry out treatment and follow up of patients who require the utilization of non-encapsulated radioactive ***isotopes***. In addition, the specialist in nuclear medicine may extend his/her sphere of action to include diagnostic, morphological, or functional techniques that use non-***ionizing*** physical agents.

Specific objectives

Basic Sciences

After completing the training program, the PSNM will be able to do the following in the disciplines listed below:

Mathematics and Statistics:

- Give mathematic descriptions of linear, exponential, and logarithmic functions.
- Explain the basic concepts of compartmental analysis and name its most important clinical applications.
- Apply the basic concepts of statistics and correlation techniques, evaluating the significance of the results.

Physics:

- Describe the atomic and nuclear structure of matter.
- Name the characteristics of the following elementary particles: ***electron***, ***proton***, ***neutron***, positron, and neutrino.
- Define the following concepts: atomic mass, atomic number, ***nuclide***, and ***radionuclide*** (RN).
- Distinguish between isotopic, isobaric, isotonic, and isomeric elements.
- Interpret nuclear stability in relation to mass defect, atomic number, and atomic mass.
- Describe the principal methods and systems used to produce artificial ***radionuclides***.
- Describe the cyclotron and list the cyclotron products normally used in nuclear medicine.
- Describe ***radiation*** and the particles emitted by radioactive nuclei.
- State and apply the law of ***radioactive decay***.
- Explain the meaning of the following terms: decay constant, physical ***half-life***, biological ***half-life***, and radioactive equilibrium.
- Illustrate the following processes: ***beta*** emission, electronic capture, internal conversion, and isomeric transition.

- Interpret the energy spectra associated with the aforementioned processes.
- Explain the interaction of radiation with matter and describe the basic characteristics of the photoelectric, Compton, and pair-production effects.
- Describe the interaction of charged and neutral particles with matter.
- Define the following radiological quantities: ***activity***, ***exposure***, ***absorbed dose***, ***equivalent dose***, as well as their units. Describe the basis for the various components of a detection and measurement chain.
- Describe and explain the operation of the equipment used in nuclear medicine.
- Identify and describe the physical properties of the RN used in nuclear medicine.
- Explain the basic principles of image production and the factors that modify it in the various systems used in nuclear medicine services.

Information Management:
- Explain the basic physical components (hardware) of a computer.
- Describe operating systems (software).
- Describe the input/output units (peripherals) of a computer.

Radiation Biology:
- Explain the mechanisms of direct and indirect action of ***ionizing radiation***.
- Define linear energy transfer (LET) and relative biological efficiency (RBE).
- Explain the action of radiation on DNA.
- Explain the action of radiation on cells and the cellular cycle. Explain the mechanisms that intervene in cellular repair. Define the concept of radiosensitivity and list factors that modify it.
- Explain the factors and mechanisms that modify the action of radiation: fractionation.
- Describe somatic and genetic effects in general: irradiation syndrome.

Radiopharmacology:
- Define the term "radiopharmacology."
- Distinguish between the terms radiopharmaceutical, ***radionuclide*** (RN), and radiotracer.
- Evaluate which ***radionuclides*** and radiopharmaceuticals are most suitable for each specific procedure.
- Describe the different ways in which the various radiopharmaceuticals are administered, metabolized, and eliminated.
- Describe the mechanisms for localizing radiopharmaceuticals and their application in the design of nuclear medicine studies.
- Define and distinguish between chemical, radiochemical, and radioactive purity.
- Define the isotonic, apyrogenic, sterile, pH, toxic, and biological suitability characteristics of a radiopharmaceutical.
- Define the terms "synthesis" and "labeling."

- Describe the general methods of labeling.
- Recognize the factors that can affect the purity and stability of labeled compounds.

***Radionuclide Generators** in Nuclear Medicine:*
- Define the concept "***generator***" and describe its elements and characteristics.
- Name the most commonly used ***generators*** and select the most appropriate ***generator*** system for each use.
- Analyze the problems that can arise with ***generator*** use.

*Molybdenum-Technetium **Generator**:*
- Describe the Mo-Tc ***generator*** and analyze its various characteristics.
- Describe the principal characteristics involved in the radiochemistry of technetium-99m (oxide-reduction reactions, presence of Mo-99).
- Describe the various Tc-99-labeled compounds used in nuclear medicine.

Diagnostic Ultrasound:
- Define the concept of diagnostic ultrasound.
- List, apply, and describe the physical processes by which ultrasounds interact with matter.
- Relate the frequency, penetration, and resolution of ultrasound waves. Relate the amplitude and attenuation of ultrasound waves.
- Describe the various types of diagnostic ultrasound and list their applications in medical diagnosis.
- Explain the basic principles of image production and the factors that modify it in the various systems used in diagnostic ultrasound.

Nuclear Magnetic Resonance:
- Explain the physical basis of nuclear magnetic resonance.
- Describe the block diagram of a nuclear magnetic resonance unit.
- Describe the imaging and spectroscopy possibilities of nuclear magnetic resonance.

In Vitro Studies

Radiochemical Analysis:
- Define the concept of radiochemical analysis and state the theoretical principles on which it is based.
- Define competition, activation, and substitution analysis.
- Describe the various types of competition analysis (protein, RIA, IRMA, ELISA, and hormone receptors).

RIA:
- Give a general description of RIA.
- Define monoclonal and polyclonal antibodies, antigens, haptens. Define the binding capacity and affinity of an antibody.

- Explain the basic principles and characteristics of the antigen-antibody reaction. Assess the various factors that influence this reaction.
- Explain the various methods of labeling in RIA.
- Draw and interpret a standard curve.
- Select the best method for automatic calculations.
- Perform ***quality control*** of the elements used in RIA.
- Prescribe and plan the stimulation and suppression tests used in nuclear medicine.
- Monitor and clinically assess the results obtained by RIA.

Autoradiography:
- Describe the principal autoradiography techniques.
- Describe and explain the basic principles of autoradiography.

In Vivo Techniques

After completing the training program, the physician specialized in nuclear medicine (PSNM) will be able to:
- Describe all the studies used in the examination of each organ or system, including:
  · Patient preparation
  · Radiopharmaceuticals and ***doses*** to be used
  · Views to be used
  · Technical data on instruments
  · Need for auxiliary equipment
  · ***Risks*** of the study and their prevention and treatment
- Plan the study, taking into account the clinical data on the patient, including:
  · Clinical information on the patient:
    Physical and psychological condition
    Results of previous studies
    Socioeconomic status
  · Instruments and equipment available:
    Own equipment
    Equipment belonging to another facility (regional)
  · Current availability (extent of equipment use, waiting list, stock of radiopharmaceuticals).
- Correlation with other diagnostic techniques in the facility.
- Identify and describe the anatomical structures imaged, the normal variants, the artifacts and/or parameters of normalcy and their variations in morphofunctional studies.
- Assess ***activity***/time curves and quantitative data obtained in functional studies.
- Identify and describe pathological findings and their semiologic characteristics.
- Process the analog and digital data obtained from the study in order to carry out the necessary calculations to quantitatively determine the parameters for defining the function studied.

- Make timely decisions in order to resolve medical emergencies that may occur in the nuclear medicine service.
- Produce a report of the findings of the study, always including diagnostic guidance.
- Define the possibilities, limitations, and ***risks*** of nuclear medicine studies.
- Calculate the diagnostic efficiency and cost-benefit ratios for each study.

Therapeutic Applications of Nuclear Medicine

After completing the training program, the PSNM will be able to:

- Describe the radiopharmaceuticals utilized in nuclear medicine therapy as well as their pharmacological and pharmacokinetic properties.
- Describe the radiobiological basis for the therapeutic action of the ***radionuclides*** utilized in nuclear medicine therapy.
- Describe the natural history (etiology, pathogenesis, clinical course, etc.) of diseases susceptible to treatment with nuclear medicine.
- Establish the diagnosis and prognosis, monitoring the evolution of pathologies susceptible to treatment with nuclear medicine.
- Formulate the treatment prescription and describe the nuclear medicine techniques to be used with pathologies susceptible to treatment with nuclear medicine.
- Make the necessary calculations (volume, ***activity***, ***dose***) for nuclear medicine therapy.
- Diagnose and assess pathologies deriving from the therapeutic application of ***radionuclides*** in nuclear medicine.
- Determine when other associated treatment modalities should be used.

Radiation Protection (RP) and Safety in the Workplace

After completing the training program, the PSNM will be able to:

- Describe the physical principles of RP.
- Describe the biological principles of RP.
- Describe radiobiological phenomena and prevention of the harm caused by the radiation emitted by ***radionuclides***.
- Put in place the radiation protection measures provided for in current legislation on nuclear medicine services.
- Establish special protective measures in each case for the management of ***radionuclides*** in solid, liquid, or gas form.
- Evaluate protective measures for the management of ***radioactive waste***.
- Establish radiation protection and safety measures at work for diagnostic and therapeutic applications of nuclear medicine.
- Plan radiation protection and safety measures at work for potentially exposed persons of ***members of the public*** and general population.
- Establish and carry out ***emergency plans*** in the event of ***accidents*** involving ***radionuclides***.

Psychomotor Objectives

After completing the training program, the PSNM will be able to:

- Collect qualitative and quantitative data and process them with a computer in order to solve applied statistics problems.
- Correctly handle non-encapsulated ***radioisotopes*** and ***generators***, employing optimal radiation protection measures and consistently ensuring:
  · Desired dilutions and/or concentrations.
  · Dose extraction.
  · Measurements of the ***activity*** to be administered.
  · Administration of the ***dose*** to the patient by the appropriate route.
  · Safe handling of waste.
- Correctly utilize ***radionuclide*** decay tables.
- Operate a ***gamma camera*** in order to obtain the best possible information on the object under study for morphological and morphodynamic studies.
- Establish and carry out, with appropriate frequency, ***quality control*** tests of the ***gamma camera***, checking:
  · Homogeneity
  · Spectrometry
  · Linearity
  · Resolution
- Handle automatic and manual gamma counting systems to obtain the most exact results possible in terms of:
  · Voltage adjustment
  · Photo-peak determination
  · Handling of scalers, analyzers, counting rate meters, and plotters.
  · Handling of scintillation probes and well counters
  · Determination of measurement times and number of counts.
- Utilize, calibrate, and periodically check monitoring systems for the protection of personnel and areas.
- Use the nuclear medicine computer to:
  · Make extensive use of programs devoted to nuclear medicine
  · Use operating system resources related to nuclear medicine programs.
- Handle the laboratory materials necessary for the use of commercial equipment.
- Establish and carry out ***quality control*** tests of:
  · Radiopharmaceutical labeling
  · Radiochemical purity
  · Validation of RIA methods
- Perform radiopharmaceutical labeling.
- Perform cell labeling.
- Carry out by him/her-self, with the necessary collaboration, the techniques of NM.
- Monitor systems of protection and excreta disposal in areas in which patients are treated with ***radionuclides***.
- Handle and complete the required legal documentation.
- Establish and carry out ***quality control*** tests of diagnostic ultrasound.

Affective Objectives

After completing the training program, the PSNM will be able to:

- Train the personnel assigned to the various functional units of the service.
- Promote professional and human relations within the workplace.
- Adequately inform patients and their family members of the characteristics of studies, their ***risks***, and the benefits that justify them.
- Participate actively in the preparation of patient follow-up plans.
- Critically evaluate treatment outcomes, employing all available scientific means of verification, and complete the information acquired using all the resources available to him/her professionally.
- Collect, organize, and transmit data from studies, following the most appropriate method to contribute to scientific progress.
- Identify opportunities for utilizing applied research in his/her work.
- Promote scientific meetings and participate in them.
- Update his/her knowledge and abilities, utilizing the necessary sources.
- Systematize the sources necessary for periodic review of the data acquired from patients.
- Inform the public of the type and magnitude of the potential ***risks*** associated with nuclear medicine activities.
- Assess cost-effectiveness and cost-benefit ratios in choosing among possible test options, selecting the safest, most sensitive, and most specific test available at the least economic cost.
- Monitor the application of radiation protection measures and measures taken to prevent the ***contamination*** of people, installations, and the environment.
- Monitor the administration of ***radioactivity*** doses for diagnostic purposes to ensure that the best possible information is obtained with the lowest possible total ***dose*** and the lowest potential ***risk***.
- Organize a secondary/tertiary-level radiology installation.

Quantitative objectives

1. *Morphofunctional studies*
   By the end of the training period, the nuclear medicine specialist will have interpreted a minimum of 2,000 morphofunctional studies.
2. *In vitro studies*
   The specialist will have carried out 150 radioimmunoassays, utilizing at least 10 different techniques.
3. *Therapeutic applications*
   The specialist will have administered and monitored a minimum of 25 radiation therapy treatments during the four years of training.

Training program for supervisors of installations utilizing radioactive materials

Total duration: four weeks (160 hours)

A) *Theory component (46 hours)*

1. ***Radioactivity*** (6 hours):

- Fundamental concepts
- ***Radioactivity***
- Basic principles of the interaction of ***particles*** and ***radiation*** with matter
- Properties and interaction of ***particles*** with matter
- Properties and interaction of ***gamma rays*** with matter

2. Detection and measurement of ***radioactivity*** (5 hours):
   - Gas-***ionization*** detectors
   - Scintillation counters and semiconductor detectors
   - Errors in the measurement of ***radioactivity***
3. Radiation protection (10 hours):
   - Dosimetry
   - ***Dose*** calculation
   - Radiation protection
   - Maximum permissible ***doses***
   - Radiation protection techniques
   - Safety criteria for installations that utilize radiation ***sources***
   - ***Shielding*** calculations
   - Effects of radiation on the human body
4. Safe production and handling of ***radionuclides*** (8 hours):
   - ***Radionuclide*** production
   - ***Radioisotope*** handling without ***risks***
   - Design and construction of installations that utilize radioactive materials
   - Preparation of radioactive samples
5. Legislation and regulation (8 hours):
   - Spanish legislation
   - ***Licensing*** of installations that utilize radioactive materials
   - Inspection of installations that utilize radioactive materials
   - Analysis of safety regulations
6. Calculation problems (9 hours).

B) *Practical training component (100 hours)*
1. ***Radioactivity***. Detection and measurement (40 hours):
   - ***Contamination*** and radiation dosimeters
   - Counter resolution time
   - Sources of error in the measurement of ***activity***
   - NaI (Tl) scintillation counters
   - Particle and radiation absorption
   - Calibration of liquid-type scintillation counters
   - ***Beta particle*** back-scattering.
2. Radiation protection and safe handling of ***radionuclides*** (40 hours):
   - Operation and calibration of equipment
   - Attenuation of radiation as it passes through matter
   - Delimitation of work areas
   - Warning sign placement and control of operations with encapsulated ***sources***
   - Control of operations with non-encapsulated ***sources***

- Handling of ***beta*** emitters.
- Handling of ***gamma*** emitters
- Preparation of samples from precipitates
- Preparation of encapsulated ***gamma sources***

3. Legislation (20 hours):
   - Preparation of documentation for the establishment of installations utilizing ***radioactive*** materials
   - Practical applications

C) *Seminars and colloquia (14 hours)*

Appendix III-D

Curriculum for the Course of Study Leading to the Degree of

*Professional Diagnostic Imaging Technologist**

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* Taken from: Ministerio de Educación y Ciencia. Currículo del Ciclo Formativo de Grado Superior correspondiente a Técnico Superior en Imagen para el Diagnóstico. Real Decreto Español. Abril 1995. *Boletín Oficial del Estado* 1995;133(12). (Free translation).

Curriculum for the Course of Study
Leading to the Degree of Professional Diagnostic Imaging Technologist
Spanish Royal Decree, April 1995

ROYAL DECREE 557/1995, issued 7 April, establishing the curriculum for the training of professional diagnostic imaging technologists.

Royal Decree 545/1995, issued 7 April, established the degree of Diagnostic Imaging Technologist and its corresponding minimum instructional requirements, in consonance with Royal Decree 676/1993, issued 7 May, which in turn set the general guidelines for professional training and the minimum instructional requirements to obtain the degree.

In accordance with Article 4 of Organic Law 1/1990, enacted 3 October, on the general organization of the educational system, it is the responsibility of educational administrations or, where appropriate, the Government to establish the curriculum for training programs in their respective spheres of action. The principles relative to the academic system, its organization, and the instruction imparted in accordance with the curriculum of the training program established in the present Royal Decree are the same as those set forth in the preamble of Royal Decree 548/1995, issued 7 April.

By virtue of the foregoing, in accordance with a proposal of the Minister of Education and Science, and having examined the report of the National Academic Council and consulted with the Cabinet at its meeting on 7 April 1995,

I HEREBY DECREE:

Article 1:

1. The present Royal Decree determines the curriculum for the course of study leading to the degree of diagnostic imaging technologist. Reference to the productive system is established in Royal Decree 545/1995, issued 7 April, which approved the minimum instructional requirements for the profession. The objectives expressed in terms of capacities and the criteria for evaluation of the curriculum for the training program are established in the aforementioned Royal Decree.
2. The contents of the curriculum are established in Annex I of the present Royal Decree.
3. Annex II of the present Royal Decree establishes the physical requirements that must be met by educational centers that impart the training described herein.

Article 2:

The present Royal Decree is applicable in the territorial area under the authority of the Ministry of Education and Science.

Article 3:

The training modules of this program will be organized in two academic courses:

a) The professional training modules for the first course are:
   1. Organization and management of the assigned work area in the diagnostic imaging unit/office.
   2. Basic principles and techniques for carrying out studies with conventional radiology.
   3. Basic principles and techniques for carrying out studies with image digitization equipment.
   4. Radiological anatomy.
   5. Processing and treatment of the radiological image.

b) The training modules for the second course are:
   1. Basic principles and techniques for carrying out studies in nuclear medicine.
   2. Radiation protection.
   3. Occupational orientation and guidance.
   4. Practical training.

Sole additional provision

In accordance with the organizational and methodological requirements for adult education, both in the modality of classroom education and that of distance education, the Ministry of Education and Science may adapt the curriculum described in the present Royal Decree in accordance with the characteristics, conditions, and needs of the adult population.

First final provision

Application of the present Royal Decree will be optional in the Autonomous Communities that are fully exercising their educational authorities, in accordance with the provisions of Article 149.3 of the Constitution.

Second final provision

The weekly schedule for the various modules included in this training program will be established by the Ministry of Education and Science.

Third final provision

The Education and Science Minister will establish the pertinent standards for grading and the promotion students.

Fourth final provision

The Minister of Education and Science is authorized to issue whatever directives are necessary to ensure the application of the provisions contained in this Royal Decree.

Fifth final provision

The present Royal Decree will enter in effect on the day following the date of its publication in the Official Bulletin of the State.

Issued in Madrid on 7 April 1995. **JUAN CARLOS R.**

GUSTAVO SUAREZ PERTIERRA
Minister of Education and Science

Annex 1

Training Module 1:

Organization and Management of the Assigned Work Area in the Diagnostic Imaging Unit/Office

Content (duration 95 hours)

a) Health system organization:
   - Structure of the public health system in Spain
   - ***Levels of care*** and types of benefits
   - Public health and community health
   - Typical organic and functional structures of health institutions: public and private
   - Health indicators
   - Legislation applicable to the sector
   - Safety and health standards applicable to health centers

b) Health documentation:
   1. Clinical documentation: types of documents: hospital, extrahospital, and inter-center, uses and applications, criteria for compliance, methods of information circulation
   2. Non-clinical documentation: types of documents: hospital, extrahospital and inter-center, uses and applications, criteria for compliance, methods of information circulation

c) Supply and inventory management:
   - Storage systems: advantages and drawbacks
   - Classification of health supplies: Criteria
   - Inventory evaluation methods
   - Record-keeping
   - Inventories: classification and preparation
   - Safety and health standards applicable to health center storerooms

d) Management of information/documentation:
   - Documentation relative to purchasing and sales operations, purchase orders, receipts, invoices, payment/credit documents, legal requirements

e) Computer applications:
   - Utilization of computer applications for the operation of diagnostic radiology equipment
   - Computer applications for supply management and control

f) The process of care or service delivery:
   - Objectives, phases, operations, and resources
   - Applicable regulations

g) Quality of the delivery of services or products:
   - Introduction to ***quality control*** techniques
   - Internal and external ***quality control***

h) Fundamental concepts of health economics

Training Module 2:

Basic Principles and Techniques for Carrying Out Studies in Conventional Radiology

Content (duration 435 hours)

a) Principles of conventional radiology:
   - Properties of ***x-rays***
   - Physical characteristics of matter

b) Conventional radiology units:
   - Organization, functions, activities, and tasks
   - Installations and availability of equipment

c) Equipment for conventional radiology:
   1. Production of ***x-rays***: the ***x-ray*** tube. Procedures for heating and cooling the tube, characteristics of radiation produced by the tube, the ***x-ray generator***, penetration of ***x-rays***: scattering and contrast of ***x-rays***, collimation, grid assemblies, image intensifiers, artifacts
   2. Special techniques—tomography, xeroradiography, fluoroscopy with contrast media

d) Contrast media used in radiology:
   - Positive contrast media: composition and applications
   - Negative contrast media: composition and applications
   - Liposoluble contrast media: composition and applications
   - Double-contrast techniques
   - Complications and adverse reactions produced by contrast media

e) Radiological techniques:
   - Radiological studies of the scapula, acromioclavicular articulation, and shoulder: simple radiographic technique
   - Radiological studies of the upper limb: simple radiographic technique
   - Radiological studies of the pelvis and hip joint: simple radiographic technique
   - Radiological studies of the lower limb: simple radiographic technique
   - Radiological studies of the osseous portion of the chest: simple radiographic technique
   - Radiological studies of the skull, face, and neck: simple radiographic technique; special radiographic techniques
   - Radiological studies of the chest: simple radiographic technique; special radiographic techniques; fluoroscopy
   - Radiological studies of the abdomen: simple radiographic technique; special radiographic techniques
   - Radiological studies of the digestive system: simple radiographic technique; special radiographic techniques
   - Radiological studies of the urinary tract: simple radiographic technique; special radiographic techniques
   - Radiological studies of the bile duct: special radiographic techniques
   - Hysterosalpingography
   - Mammography

f) Interventional radiological techniques:
   - Radiological studies of the chest
   - Radiological studies of the heart
   - Radiological studies of the abdomen
   - Radiological studies of the pancreas and spleen
   - Radiological studies of the liver
   - Radiological studies of the urinary tract
   - Radiological studies of hollow viscera
   - Radiological studies of the reproductive system
   - Radiological studies of the face and neck
   - Radiological studies of the skull
   - Angiography
   - Phlebography

Training Module 3:

Basic Principles and Techniques for Carrying Out Studies with Digital Imaging Equipment

Content (duration 225 hours)

a) Principles of computed axial tomography (CT):
   - Properties of ***x rays***
   - Physical characteristics of matter
   - Technical aspects of CT

b) Principles of magnetic resonance (MR):
   - Properties of magnetic fields
   - Characteristics of the magnetic moments of ***protons***
   - Technical aspects of MR

c) Radiology units with computerized image processing equipment:
   - Organization, functions, activities, and tasks
   - Installations and availability of equipment

d) Equipment for computed axial tomography:
   1. Production of ***x-rays***, the ***x-ray*** tube, automatic procedures for heating and cooling the tube, characteristics of the radiation produced by the tube, detector ring
   2. Production of high-intensity magnetic fields: the external-magnetic-field-producing magnet
   3. Data collection system
   4. Equipment data intake
   5. Mathematical data processing
   6. Reconstruction of the object
   7. Special techniques: use of contrast media

e) Contrast media utilized in CT and MR:
   - Positive contrast media: composition and applications
   - Negative contrast media: composition and applications
   - Liposoluble contrast media: composition and applications
   - Double-contrast techniques
   - Complications and adverse reactions produced by contrast media

f) Radiological techniques with CT:
   - Studies with and without contrast media
   - High-definition studies
   - Sequential dynamic and single-plane studies
   - Volumetric acquisition
   - Angio-CT
   - Multiplane and 3D reconstruction
   - Bone densitometry

g) Radiological techniques with MR:
   - Studies with and without contrast media
   - Contraindications
   - Spin-echo techniques
   - Echo-gradient techniques
   - Ultra-rapid techniques
   - Angio MR
   - Spectroscopy

h) Radiological studies with CT and MR:
   - Radiological studies of the chest
   - Radiological studies of the heart
   - Radiological studies of the abdomen
   - Radiological studies of the pancreas and spleen
   - Radiological studies of the liver
   - Radiological studies of the urinary tract
   - Radiological studies of hollow viscera
   - Radiological studies of the male reproductive system
   - Radiological studies of the female reproductive system
   - Radiological studies of the neck
   - Radiological studies of the face
   - Radiological studies of the skull
   - Radiological studies of the temporal bone region

Training Module 4:

Basic Principles and Techniques for Carrying Out Studies in Nuclear Medicine

Content (duration 165 hours)

a) Principles of nuclear medicine
   1. ***Radionuclides***: concept, ***radionuclide*** production, ***generators***
   2. Radiotracers: concept, techniques, duration, ***quality control***, presentation, dosage, and administration
   3. Mechanisms of distribution and localization of radiopharmaceuticals
   4. Imaging techniques
   5. Information processing techniques

b) Nuclear medicine units
   - Organization, functions, activities, and tasks
   - Installations and availability of equipment

- Response protocols

h) National and international regulation:
   - National regulation
   - International harmonization and standardization regulation
   - Registries: types and maintenance

i) ***Quality control*** of the process:
   - Factors that affect the quality of the process
   - ***Quality control*** instruments
   - ***Quality assurance*** and maintenance
   - ***Quality control*** documentation

Training Module 6:

Radiological Anatomy

Content (duration 105 hours)

a) Radiological anatomy of the upper limb
   - Anatomy of the shoulder girdle
   - Anatomy of the arm
   - Anatomy of the elbow
   - Anatomy of the forearm
   - Anatomy of the wrist
   - Anatomy of the hand

b) Radiological anatomy of the lower limb
   - Bone anatomy of the pelvic girdle
   - Anatomy of the femur
   - Anatomy of the knee
   - Anatomy of the leg
   - Anatomy of the ankle
   - Anatomy of the foot

c) Radiological anatomy of the thoracic cage:
   - Ribs
   - Sternum
   - Clavicle

d) Radiological anatomy of the spinal column:
   - Cervical
   - Dorsal
   - Lumbar
   - Sacroiliac

e) Radiological anatomy of the craniospinal region:
   - Skull
   - Base of the skull
   - Hypophysis
   - Orbitae
   - Face

f) Radiological anatomy of the thoracic viscera:
   - Lungs and pleura
   - Heart and pericardium

- Mediastinum, large vessels

g) Radiological anatomy of the abdominal viscera:
   - Liver
   - Spleen
   - Stomach
   - Duodenum and pancreatic area
   - Small and large intestine
   - Mesentery and peritoneum
   - Kidneys and suprarenal glands
   - Retroperitoneum

h) Pelvic cavity:
   - Female
   - Male

i) Brain and brain stem:
   - Cerebral hemispheres
   - Midbrain and brain stem
   - Cerebellum
   - Cerebral ventricles
   - Subarachnoid space—cisterns
   - Spinal cord

j) Radiological anatomy of the breast

Training Module 7:

Processing and Treatment of the Radiological Image

Content (duration 105 hours)

a) Radiological image:
   - Concepts of analog image and digital image
   - Image receptors
   - Image processing

b) Fluoroscopic image:
   - Characteristics of the image
   - Intensifier
   - Image receptors
   - Cinefluorography
   - Digital fluorography

c) Computed tomography:
   - Image reconstruction process
   - Image quality
   - Artifacts
   - Image manipulation

d) Magnetic resonance:
   - Instrumentation
   - Imaging
   - Image contrast
   - Coding of the signal

e) Radiographic film:
   - Types and classes
   - Applications and indications
   - Development procedures
   - Filing procedures
   - Automatic developing and processing procedures

f) Computer image processing applied to radiology:
   - Coding system
   - Operating systems
   - Programs for processing radiological images
   - Digital image: digital-analogue and analogue-digital converters, processing

Training Module 8:

Occupational Orientation and Guidance

Content (duration 65 hours)

a) Occupational health
   - Safety and working conditions. Occupational health and quality of life. The environment and environmental protection
   - ***Risk*** factors: physical, chemical, biological, organizational. Prevention and protection measures
   - Applied techniques for safe organization of the workplace
   - General preventive/protective techniques. Analysis, assessment, and proposal of measures
   - Case studies
   - Priorities and sequences of action in case of ***accidents***
   - First aid techniques: consciousness/unconsciousness, cardiopulmonary resuscitation, injuries, rescue and transport of injured persons

b) Labor legislation and labor relations:
   - Labor law: Basic standards
   - Labor relations: Contracting modalities, wages and benefits, layoff and termination
   - Social security and other benefits
   - Labor organizations
   - Collective bargaining and agreement

c) Socio-occupational orientation and guidance
   - The labor market, structure, job prospects
   - The job search process: sources of information, supply-demand mechanisms, procedures and techniques
   - Self-employment initiatives. Procedures and resources for establishing small businesses
   - Resources for occupational self-assessment: Analysis—evaluating one's own potential and interests. Overcoming discriminatory social practices. Pursuing professional training and continuing education opportunities. Decision-making

d) Principles of economics:
   - Macroeconomic variables, socioeconomic indicators, their interrelationships
   - Market economy: Supply and demand, competitive markets
   - International socioeconomic relations: European Union (EU)

e) Business economics and organization:
   - Economic activity of the business: Criteria for classification
   - Businesses: Types of organizational models, functional areas, organizational structure

Practical Training Module

Content (duration 710 hours)

a) Introduction to the workplace:
   - Organization of the workplace: organizational structure
   - Chain of command. Reporting of all incidents. Needs and contingencies in the course of activities
   - Technical information on the process. Procedures manual. Quality standards
   - Correct behavior within the organizational structure of the company and the working team

b) Preparation and adjustment of diagnostic radiology equipment:
   - Organization of work, interpretation of documentation on techniques and equipment
   - Selection of procedures to be carried out
   - Verification of compliance with safety standards for the start-up and operation of diagnostic radiology equipment
   - Start-up, programming, automatic monitoring and control of diagnostic radiology equipment
   - Detection of anomalies in equipment, reporting of incidents and/or breakdowns detected
   - Maintenance of the corresponding logbooks

c) Documentation used in the diagnostic radiology unit/office:
   - Recording of receipt and dispatch of documentation and requests for studies
   - Interpretation of requests for studies
   - Application of priority, safety, confidentiality, punctuality, and efficiency criteria
   - Preparation of job lists by conventional and/or computerized means
   - Identification of applicable legal regulations
   - Utilization of appropriate technical terminology to describe the procedures and processes to be carried out
   - Maintenance of supply records applying established criteria of inventory valuation

d) Patient care and information:
   - Adherence to accepted standards of professional behavior, communication and transmission of information to patient/clients
   - Identification, in requests for studies, of patient/client preparation protocols
   - Provision of contextualized information for each patient/client
e) Application of safety and health standards:
   - Identification of the ***risks*** associated with different procedures
   - Monitoring of protective measures, preventive behavior
   - ***Risk*** assessment, corrective action
   - Verification of compliance with safety and health standards
   - Verification of correct ***waste*** management
   - Environmental protection
f) Diagnostic radiology study techniques:
   - Dosimetric planning and ***dose*** calculation for various radiological studies
   - Verification of the functioning of alarm and interlocking systems and emergency shut-off switches
   - Personnel and area dosimetry controls, monitoring, control of radiation levels
   - Patient positioning, anatomical localization
   - Audiovisual monitoring of the patient during studies
   - Application of simple radiological study techniques on different parts and organs of the human body
   - Use of study techniques with portable equipment
   - Programming of processing equipment for digital image manipulation
   - Application of radiographic film processing techniques, identification of appropriate equipment and processes
   - Verification of compliance with quality standards for procedures carried out
   - Discussion of technical interpretation of the results obtained

Annex II

Physical requirements for centers that impart training for diagnostic imaging technologists

In accordance with the second final provision of Royal Decree 545/1995, issued 7 April, which established the degree and curriculum for the training of diagnostic imaging technologists, the physical requirements for centers imparting such training are:

Training Area	Size - Area in m^2	Use Rate -Percentage
Radiology laboratory	120	45
CT/MR laboratory	60	30
Multipurpose classroom	60	25

The "use rate" expresses as a percentage the amount of time a group of students is expected to spend in each area during the training program.

When the training areas are not being used for the training program, they may be used by other groups of students who are enrolled in the same or other training programs, or who are at other stages of their education.

In any case, the learning activities that take place in the training areas (with the amount of time devoted to each expressed by the use rate) can be carried out in areas that are also utilized for other related instructional activities.

The various training areas need not necessarily be physically separated from one another by partitions.

Appendix III-E

Draft Curriculum for the

Profession of Radiological Technologist:

*Diagnostic Radiology - Radiation Therapy - Nuclear Medicine**

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* Taken from: Asociación Española de Técnicos en Radiología. Borrador de Programa Educativo para la Profesión de Técnico en Radiología. Madrid: Asociación Española de Técnicos en Radiología. (Free translation).

Draft Curriculum for the
Profession of Radiological Technologist:
Diagnostic Radiology - Radiation Therapy - Nuclear Medicine

Introduction

This proposed curriculum for the education of **Medical Radiological Technologists** has the following features:

a. It is only a proposal and is therefore subject to such modifications as the "University" deems appropriate.

b. The curriculum comprises subject matter common to the following three specialties:

Diagnostic Radiology, Radiation Therapy, and Nuclear Medicine

c. The expected duration of the training program is three years.

d. It provides for a mandatory practical examination.

e. It permits European Community accreditation inasmuch as it complies with Article l-A of Directive 89-48-EEC of 21 December 1988, previously Common Position of June 1988.

f. It facilitates transfer between specialties for **Technical** professionals who are interested, and in order to fill social needs.

g. It provides a standardization module for current **Radiological Technologists**, enabling them to obtain European Community accreditation.

h. The proposed course load distribution is only an example. It is understood that it is the prerogative of the "University" to establish the course load according to its own criteria or considerations.

Degree: MEDICAL RADIOLOGICAL TECHNOLOGIST*

Specialist in: *Diagnostic Radiology*
Radiation Therapy
Nuclear Medicine

* International nomenclature adopted by the ISRRT (International Society of Radiographers and Radiological Technicians).

	Areas of knowledge
1.	Radiation physics
2.	Medical and biological knowledge
3.	Pharmacology
4.	Radiation biology and radiation protection
5.	Biostatistics and information science
6.	Public health, hygiene, and hospital organization
7.	Patient care
8.	Diagnostic radiology Radiation therapy Nuclear medicine
9.	Legislation and professional ethics
10.	Language

Note: This is only an example of how the course load might be distributed.

Medical Radiological Technologist
Graduate in Diagnostic Radiology

Course	hours*
Anatomy and Physiology	150
General Pathology and Semiology	120
Radiation Physics	150
Biology and Genetics	90
Radiation Biology	40
Radiation Protection	100
Biostatistics	80
Information Science	60
Hospital Administration and Organization	30
Public Health and Hygiene	50
Patient Care	50
Legislation and Occupational Ethics	40
Language	180
* Hours common to the three specialties	1,140

Diagnostic Radiology

Radiological Pathology	180
Radiological Technology	180
Applied Pharmacology	30
Diagnostic Imaging Technique	150
Positions in Radiology	90
Practicum Diagnostic Radiology	1,330
Specific hours	1,960

Total course hours: 3,100
- Practical 43%
- Theory 57%

Note: This is only an example of how the course load might be distributed.

Medical Radiological Technician
Graduate in Diagnostic Radiology

First course	**hours**
Anatomy and Physiology	150
Radiation Physics	150
Biology and Genetics	90
Biostatistics	80
Language	60
Positions in Radiology	90
Theory	620
Practicum I	
Second course	
General Pathology and Symptomatology	120
Radiation Biology and Radiation Protection	40
Information Science	60
Language	60
Diagnostic Imaging Technology I	75
Radiological Pathology I	90
Radiological Technology I	90
Radiation Protection I	50
Patient Care	50
Theory	635
Practicum II	
Third course	
Radiological Pathology II	90
Radiological Technology II	90
Applied Pharmacology	30
Diagnostic Imaging Technology II	75
Radiation Protection II	50
Public Health and Hygiene	50
Legislation and Occupational Ethics	40
Hospital Organization and Administration	30
Technical Language	60
Theory	515
Practicum III	

Total for Diagnostic Radiology: 3,100 hours
- Theory 57%
- Practical 43%

Medical Radiological Technician
Graduate in Radiation Therapy

Course	**hours***
Anatomy and Physiology	150
General Pathology and Symptomatology	120
Radiation Physics	150
Biology and Genetics	90
Radiation Biology	40
Radiation Protection	100
Biostatistics	80
Information Science	60
Hospital Administration and Organization	30
Public Health and Hygiene	50
Patient Care	50
Legislation and Occupational Ethics	40
Language	180
* Hours common to the three specialties	1,140

Radiation Therapy
Radiation Therapy Technology
Clinical Radiation Therapy
Instrumentation and Dosimetry
Psychology of the Oncological Patient

Course Load	630
Practicum in Radiation Therapy	1,330

Total Course Load: 3,100 hours
- Theory 57%
- Practical 43%

Medical Radiological Technician
Graduate in Nuclear Medicine

Course	hours*
Anatomy and Physiology	150
General Pathology and Symptomatology	120
Radiation Physics	150
Biology and Genetics	90
Radiation Biology	40
Radiation Protection	100
Biostatistics	80
Information Science	60
Hospital Administration and Organization	30
Public Health and Hygiene	50
Patient Care	50
Legislation and Occupational Ethics	40
Language	180
* Hours common to the three specialties	1,140

Nuclear Medicine

Nuclear Medicine Technology
Instrumentation in Nuclear Medicine
Radiation Chemistry and Radiopharmacology
Clinical Nuclear Medicine

Course Load	630
Practicum in Nuclear Medicine	1,330

Total Course Load: 3,100 hours
- Theory 57%
- Practical 43%

APPENDIX IV

Specific Technical and Performance Information

for *CT Scanner* Bid Submission*

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* Taken from: American Association of Physicists in Medicine. *Specification and acceptance testing of computed tomography scanners. Report of Task Group 2 Diagnostic X-Ray Imaging Committee.* New York: American Institute of Physics; 1993.(AAPM Report 39).

Specific Technical and Performance
Information for *CT Scanner* Bid Submission*

Manufacturer: _____

Model: _____

Address: _____

_____

_____

_____

Phone: (_____) _____

Response prepared by:

Name: _____

Title: _____

Authorized Signature: _____

Date: _____

* Use one set of forms for each model bid.

A. SYSTEM ENVIRONMENTAL REQUIREMENTS

1. Electrical Power Sources: List voltage, power, and phasing for each; indicate locations on architectural drawing.

_____

_____

2. Power Conditioning: Give manufacturer and model numbers of power conditions system provided:

_____

3. Air Conditioning Requirements:

Control Area: _____BTU/hr
Gantry Area: _____BTU/hr
Computer Room: _____BTU/hr
Other _____ : _____BTU/hr

4. Mechanical Requirements:

a. Areas where raised "computer floor" is required:

_____

_____

b. Under-floor cable runways required: (Specify depth, width and locations on architectural drawings)

c. Total weight of equipment: _____ lb. (kg)
Gantry: _____ lb. (kg)
Control Console: _____ lb. (kg)
HV *Generator* & Controller: _____ lb. (kg)
Computer System: _____ lb. (kg)
Other _____ : _____ lb. (kg)

d. Minimum floor space required (entire system): _____ sq.ft.(m^2)

5. Plumbing Requirements:

a. Number of drains required*: _____
b. Number of water inlets required*: _____

* Specify location, flow rate, temperature range, etc., on architectural drawings.

6. Physical modifications: Specify the extent to which facility modifications will be performed by the vendor, with respect to installation of electrical troughs, plumbing, electrical power, air conditioning, etc.

_____

_____

_____

7. Radiation Protection: Specify measured maximum ***exposure*** rate 1 meter in any direction from scan isocenter, for widest slice width and highest kVp using a cylindrical tissue equivalent ***phantom*** at least 20 cm in diameter:

Kilovoltage: _____ kVp
Slice width: _____ mm
Phantom diameter: _____ cm
Phantom material: _____
Air ***kerma***: _____ mGy/mAs (mR/mAs)

B. SYSTEM CHARACTERISTICS

1. *X-ray Generator*:

a. Voltage waveform: Continuous: _____
Pulsed: _____

b. kVp settings available (List):

_____

c. mA (mAs) stations available (list for each kVp):
settings at ____ kVp _____
settings at ____ kVp _____
settings at ____ kVp _____
settings at ____ kVp _____

d. Available Scan Times:

Time	*Scan Angle*
_____s	_____°
_____s	_____°
_____s	_____°
_____s	_____°
_____s	_____°
_____s	_____°

2. *X-ray* Tube:

a. Type: Rotating anode: _____
Stationary anode: _____

b. Focal spot sizes (Nominal):

	Scan Plane Dimension	*Axial Dimension*
Focus #1	_____ mm	_____ mm
Focus #2	_____ mm	_____ mm

c. ***X-ray*** beam filtrations (operator variable - include both hardening filters and beam flattering or bow tie filters).

Material	*Thickness**	*Intended Use*
_____	_____	_____
_____	_____	_____
_____	_____	_____

* Specify for hardening filters only.

d. Thermal Characteristics:

Housing cooling rate:	_____ J/min
Anode cooling rate:	_____ J/min
Anode heat storage capacity (cold):	_____ J
Housing heat storage capacity:	_____ J

Type of thermal overload protection system provided:

_____

e. Does ***x-ray*** tube employ a mechanical shutter? _____

3. **Beam Collimation System:**

a. List all available (nominal) slice thicknesses in mm:

_____

b. Slice width settings where prepatient collimator is adjustable in axial dimension

_____

c. Slice width settings where prepatient collimator is fixed in axial dimension

_____

d. Slice width settings where postpatient collimator is adjustable in axial dimension

_____

e. Slice width settings where postpatient collimator is fixed in axial dimension

_____

4. ***Gantry*:**

a. Type of Scan Motion:

Rotate/translate:	_____
Symmetric fan beam, rotating detectors:	_____
Asymmetric fan beam, rotating detectors:	_____
Fan beam, stationary detector ring:	_____
Fan beam, nutating detector ring:	_____

Other: _____

b. Variable geometric magnification available? _____

c. Continuous rotation available? _____

d. ***Gantry*** Aperture:

Maximum ***gantry*** aperture diameter:	_____ cm
Maximum scan (sampled) diameter:	_____ cm

e. ***Gantry*** Tilt (maximum):

Gantry top toward table:	_____ °
Gantry top away form table:	_____ °
Angulation accuracy:	± _____ °

f. Light-field Localizer:

Type:	Laser:	_____
	Focused Light Beam:	_____
Configuration:	Transaxial:	_____
	Sagittal:	_____
	Coronal:	_____
Position of transaxial localizer:		
	At scan plane:	_____
	External to scan aperture:	_____
Accuracy of transaxial localizer*		± ___ mm

*Coincidence of light and *x-ray* field centers.

5. Patient Scanning Table

a. Maximum motions:

Longitudinal (full out to full in):	_____ cm
Accuracy of table incrementation*:	± _____ mm
Reproducibility*	
* Table loaded with 180 lb (80 kg)	± _____ mm
Minimum table height:	_____ cm
Maximum table height:	_____ cm

b. Location(s) of table position indicators:

Gantry:	_____
Table:	_____
Control console:	_____
Scan image:	_____

c. Table detachable from ***gantry***? _____

Specific cost if optional:	$ _____
Cost of extra beds:	$ _____ ea

d. Table tilt (maximum):

Head end up:	_____ °
Head end down:	_____ °
Angulation accuracy:	± _____ °

6. Detectors

a. Type:

Scintillator/photodiode:	_____
Scintillator/PM tube:	_____
Type of scintillator:	_____
Pressurized xenon:	_____
Other:	_____

b. Number (exclude reference detectors): _____

c. Efficiency:

Scan Mode	*kVp*	*Geometric (%)*	*Total (%)*
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

d. Data sampling:

Scan Time		*# Projections*	*# Ray Samples**
_____	$	_____	_____
_____	$	_____	_____
_____	$	_____	_____
_____	$	_____	_____
_____	$	_____	_____

* Give all values if independently variable.

e. Recommended calibration frequency:

"Air calibration" scans: _____

"Water calibration" scans: _____

7. Computer System:

a. Image reconstruction time: (measure from scan start to completion of display, i.e., include scan time)*.

Scan Mode	*Reconstruction Matrix*	*Scan Time*	*FOV*	*Reconstruction Time*
Standard Head	_____	_____ s	_____cm	_____ s
Standard Adult Body	_____	_____ s	_____cm	_____ s
Highest Resolution	_____	_____ s	_____cm	_____ s
Fastest Scan	_____	_____ s	_____cm	_____ s

* Indicate when display matrix differs from reconstruction matrix.

b. Faster reconstruction options (Specify)

Option: _____ $ _____

Performance (Optional conditions):

Scan Mode	*Reconstruction Time*
Standard Head	_____ s
Standard Adult Body	_____ s
Highest Resolution	_____ s
Fastest Scan	_____ s

c. Simultaneous reconstruction and scanning? _____

d. Data storage and image archiving:

Storage Capacity*

Device	*MBytes*	512^2	256^2	*Raw Data*
	Images	*Images*	*Images*	*Files*
Magnetic tape	_____	_____	_____	_____
Magnetic tape	_____	_____	_____	_____
Fixed disc drive	_____	_____	_____	_____
Fixed disc drive	_____	_____	_____	_____
Optical disc	_____	_____	_____	_____

* Uncompressed data files

List optional storage devices and additional cost:

_____ $ _____

_____ $ _____

Nondestructive data file compression available? _____

Compression ratio(s): _____

e. Convolution ***kernels*** (reconstruction filter functions):

Name	*Design Purpose*
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

f. Image display system:

Pixels displayed (entire screen): Horizontal _____

Vertical _____

Image screen size (diagonal):

Operator's console: _____ in (cm)

Physician's console: _____ in (cm)

Gray scale bar displayed? _____

Alphanumeric information displayed

(Check where appropriate):

	On Image	*On Separate Data Screen*
Patient's name:	_____	_____
ID number:	_____	_____
Age:	_____	_____
Sex:	_____	_____
Date of exam:	_____	_____
Time of exam:	_____	_____

Slice #	_____	_____
kVp:	_____	_____
mA(s):	_____	_____
Scan time:	_____	_____
Slice width:	_____	_____
Bed position:	_____	_____
Bed increment:	_____	_____
Convolution ***kernel***:	_____	_____
Gantry tilt angle:	_____	_____
Body side (R/L):	_____	_____

g. Diagnostic software features (check if standard, give cost if optional).

Feature	*Standard*	*Cost**
Square region-of-interest (ROI):	_____	$ ____
Rectangular ROI:	_____	$ ____
Circular ROI:	_____	$ ____
Arbitrarily shaped ROI:	_____	$ ____
Average CT number within ROI:	_____	$ ____
Std. deviation of CT number:	_____	$ ____
Histogram of CT numbers within ROI:	_____	$ ____
Distance measuring utility:	_____	$ ____
Accuracy:		± ____ mm
Grid overlay:	_____	$ ____
Profile utility (CT number plot between image points):	_____	$ ____
Highlighting of ***pixels*** within specific CT number range:	_____	$ ____
Multiple image display (e.g., 2 x 2, 3 x 3):	_____	$ ____
Gray scale inversion:	_____	$ ____
Image reversal (left to right):*	_____	$ ____
Image inversion (top to bottom):	_____	$ ____
Subtraction of two images:	_____	$ ____
Reconstruction magnification (arbitrary FOV within limits):	_____	$ ____
Non-reconstruction magnification:	_____	$ ____
High density artifact removal:	_____	$ ____
Programmable window settings:	_____	$ ____
Multi-planar reconstruction:	_____	$ ____
Arbitrary angle reconstructions:	_____	$ ____
Dual windowing (simultaneous display of two CT number ranges):	_____	$ ____
Three dimensional image display:	_____	$ ____
Surface rendering:	_____	$ ____
Transparency rendering:	_____	$ ____
Bone mineral density measurement:*	_____	$ ____
Dual energy material decomposition:	_____	$ ____
Xenon (cerebral blood flow) imaging:*	_____	$ ____
Cardiac gating:*	_____	$ ____

Radiation therapy treatment planning:* _____ $ ____
Compiler (Fortran, C, etc.) for research programming: _____ $ ____
ACR/NEMA image transfer interface:* _____ $ ____
Gamma correction to match CRT phosphor to sensitivity curve of film? _____ $ ____
SMPTE pattern for *QA*: _____ $ ____
Other features* (list):

_____ _____ $ ___
_____ _____ $ ___
_____ _____ $ ___

* Include cost of additional hardware required.

8. Hardware Accessories: (check if standard, give cost if optional).

Feature	*Standard*	*Cost**
Head holder:	_____	$ ____
Infant holder:	_____	$ ____
Flat (radiation therapy simulation) tablet insert:	_____	$ ____
Other: (specify) _____	_____	$ ____
_____	_____	$ ____

9. Radiographic Scan Mode:

a. Projections available: AP: _____
Lateral: _____
Arbitrary angle: _____

b. Maximum scan dimensions (at ***gantry*** axis):
length: ____ mm
width: ____ mm

c. Software for scan localization from radiograph: ____
Localization of slice positions: ____
Accuracy: ____
Localization of ***gantry*** (table) tilt: ____
Accuracy: ____

10. Hard Copy Images:

a. Standard multiformat camera provided: (Manufacturer, model

_____

b. Film sizes and display formats:

Film size(s)	*Display Format*
8" x 10" (20 cm x 25 cm)	1 on 1 _____
	4 on 1 _____
	9 on 1 _____
	other: _____

10" x 12" (25 cm x 30 cm) 1 on 1 _____
4 on 1 _____
9 on 1 _____
other: _____

14" x 17" (35 cm x 43 cm) 4 on 1 _____
9 on 1 _____
16 on 1 _____
other: _____

Other film size: _____ _____
_____
_____

c. Optional hard copy imaging devices available:

Device	*Cost*
_____	$ _____
_____	$ _____
_____	$ _____

11. System Performance:

a. Specification of Performance Data:

Spatial Resolution: Measured in cycles/cm at an MTF of 10%.

Image Noise: Measure within an ROI of ≈1 cm^2, centered within a 15-21 cm diameter cylindrical water ***phantom*** for head and pediatric scans, and a 30-32 cm ***phantom*** for adult body scans. Express as a percent of the effective linear attenuation coefficient of water, corrected for the scanner contrast scale.

Radiation Dose: Specify all ***dose*** data in cGy (rads) as either multiple scan average *dose* (MSAD) or computed tomography *dose* index (CTDI), check as appropriate:

CTDI _____
MSAD _____

Dose must be measured at a radial depth of 1 cm in acrylic ***phantoms*** meeting specifications of the U.S. CDRH (FDA). For all 360° scans measure at the 12 o'clock position in the ***phantom***.

Measure at mid scan arc for scans < 360°, and at midpoint of overlap region for scans > 360°.

Performance Conditions:

Scan Mode	*Reconstr. Matrix*	*FOV (cm)*	*Convol. Kernel*	*kVp*	*Scan Time*	*mAs*	*Slice Width*
Std. Head	_____	___	_____	___	_____	_____	_____
Std. Adult Body	_____	___	_____	___	_____	_____	_____
Best Resolution	_____	___	_____	___	_____	_____	_____
Fastest Scan	_____	___	_____	___	_____	_____	_____
Lowest Noise Body	_____	___	_____	___	_____	_____	_____
Lowest Noise Head	_____	___	_____	___	_____	_____	_____
Pediatric Head	_____	___	_____	___	_____	_____	_____

Pediatric Body _____ ___ _____ ___ _____ _____ _____

Performance Specifications:

Scan Mode	*Resolution cycles/cm*	*Noise % SD*	*Dose (cGy)*
Std. Head	_____	_____	_____
Std. Adult Body	_____	_____	_____
Best Resolution	_____	_____	_____
Fastest Scan	_____	_____	_____
Lowest Noise Body	_____	_____	_____
Lowest Noise Head	_____	_____	_____
Pediatric Head	_____	_____	_____
Pediatric Body	_____	_____	_____

b. Collimation performance: Measure sensitivity and radiation profiles in mm at full width half maximum (FWHM) within a radius of 5-15 cm of ***gantry*** axis. Tolerances should reflect manufacturer's range of acceptance error.

Nominal Slice Setting	*Sensitivity Profile*		*Radiation Profile*	
	Width	*Tolerance*	*Width*	*Tolerance*
(min) _____	_____	±_____	_____	±_____
_____	_____	±_____	_____	±_____
_____	_____	±_____	_____	±_____
_____	_____	±_____	_____	±_____
_____	_____	±_____	_____	±_____
_____	_____	±_____	_____	±_____
(max) _____	_____	±_____	_____	±_____

C. ADMINISTRATIVE DETAILS

1. Warranties:

a. Warranty Period (months beyond formal acceptance): _____

Exclusions:

X-ray tubes* _____

Other exclusions (specify):

_____

_____

* If excluded, give additional cost of ***x-ray*** tube warranty during base warranty period: $ _____

b. Normal service hours: _____ AM to _____ PM,

_____ (day) through _____ (day).

2. **Down Time:**
a. Definition: Down time is defined as time when the scanner is unavailable for patient use due to failure of critical hardware or software component(s). Down time is defined over the base time
period from _____ AM to _____ PM,
from _____ (day) through _____ (day).
Excludes time for required preventive maintenance, component failure directly resulting from inadequate (owner-supplied) preventive maintenance or operation beyond performance specifications.
b. Guarantee: Down time shall not exceed _____ % of the base time period over any calendar month of the warranty period.
c. Penalty: The warranty period will be extended by _____ days for every 1% of down time beyond the guaranteed minimum.

3. **Required Preventive Maintenance:**
_____ hrs per week
_____ hrs every two weeks
_____ hrs per month

4. **Service Contracts:** (Use plans B and C as necessary for optional contracts)

Plan A (check all that apply)

All parts excluding ***x-ray*** tubes:	_____
X-ray tubes:	_____
All labor from 8:00 AM to 5:00 PM Monday through Friday:	_____
Night labor: between _____ PM and _____ AM, Monday through Friday:	_____
Weekend and holiday labor:	_____
Cost: Year 1 after warranty:	$ _____
Maximum annual increase in years 2-5 after acceptance:	_____ %

Plan B (Check all that apply):

All parts excluding ***x-ray*** tubes:	_____
X-ray tubes:	_____
All labor from 8:00 AM to 5:00 PM Monday through Friday:	_____
Night labor: between _____ PM and _____ AM Monday through Friday:	
Weekend and holiday labor:	_____
Cost: Year 1 after warranty:	$ _____
Maximum annual increase in years 2-5 after acceptance:	_____ %

Plan C (Check all that apply):

All parts excluding ***x-ray*** tubes: _____
X-ray tubes: _____
All labor from 8:00 AM to 5:00 PM
Monday through Friday: _____
Night labor: between _____ PM and _____ AM,
Monday through Friday: _____
Weekend and holiday labor: _____
Cost: Year 1 after warranty $ _____
Maximum annual increase in years 2-5 after
acceptance: _____ %

5. **Maximum Service Response Time** (normal business hours):
_____ hrs

6. **Other Users:**
If possible, provide list of names, addresses, telephone numbers and a contact person for 3 purchasers of the ***CT scanner*** model bid in this document.

Name: _____
Address: _____
_____
_____
Telephone No.: _____
Contact Person: _____

Name: _____
Address: _____
_____
_____
Telephone No.: _____
Contact Person: _____

Name: _____
Address: _____
_____
_____
Telephone No.: _____
Contact Person: _____

APPENDIX V

Quality Control in Diagnostic Imaging*

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* Taken from: National Council on Radiation Protection and Measurements. *Quality assurance for diagnostic imaging. Recommendations of the National Council on Radiation Protection and Measurements.* Bethesda: NCRP; 1988. (NCRP Report 99).

Note: The following publication is also recommended. Sociedad Española de Protección Radiológica, Sociedad Española de Física Médica. *Protocolo español de control de calidad en radiodiagnóstico. Aspectos técnicos.* Madrid: SEFM-SEPR; 1996.

Table 1
Photographic *quality control*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Film and chemical storage	Essential	Visual inspection, thermometer, hygrometer	Fumes? Radiation? 65 ± 5 °F 50% ± 10% Humidity	Monthly
Darkroom conditions	Essential	Visual inspection, thermometer, hygrometer	Clean? 70 ± 5°F 50% ± 10% Humidity	Monthly
Darkroom fog	Essential	Visual inspection, film, cassette, step wedge. Opaque material	<0.05 increase in density in 2 min	Semiannually
Manual processing				
Timer and Thermometer	Essential	Comparison: timer and thermometer	Timer—± 5% Thermometer— ± ½ °F	Monthly
Chemicals	Essential	Sensitometer, Densitometer, Control emulsion	B + F + 0.05 Mid density ± 0.15 Density difference ± 0.15	Daily or before processing any films
Processor sensitometric evaluation	Essential	Sensitometer, Densitometer, Control emulsion	B + F + 0.05 Mid density ± 0.10 Density difference ± 0.10	Daily— before processing any film
Tank level checks clean-up films, clean crossovers	Essential	Visual inspection, Clean-up films	Full tanks, No scratches on films, Clean cross-overs	Daily
Cleaning and preventive maintenance	Essential	As suggested by manufacturer	As indicated by manufacturer	Manufacturer's instructions
Fixer				
Replenishment rate	Essential	Visual inspection	± 5%	Daily
Flow meter accuracy	Essential	Stop watch and graduated cylinder	± 5%	Quarterly
Film washing				
Wash water flow rate	Essential	Visual inspection of water flow meter	± 10%	Daily
Film fixer retention	Essential	Fixer retention test kit	<2 $\mu g/cm^2$ retained thiosulfate	Semiannually

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Processor transport time	Essential	Stop watch	± 3%	Annually
Developer temperature	Essential	Thermometer built into processor	± 0.5 °F	Daily
Wash water temperature	Essential	Thermometer built into processor	± 5.0 °F	Daily
Built-in developer thermometer accuracy	Essential	Calibrated thermometer	± 0.5 °F	Monthly
Developer recirculation filter	Essential	As suggested by manufacturer	As indicated by manufacturer	Manufacturer's instructions
Water filters	Essential	Visual inspection of flow meter	Change when flow rate decreases by more than 10%	Daily
Replenishment rate	Essential	Visual inspection	± 5%	Daily
Flow meter accuracy	Essential	Stop watch and graduated cylinder	± 5%	Quarterly
Daylight systems	Essential	As suggested by manufacturer	As indicated by manufacturer	Manufacturer's instructions
Processor stand-by units (verify function)	Essential	Visual inspection	As indicated by manufacturer	Daily
Automatic chemical mix system	Essential	As suggested by manufacturer	As indicated by manufacturer	Manufacturer's instructions
Silver recovery efficiency	Desirable	Silver test paper, direct reading device, or Hospital laboratory	± 10% of estimated weight	Quarterly

Table 2
Radiographic *quality control*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Filtration (HVL)	Essential	Dosimeter, type 1100 aluminum sheets, semi-log paper	See (*40*)	Annually
Light field and *x-ray* field alignment	Essential	Alignment template or nine pennies and tape measure	± 2% of *source*-to-image distance	Semi-annually
Automatic collimation or positive beam limitation and accuracy of x-y scales	Essential	Alignment template or nine pennies and tape measure	± 3% of *source*-to-image distance	Semi-annually
X-ray beam, bucky motion and centering	Essential	Homogeneous *phantom* and lead strips	Lead strips should be centered. Density uniform to ± 0.10 perpendicular to anode-cathode axis	Annually
X-ray beam perpendicularity, and SID indicator accuracy	Essential	Perpendicularity test tool and tape measure	Perpendicularity accuracy provided by tool manufacturer. SID indicator should be within ± 2% of measured value.	Annually
Focal spot size	Essential	Pinhole camera, lead star pattern, or slit	See (*40*)	Acceptance test
Visual checks	Essential	Visual check list	Pass-fail	Annually
Mechanical and electrical safety checks	Essential	See (*40*)	See (*40*)	Annually
Overload protection	Essential	Single *exposure* rating chart	Prevent *exposures* that exceed 80% of tubes's maximum rated load	Annually
kVp	Essential	kVp cassette or direct reading kVp device	± 5%; less over limited range, e.g., ± 2 kVp for 60 to 100 kVp	Annually
timers	Essential	Timing device	Single phase, see (*40*). Three phase, ± 5%	Annually
mR/mAs	Essential	Dosimeter, homogeneous *phantom*	± 10%	Annually

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Linearity	Essential	Dosimeter	± 10% over clinical range	Annually
Exposure reproducibility	Essential	Dosimeter	± 5%	Annually
Phototimers				
Abbreviated tests Sensor panel function	Essential	Lead sheets and dosimeter	± 10% in ***exposure***	Semi-annually
kVp correction circuit		Homogenous ***phantom***	Density of 1.20 ± 0.30	
Proper ***exposure*** at various mA stations		Homogeneous ***phantom*** and dosimeter	± 10% in ***exposure***	
Proper ***exposure*** for various field sizes		Homogeneous ***phantom***	Density of 1.20 ± 0.10	
Phototimer reproducibility		Homogeneous ***phantom*** and dosimeter	± 5% in ***exposure***	
Density control function		Homogeneous ***phantom*** and dosimeter	Steps of 25% in ***exposure***, verify button function, i.e., + gives increase, - gives decrease	
Complete tests All of "abbreviated tests" plus--	Essential			Annually
Sensor panel location		Lead sheets	Pass-fail	
Minimum ***exposure*** time		***Exposure*** timing device	<10 ms	
Back-up ***exposure*** time		***Exposure*** timing device and lead sheet	<600 mAs	
Proper ***exposure*** with change in patient size		Homogeneous ***phantom***	Density of 1.20 ± 0.30	
Grid uniformity Bucky grids	Essential	Homogeneous ***phantom***	Uniform films, no grid lines, density of 1.20 ± 0.10 perpendicular to anode-cathode axis	Annually
Grid cassettes and clip-on grids	Essential	Homogeneous ***phantom***	Uniform films, density of 1.20 ± 0.10 perpendicular to anode-cathode axis	Semi-annually
Grid alignment	Essential	Homogeneous ***phantom***	Uniform films, density of 1.0 ± 0.10 perpendicular to anode-cathode axis	Annually

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Screen-film-cassette speed matching	Essential	Standard (comparison) cassette	Densities within ± 0.05 for all cassettes used in one area	Annually
Screen-film contact	Essential	Coarse copper mesh	No significant areas of poor contact	Annually
Exposure per film	Essential	Homogeneous ***phantom*** and dosimeter	Film density of 1.20 ± 0.15 for AP lumbar spine technique and appropriate ***phantom***. ***Exposure*** for AP lumbar spine in 100 to 160 $\mu C\ kg^{-1}$[a] range or less	Every ***quality control*** check
Matching images and ***exposures***	Essential	Homogeneous ***phantom*** and dosimeter	Film densities within ± 0.15 of average for all rooms. Entrance ***exposures*** within ± 10% for identical rooms	Every ***quality control*** check
X-ray output waveform	Desirable	***X-ray*** detector and oscilloscope	Check for spikes, aberrant wave shapes, etc.	Annually

[a] 100 $\mu C\ kg^{-1}$ is equal to 400 mR

Table 3
Fluoroscopic and cine *quality control*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
X-ray tubes, collimators, and generators				
All indicated tests	Essential	See (*40*)	See (*40*)	Semi-annually
Maximum fluoroscopic ***exposure*** rates	Essential	Lead sheets and dosimeters	≤1.3 mC kg^{-1a}/min for manual systems; ≤2.6 mC kg^{-1a}/min for automatic ***exposure*** control systems.	Semi-annually
Standard fluoroscopic *exposure* rates	Essential	Homogeneous ***phantom*** and dosimeter	0.5 to 0.8 mC kg^{-1a}/ min, 6-inch mode, without grid; 0.4 to 0.7 mC kg^{-1a}/min, 9-inch mode, without grid. Automatic ***exposure*** control should set 80 to 90 kVp.	Semi-annually
Spot film and spot film camera ***exposures***	Essential	Homogeneous ***phantom*** and dosimeters	13 to 50 nC kg^{-1a}/ image at intensifier; film density of 1.20 ± 0.15. See (*40*)	Semi-annually
Cine film ***exposure***	Essential	Homogeneous ***phantom*** and dosimeter	Approx. 4 nC kg^{-1a}/ frame at intensifier for 9-inch mode; approx. 7 nC kg^{-1a}/frame at intensifier for 6-inch mode. See (*40*)	Semi-annually
Automatic brightness, *exposure*, and gain control systems	Essential	Homogeneous ***phantom*** and dosimeter	ABC-AEC systems should function similar to same installations and other similar systems. AGC should be able to compensate from 3 to 9 inches of acrylic.	Semi-annually
Fluoroscopic, spot film, and cine image size and beam limitation	Essential	Radiographically opaque template, direct ***exposure*** x-ray film	Displayed diameter not less than 1 cm smaller than specified diameter. Error between beam size and image size should be no greater than 3% of SID for all modes and at any tower height.	Semi-annually

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Fluoroscopic, spot film, and cine resolution and distortion	Essential	High and low contrast resolution patterns, homogeneous *phantom*, distortion grid	See (*40*). Distortion symmetric, same for fluoroscopic, spot film, and cine images	
Radiographic/ Fluoroscopic				Semi-annually
Special procedures labs				Semi-annually
Cardiac catheterization labs				Semi-annually (Each case)
Cine projectors	Essential	SMPTE cine test film	Resolve all resolution elements in image, minimal jitter, clean lenses, prisms, and projection surface, projection bulb clean without metallic deposits	
Image lag	Desirable	Lag shutter, storage oscilloscope and camera	See (*40*)	Semi-annually
Flare	Desirable	Lead disc, video waveform monitor	See (*40*)	Semi-annually
Where low contrast image is important				Quarterly
Relative conversion factor	Desirable	Dosimeter, radiometer	Look for changes over time indicating deterioration of intensifier	Semi-annually

[a] 0.26 mC kg^{-1} = 1 R; 0.26 nC kg^{-1} = 1 μR

Table 4
Mobile radiographic, capacitor discharge, and fluoroscopic systems *quality control*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Mobile radiographic				
Batteries (completely discharged, fully charged and serviced)	Essential	As suggested by manufacturer	As indicated by manufacturer	Annually or manufacturer's instructions
All applicable tests	Essential	See (*40*)	See (*40*)	Annually
Capacitor discharge radiographic systems	Essential	See (*40*)	See (*40*) kVp-acceptance test value becomes operating level rather than indicated kVp	Annually
Mobile fluoroscopic systems				
All applicable tests including tests of analog and digital video recording systems	Essential	See (*40*)	See (*40*)	Semi-annually

Table 5
Quality control tests for conventional tomography

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Section level	Essential	Tomographic *phantom*	± 5 mm	Annually
Level incrementation	Desirable	Tomographic *phantom*	± 2 mm	Annually
Section thickness	Essential	Tomographic *phantom*	To be established for the particular unit	Annually
Exposure angle	Desirable	Tomographic *phantom*	± 5 degrees for wide angle tomography; less for small angle tomography	Annually
Exposure uniformity and pattern	Desirable	Tomographic *phantom*	Qualitative evaluation	Annually
Spatial resolution	Essential	Tomographic *phantom*	40 mesh or better	Annually
Patient *exposure*	Essential	Radiation dosimeter	To be established for the particular unit. See (*40*)	Annually

Table 6
Quality control tests for mammographic equipment

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
kVp accuracy	Essential	Mammographic kVp device	± 2 kVp	Semi-annually
Entrance *exposure*	Essential	Low-energy *ionization chamber*	± 10%	Semi-annually
Mammographic low and high contrast resolution	Essential	Resolution *phantom*	No noticeable deterioration in performance	Semi-annually

Table 7
Dental radiography *quality control*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Test film	Essential	Film, CDRH device	± 2 optical density steps	Daily
Test radiograph	Essential	Film	Visual	Daily
Retake log	Essential			Daily
Film processing	Essential	Film, sensitometer, densitometer	< ± 0.1 density	Daily
Operation of darkroom	Essential			Quarterly
Cassette and Screens	Essential	Film, wire mesh	Visual	Annually
Viewboxes	Desirable	Light meter		Annually
X-ray unit leakage radiation	Essential	Survey meter	$<26\ \mu C\ kg^{-1}$[a]/h at 1 m	Annually
source-end of cone	Essential		>4 in. (<50 kVp) >7 in. (>50 kVp)	Annually
beam alignment and collimators	Essential	Film	$<2^{3}/_{4}$ in. (end of cone)	Annually
filtration (HVL)	Essential	Type 1100 Al filters, *ion chamber*	See (*40*)	Annually
timer	Essential	Spinning top, film		Annually
exposure switch	Essential			Annually
radiation *exposure*	Essential	Calibrated *ion chambers*	Range of acceptable *exposures*	Annually

[a] $26\ \mu C\ kg^{-1} = 100$ mR.

Table 8
Quality control test for special procedures equipment

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Film changer screen-film contact	Essential	Wire mesh	No significant difference between static and dynamic conditions	Semi-annually
Low and high contrast resolution	Essential	Fluoroscopic resolution test device	No significant difference between static and dynamic conditions	Semi-annually
Optical density of films over duration of filming run	Essential	Fluoroscopic *phantom*	Optical density difference $< \pm 0.2$	Semi-annually
Cinefluorographic *exposure* rates	Essential	Fluoroscopic *phantom* and *ionizing chamber*	Approx. 2.6 to 5 nC/kg^{-1}[a]/frame at intensifier for 23 cm mode; Approx. 5 to 8 nC/kg^{-1}[a]/frame at intensifier for 15 cm mode. See (*40*)	Semi-annually
Cinefluorographic low and high contrast resolution	Essential	Fluoroscopic resolution test device	No degradation from fluoroscopic measurements	Semi-annually
Ancillary special procedures equipment	Essential	Recommendations of equipment manufacturer	Recommendations of equipment manufacturer	Recommendations of equipment manufacturer

[a] 2.6 nC kg^{-1} = 10 μR.

Table 9
Quality control tests for *CT scanners*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
CT number calibration	Essential	20 cm diameter ***phantom***[a]	Air: - 1000 ± 3 CT numbers Water: 0 ± 1.5 CT numbers	Monthly
CT number constancy	Desirable	20 cm diameter ***phantom***[a]	Value and std. dev. for water relatively constant	Daily
Hard copy output and visual display	Essential	"Standard" image stored on disk. See (*40*)	Luminance & contrast not significantly different	Daily
Low contrast resolution	Essential	Low contrast ***phantom***	0.5 cm holes	Monthly
CT number uniformity	Essential	20 cm diameter ***phantom***[a]	Variation ± 5 CT numbers among mean of 100 ***pixels***	Monthly
Patient dosimetry	Essential	Dosimetry ***phantom***	± 20%	Semi-annually
Table position	Essential	Ruler	± 2 mm	Semi-annually
Table indexing	Essential	Ruler or prepackaged film	± 0.5 mm for each increment	Semi-annually
Table backlash	Essential	Ruler or prepackaged film	± 1 mm	Semi-annually
CT number dependence on slice thickness	Essential	20 cm diameter ***phantom***[a]	Mean ± 3 CT numbers ave. over 100 ***pixels***	Semi-annually
Dependence of CT number on ***phantom*** size	Desirable	5 cm to 30 cm diameter ***phantom***[a]	± 20 CT numbers	Semi-annually
Accuracy of scout localization view	Essential	Small object in ***phantom***	± 1 mm	Annually
Accuracy of distance measurements	Essential	1 cm spaced holes	± 1 mm	Annually
High contrast resolution	Desirable	High contrast ***phantom***	0.1 cm holes	Monthly
Distortion of video monitor	Desirable	1 cm spaced holes	± 1 mm anywhere on image projection to life size	Monthly
Sensitivity profile	Desirable	45° wire in ***phantom***	FWHM within 1 mm of nominal (5-15 mm) and within 0.5 mm (<5 mm)	Monthly

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Noise characteristics	Desirable	20 cm diameter *phantom*[a]	Std deviation of CT numbers $(mAs)^{-1/2}$	Semi-annually
Dependence of CT number on *phantom* position	Desirable	20 cm diameter *phantom*[a]	± 5 CT numbers	Annually
Dependence of CT number on algorithm	Desirable	20 cm diameter *phantom*[a]	± 3 CT numbers	Annually

[a] Water filled or water equivalent solid material.

Table 10
Digital imaging systems *quality control*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Digital subtraction angiographic imaging systems				
Fluoroscopic and conventional film imaging portions of system	Essential	See (*40*)	See (*40*)	Semi-annually
Digital imaging portion of system	Essential	Patient equivalent *phantom* with removable simulated iodine-filled vessels, step wedge, low contrast resolution pattern, mesh pattern, dosimeters	Low contrast resolution 1.6 c/mm for 6-inch and 1.2 c/mm for 9-inch intensifier; Other tests—similar results to acceptance tests and similar pieces of equipment	Quarterly
Visual (video) display and hard copy camera	Essential	SMPTE test pattern	See (*40*)	Daily

Table 11
Nuclear medicine *quality control*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Radiation Calibrator				
Zero setting	Essential			Daily
Background setting	Essential			Daily
Test setting	Essential			Daily
Precision	Essential	^{137}Cs ***source***	± 5%	Daily
Relative response to reference	Essential	^{57}Co, ^{137}Cs and ^{133}Ba ***sources***	± 2-5%	Quarterly
Linearity response	Essential	^{99m}Tc eluant, lead filters	± 5%	Quarterly
Accuracy	Essential	^{57}Co, ^{137}Cs and ^{133}Ba standards	± 5%	Annually
Geometry	Desirable	^{99m}Tc liquid	± 2%	Bi-annually
Scintillation Spectrometer				
Pulse height analyzer	Essential	^{137}Cs ***source***	Voltage or gain adjust	Daily
Background	Essential		$< \pm 3\sigma$	Daily
Precision	Essential	^{137}Cs ***source***	$< \pm 3\sigma$	Daily
60-cycle	Essential	60 cycle pulse signal	3600 ± 1 or 2 counts	Weekly
Chi-square test	Essential	^{137}Cs ***source***	$0.1 < p < 0.9$	Quarterly
Energy calibration	Essential	^{137}Cs ***source***	Voltage or gain adjust	Quarterly
Energy resolution	Essential	^{137}Cs ***source***	8-9% solid crystal 10-12% well crystal	Annually
Linearity	Essential	^{99m}Tc, ^{131}I, ^{137}Cs ***sources***	± 2 keV	Annually
Zero offset	Essential	^{99m}Tc, ^{131}I, ^{137}Cs ***sources***	± 2 keV	Annually
Count rate effects	Essential	^{99m}Tc liquid (high ***activity***), paired ***sources***	correction	Annually
Nonimaging Scintillation Systems				
Precision	Essential	^{137}Cs ***source***	$< \pm 3\sigma$	Daily

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Geometry	Essential	liquid *source*	correction factor	Bi-annually
Rectilinear Scanners				
Precision	Essential	^{137}Cs flood *source*	$< \pm 3\sigma$	Daily
Density calibration	Essential	Point *source*, pulse generator	Within $\pm$ 0.2 density	Weekly
Contrast enhancement	Essential	Step wedge	Compare with baseline O.D. vs count density	Quarterly
Collimator spatial resolution	Desirable	Point *source*	Compare 50% response	Annually
Collimator depth of focus	Desirable	Point *source*	Compare 50% response	Annually
Scintillation Cameras				
Uniformity	Essential	^{99m}Tc or ^{57}Co Flood or point *source*	$\pm$ 6-7% or computer corrected	Daily
Linearity	Essential	Flood or point *source*; bar or hole *phantom*	Visual	Weekly
Resolving power	Essential	Same as above	Visual	Weekly
Relative sensitivity	Essential	Flood or point *source*	$\pm$ 10%	Weekly
Count rate characteristics	Essential	Different *source activities*	Input count rate for 20% loss	Semi-annually
Energy resolution	Essential	^{99m}Tc or ^{57}Co point *source*	Minimum of 50 channels per FWHM	Annually
System spatial resolution	Desirable	^{99m}Tc line source, scatter material	Comparison with acceptance value	Annually
Imaging Accessories				
Multiformat çamera	Essential	Bar or hole *phantom*	See (*40*)	
Video tape systems	Essential		See (*40*)	
Single Photon Emission Computed Tomography				
Uniformity	Essential	Flood *source*	$< \pm$ 1% corrected	Daily
Center of rotation	Essential	Point *source*	$< \pm$ 0.5 *pixels* ($< \pm$ 2 mm)	Weekly
Pixel sizing	Essential			Weekly

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Table-camera	Essential		Within ± 2 mm	Weekly
Spatial resolution	Desirable	Line *sources*, scattering medium, high or medium sensitivity collimator		Annually
Phantoms	Desirable			
Camera-computer interface	Desirable	Point *source*		Annually

Table 12
Ultrasound *quality control*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Depth calibration accuracy	Essential	***Phantom*** or test object	± 1%	Monthly
Digital caliper accuracy	Essential	***Phantom*** or test object	± 1% vertical ± 3% horizontal	Monthly
Compound scan misregistration	Essential	***Phantom*** or test object	5 mm maximum separation	Quarterly
Externally referenced measurement accuracy	Essential	***Phantom*** or test object	Tolerance varies with the clinical need	Annually
System sensitivity	Essential	Tissue-mimicking ***phantom***	Max. visualization depth within ± 1 cm	Monthly
Gray scale display and photography	Essential	Tissue ***phantom***/patient image	Same gray bars visualized; All parenchymal scatterers detected	Daily
M-mode depth calibration and Time markers	Essential	***Phantom*** or test object	± 1% depth calibration; time markers ± 10%	Quarterly
Spatial resolution	Desirable	***Phantom***		Annually
Gray scale dynamic range	Desirable	Gray scale ***phantom***; Electronic burst ***generator***	Within ± 5 dB	Annually
Air filters	Essential	Examination	Clean	Monthly
Cables	Essential	Examination	Intact	Monthly

Table 13
Video imaging systems *quality control*

Test	Essential or desirable	Test device	Suggested performance criteria	Minimum frequency
Video signal levels and line terminations	Essential	Video waveform monitor or oscilloscope	75 —ohm termination at *end* of video cable; video signal— ± 5% of peak-to-peak voltage.	Semi-annually
Television monitors	Essential	Video signal generator	All 10% steps visible, minimal distortion, resolution as specified by manufacturer	Semi-annually
Hard copy cameras and visual displays	Essential	SMPTE test pattern	Mid-density ± 0.15, film and visual display should give similar appearing images, 5% and 95% patches should be visible on film and visual display. Resolution should be consistent.	Daily
Video tape, disc, and digital recorders	Essential	Video signal generator, SMPTE video test tapes, video waveform monitor, high & low contrast *x-ray* resolution patterns	All 10% steps visible, minimal distortion, resolution as specified by manufacturer, drop-outs and jitter minimal, some increase in noise will be apparent in gray scale, some (minimal) loss in contrast between *x-ray* (fluoroscopic) and recorded image should be anticipated	Semi-annually

APPENDIX VI

Quality Control in Radiation Therapy*

* Taken from: American Association of Physicists in Medicine. Comprehensive QA for radiation oncology: Report of the AAPM Radiation Therapy Committee Task Group No. 40. *Med Phys* 1994;21(4);581-618.

Table I
QA of Cobalt-60 units

Frequency	Procedure	Tolerance[a]
Daily	Safety	
	Door interlock	Functional
	Radiation room monitor	Functional
	Audiovisual monitor	Functional
	Mechanical	
	Lasers	2 mm
	Distance indicator (ODI)	2 mm
Weekly	Check of ***source*** positioning	3 mm
Monthly	Dosimetry	
	Output constancy	2%
	Mechanical checks	
	Light/radiation field coincidence	3 mm
	Field size indicator (collimator setting)	2 mm
	Gantry and collimator angle indicator	1 deg.
	Cross-hair centering	1 mm
	Latching of wedges, trays	Functional
	Safety interlocks	
	Emergency off	Functional
	Wedge interlocks	Functional
Annual	Dosimetry	
	Output constancy	2%
	Field size dependence of output constancy	2%
	Central axis dosimetry parameter constancy (PDD/TAR)	2%
	Transmission factor constancy for all standard accessories	2%
	Wedge transmission factor constancy	2%
	Timer linearity and error	1%
	Output constancy vs ***gantry*** angle	2%
	Beam uniformity vs ***gantry*** angle	3%
	Safety Interlocks	
	Follow test procedures of manufacturers	Functional
	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	2 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collimator, ***gantry***, couch axis with isocenter	2 mm diameter
	Coincidence of radiation and mechanical isocenter	2 mm diameter
	Table top sag	2 mm
	Vertical travel of table	2 mm
	Field-light intensity	Functional

[a] The tolerance listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under ***gantry*** rotation exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values are ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

Table II
QA of Medical *Accelerators*

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2 mm
	Distance indicator (ODI)	2 mm
	Safety	
	Door interlock	Functional
	Audiovisual monitor	Functional
Monthly	Dosimetry	
	X-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	X-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2 mm @ therapeutic depth
	X-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	X-ray and ***electron*** symmetry	3%
	Safety Interlocks	
	Emergency off switches	Functional
	Wedge, ***electron*** cone interlocks	Functional
	Mechanical Checks	
	Light/radiation field coincidence	2 mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 deg
	Wedge position	2 mm (or 2% change in transmission factor)
	Tray position	2 mm
	Applicator position	2 mm
	Field size indicators	2 mm
	Cross-hair centering	2 mm diameter
	Treatment couch position indicators	2 mm/1 deg
	Latching of wedges, blocking tray	Functional
	Jaw symmetry[e]	2 mm
	Field light intensity	Functional
Annual	Dosimetry	
	X-ray/electron output calibration constancy	2%
	Field size dependence of ***x-ray*** output constancy	2%
	Output factor constancy for ***electron*** applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs ***gantry*** angle	2%
	Electron output constancy vs ***gantry*** angle	2%
	Off-axis factor constancy vs ***gantry*** angle	2%
	Arc mode	Mfrs. specs.

Frequency	Procedure	Tolerance[a]
Annual	Safety Interlocks	
	Follow manufacturers test procedures	Functional
	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	2 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collimator, ***gantry***, couch axes with isocenter	2 mm diameter
	Coincidence of radiation and mechanical isocenter	2 mm diameter
	Table top sag	2 mm
	Vertical travel of table	2 mm

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under ***gantry*** rotation exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values are ± the deviation of the parameter with respect its nominal value; distances are referenced to the isocenter or nominal SSD.

[b] All ***electron*** energies need not be checked daily, but all ***electron*** energies are to be checked at least twice weekly.

[c] A constancy check with a field instrument using temperature/pressure corrections.

[d] Whichever is greater. Should also be checked after change in light field source.

[e] Jaw symmetry is defined as difference in distance of each jaw from the isocenter.

[f] Most wedges' transmission factors are field size and depth dependent.

Table III
QA of simulators

Frequency	Procedure	Tolerance[a]
Daily	Localizing lasers	2 mm
	Distance indicator (ODI)	2 mm
Monthly	Field size indicator	2 mm
	Gantry/collimator angle indicators	1 deg
	Cross-hair centering	2 mm diameter
	Focal spot-axis indicator	2 mm
	Fluoroscopic image quality	Baseline
	Emergency/collision avoidance	Functional
	Light/radiation field coincidence	2 mm or 1%
	Film processor sensitometry	Baseline
Annual	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	2 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collimator, *gantry*, couch axes and isocenter	2 mm diameter
	Table top sag	2 mm
	Vertical travel of couch	2 mm
	Radiographic Checks	
	Exposure rate	Baseline
	Table top *exposure* with fluoroscopy	Baseline
	kVp and mAs calibration	Baseline
	High and low contrast resolution	Baseline

[a] The tolerances mean that the parameter exceeds the tabulated value (e.g., the measured isocenter under *gantry* rotation exceeds 2 mm diameter).

Table IV
QA of measurement equipment

I, initial use for each mode used or following malfunction and repairs; E, each use (measurement sequence) or ongoing evaluation; B, each batch or box at appropriate energy (dosimeter element position should also be considered); D, documented and correction applied or noted in report of measurement; M, monthly.

Instrument type	Test	Frequency	Tolerance[a]
Local standard[b]	ADCL calibration	2y[c]	D
	Linearity	2y[c]	0.5%
	Venting	2y[c]	D
	Extra-cameral signal (stem effect)	I	0.5%
	Leakage	E	0.1%
	Redundancy check[d]	E	2%
	Recombination	I	D
	Collecting potential	E	D
Field instruments	Local std. comparison	2y	1%
	Linearity	2y	D
	Venting	2y	D
	Extra-cameral signal	2y	D
	Leakage	E	0.1%
	Recombination	I	D
	Collecting potential	E	D
Output check	Local std. comparison	M	1%
Relative *dose*			
TLD	Calibration	E	D
	Linearity	I	D
Film	*Dose* response	B	D
	Densitometer linearity	1y	D
	Processor uniformity/reproducibility	E	D
Ion chamber	Linearity	1y	D
	Extra-cameral signal	I	1%
Diodes	Energy dependence	I	D
	Extra-cameral signal	I	D
	Linearity	I	D
Positioning	Accuracy	E	2 mm
	Hysteresis	E	2 mm
Automated Scanners	Mechanical	I	2 mm
	Positional accuracy	E	1 mm
	Collecting potential of detector	E	D
	Detector linearity	I	0.5%
	Extra-cameral signal	I	0.5%
	Detector leakage	E	0.5%
	Accuracy of data analysis	I	1%
	Accuracy of printouts	I	1 mm

Instrument type	Test	Frequency	Tolerance[a]
Accessories	Thermometer Calibration	1	0.1 deg/C
	Barometer Calibration	3 mo	1 mm/Hg
	Linear rule Calibration	1	0.3%

[a] Percent values are ± the deviation of the parameter with respect to the nominal, and distances are referred to the isocenter or nominal SSD.

[b] Local standard instrument has a calibration directly traceable to NIST and should be reserved for calibration of radiation beams, field instruments, and intercomparisons.

[c] Two years required by NRC. Without a redundancy program, this may be inadequate; with a redundancy program, dosimetry systems maintain calibration factors for significantly longer periods of time.

[d] With a ***radionuclide*** (e.g., Sr-90) or chamber intercomparison.

Table V
QA for treatment planning systems and monitor unit calculations

Frequency	Test	Tolerance[a]
Commissioning and following software update	Understand algorithm	Functional
	Single field or ***source*** iso***dose*** distributions	2%[a] or 2 mm[b]
	MU calculations	2%
	Test cases	2% or 2 mm
	I/O system	1 mm
Daily	I/O devices	1 mm
Monthly	Checksum	No change
	Subset of reference *QA* test set (when checksums not available)	2% or 2 mm[c]
	I/O system	1 mm
Annual	MU calculations	2%
	Reference *QA* test set	2% or 2 mm[d]
	I/O system	1 mm

[a] % difference between calculation of the computer treatment planning system and measurement (or independent calculation).

[b] In the region of high ***dose*** gradients the distance between iso***dose*** lines is more appropriate than % difference. In addition, less accuracy may be obtained near the end of single ***sources***.

[c] These limits refer to the comparison of ***dose*** calculations at commissioning to the same calculations subsequently.

[d] These limits refer to comparison of calculations with measurement in a water tank.

Table VI
Treatment planning process

Process	Related *QA* procedures
Positioning and immobilization	Port films. Laser alignment
Simulation	Simulator *QA* including image quality and mechanical integrity
Patient data acquisition (CT, MRI, manual contouring)	CT, MRI *QA* including image quality and mechanical integrity. Accuracy of mechanical contouring
Data transfer to treatment planning system	*QA* of the entire data transfer process, including digitizers, digital data transfer, etc.
Definitions of target volumes	Peer review, e.g., new patient planning conference, chart rounds
Aperture design	Independent check of delivery (e.g., port films), and peer review
Computation of ***dose*** distributions	Machine data from commissioning and *QA* of treatment machines. Accuracy and *QA* of treatment planning system
Plan evaluation	Peer review of plan, e.g., during chart rounds Independent check by radiation oncology physicist
Prescription	Written, signed, and dated
Computation of monitor units	Treatment planning system *QA*. Independent check within 48 h
Production of blocks, beam modifiers	*QA* for block cutting and compensator systems Port film review
Plan implementation	Review of set-up by treatment planning team. Chart review
Patient *QA*	Treatment plan review. Chart review after new or modified field, weekly chart review, port film review. *In vivo* dosimetry for unusual fields, critical ***organ doses*** (e.g., gonadal ***dose***). Status check, follow up

Table VII
Factors affecting monitor unit (minute) calculations

Parameter	Related *QA*
Patient surface contour	Periodic checks of caliper accuracy. Redundant patient measurements. Treatment planning system monthly *QA*
Collimator setting	Monthly simulator & treatment machine *QA* (Tables I-III)
Dose per monitor unit (minute) on the central axis as a function of collimator settings	Part of daily & monthly machine *QA* for a 10 x 10 cm field (Tables I and II) and annual recommissioning for output vs field size
Depth of the calculation (prescription) point	Periodic checks of caliper accuracy. Use of both lasers and ODI during patient setup to verify depth. Repeat patient measurements during course of treatment
Target-to-patient-surface or target-to-isocenter distance	Monthly *QA* on simulators and treatment machines (Tables I-III)
Relative *dose* factors (PDD, TPR, TMR, etc.)	Monthly *x-ray* and *electron* energy constancy checks (Table II)
Aperture size and shape	Redundant check of magnification factor
Wedge and compensator transmission	Annual machine recommissioning. Monthly check of latches and positioning of accessories (Table II)
Blocking tray transmission	Annual machine recommissioning. Monthly check of latches and positioning of accessories (Table II)

Table VIII
Summary of *QA* recommendations for individual patients

Procedure	Recommendation
Monitor unit (minutes) calculations	1. Reviewed prior to treatment by an authorized individual who did not perform initial calculation, or when not possible (e.g., emergency treatment), then prior to 3rd fraction or before 10% of the ***dose*** has been delivered, whichever occurs first.
Graphical treatment plan review	1. Reviewed prior to treatment, or when not possible, then prior to 3rd fraction or before 10% of the ***dose*** has been delivered, whichever occurs first. 2. Reviewed by a radiation oncology physicist who did not formulate treatment plan. Where only one physicist and that person performed the plan, then reviewed by another authorized individual. 3. Review includes calculated monitor units, input-output and plan quality. 4. Independent calculation of ***dose*** at a point: Compare for each field—with an independent calculation of ***dose*** to a point using the calculated monitor units—the prescribed and calculated ***dose***. 5. If these differ by more than 5%, then the discrepancy should be resolved before continuing treatment.
Plan set-up	Radiation oncologist present at first setup or for major changes in treatment.
Beam (portal) films—curative and high morbidity ***risk*** palliative patients	Initial films reviewed by radiation oncologist prior to first treatment. In addition, ongoing portal films (the standard is weekly) also reviewed by the radiation oncologist.
Beam (portal) films—palliative patients	Films reviewed prior to second fraction.
In-vivo dosimetry	1. All institutions should have access to TLD or other *in vivo* dosimetry systems. 2. Should be used to measure ***dose*** to critical structures (e.g., lens, gonads). 3. May be used to record ***dose*** for unusual treatment. conditions.

Table IX
QA tests for brachytherapy *sources*

I, initial purchase; D, documented; and E, at every use

Type of *Source*	Test	Frequency	Tolerance
Long ***half-life***: description	Physical/chemical form	I	D
	Source encapsulation	I	D
	Radionuclide distribution and uniformity	I	D
	Location of ***radionuclide***	I	1 mm
Long ***half-life***: calibration	Mean of batch	I	3%
	Deviation from mean	I	5%[a], D
	Calibration verification	E	
Short ***half-life***: description	Physical/chemical form	I	D
	Source encapsulation	I	D
Short ***half-life***: calibration	Mean of batch	E	3%
	Deviation from mean[b]	E	5%
	Radionuclide distribution and ***source*** uniformity	E	V[c]

[a] Visual check of ***source*** color code or measurement in a ***calibrator***.

[b] For short ***half-life sources*** this may not always be practical.

[c] V, visual check, autoradiograph, or ionometric check.

Table X
QA tests for brachytherapy *source calibrator*

I, initial use or following malfunction and repairs, S, ***isotope/source*** specific, D, documented and correction applied or noted in report of measurement, when appropriate, and E, each use (measurement sequence) or ongoing evaluation.

Instrument Type	Test	Frequency	Tolerance
Well ***ionization chamber***	ADCL calibration	I,S[a]	D
	Precision	I	2%
	Linearity	I, 2 year	1%
	Collection Efficiency	I	1%
	Geometrical/length dependence	I	D
	Energy dependence	I	D
	Wall dependence	I	D
	Venting	I	D
	Redundant check	E	2%
	Leakage	E	D
In-air calibration ***chamber*** and external holder	ADCL calibration	I,S[a]	D
	Accuracy of chamber distance	1 yr, S	1%, D
	Redundancy	E	D
	See Table IV for other tests		

[a] Instrument or source have a calibration directly traceable to NIST.

Table XI
QA tests for brachytherapy applicators

I, initial use or following malfunction and repairs; D, documented and correction applied or noted in report of measurements, when appropriate; and E, as a minimum, a visual inspection to verify that the dummy source fairly represent the active ***source*** distribution.

Type of applicator	Test	Frequency	Tolerance
Intracavitary	Location	I[a], yearly	D
	Coincidence of dummy and active ***sources***	I	1 mm
	Location of shields	I[b]	D
Interstitial	Coincidence of dummy and active ***sources***	I,E	1 mm

[a] To reduce personnel ***exposure***, the dummy ***source*** location may be checked in place of the active, if it is established that the dummy and active ***source*** locations are coincident.

[b] Location of shields should be verified by radiograph before the first use. Before every use, the applicator may be shaken to listen for loose parts.

Table XII
Procedure specific parameter verification

Endpoint	Procedure	When
Accuracy of OR implant description	Direct observation	During procedure
Prescription accuracy and consistency	Consistency of loading and prescription with disease stage, therapy chart treatment plan, department treatment policies	First half of treatment
Verify correct ***source*** chosen	Spot calibration check and visual verification	preparation and ***source*** loading
Sources correctly loaded	Therapist or physicist (or individual knowledgeable in ***source*** loading) always assists physician	loading
Treatment plan	Calculation of plan and check for accuracy/consistency	First half of treatment
Implant removal	Physicist present or contact nursing staff to verify	Expected removal time
Sources all removed	Patient survey ***source*** count Final ***source*** inventory	At removal Next working day
Review treatment	Verify treatment time	After completion of procedure
Record, *QA* audit	All *QA*, treatment, and radiation safety records complete	After completion of procedure

Table XIII
QA of remote afterloading brachytherapy units

Frequency	Test	Tolerance
Each treatment day	Room safety door interlocks, lights, and alarms	Functional
	Console functions, switches, batteries, printer	Functional
	Visual inspection of ***source*** guides	Free of kinks and firmly attached
	Verify accuracy of ribbon preparation	Autoradiograph
Weekly	Accuracy of ***source*** and dummy loading (dummies used for spacing and/or simulation/verification)	1 mm
	Source positioning	1 mm
At each ***source*** change or quarterly	Calibration[a]	3%
	Timer function	1%
	Check accuracy of ***source*** guides and connectors	1 mm
	Mechanical integrity of applicators (by ***x ray*** if appropriate)	Functional
Annual	***Dose*** calculation algorithm (at least one standard ***source*** configuration for each ***isotope***). Simulate emergency conditions. Verify ***source*** inventory	3%, 1 mm

[a] It is worthwhile at ***source*** change to calibrate both new and old ***sources*** to establish and document reproducibility of calibration method.

APPENDIX VII

Standards of the American College of Radiology*

* Taken from: American College of Radiology. *Standards*. Reston: ACR; 1997.

Standards of the American College of Radiology (ACR), 1997

Diagnostic Radiology

1. ACR Standard for General (Plain) Radiography
2. ACR Standard for Communication-Diagnostic Radiology
3. ACR Standard for Teleradiology
4. ACR Standard for Diagnostic Medical Physics Performance Monitoring of Radiologic and Fluoroscopic Equipment
5. ACR Standard for the Performance of Computed Tomography in the Evaluation of Head Trauma
6. ACR Standard for Skeletal Surveys in Children
7. ACR Standard for the Performance of Pediatric and Adult Chest Radiography
8. ACR Standard for the Performance of Pediatric and Adult Bedside Chest Radiography (Portable Chest Radiography)
9. ACR Standard for the Performance of Thoracic Computed Tomography
10. ACR Standard for the Performance of Computed Tomography of the Abdomen and Pelvis
11. ACR Standards for the Performance of Screening Mammography
12. ACR Standard for the Performance of Diagnostic Mammography and Problem-Solving Breast Evaluation
13. ACR Standard for the Performance of Adult Esophagrams and Upper Gastrointestinal Examinations
14. ACR Standard for the Performance of Per Oral Barium Small Bowel Examinations in Adults
15. ACR Standard for the Performance of Adult Enteroclysis Examinations
16. ACR Standard for Performance of Adult Barium Enema Examinations
17. ACR Standard for the Performance of Pediatric Contrast Examinations of the Upper Gastrointestinal Tract
18. ACR Standard for the Performance of Pediatric Contrast Enema Examinations
19. ACR Standard for the Performance of Excretory Urography
20. ACR Standard for the Performance of Adult Cystography and Urethrography
21. ACR Standard for the Performance of Voiding Cysturethography in Children
22. ACR Standard for the Performance of Magnetic Resonance Imaging

Interventional Radiology

1. ACR Standard for the Use of Intravenous Conscious Sedation
2. ACR Standard for the Performance of Cerebral Angiography
3. ACR Standard for the Performance of Myelography
4. ACR Standards for Diagnostic Arteriography in Adults
5. ACR Standard for the Performance of Stereotactically-Guided Breast Interventional Procedures
6. ACR Standard for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures

7. ACR Standard for the Performance of Imaging-Guided Trans-Thoracic Needle Biopsy in Adults
8. ACR Standard for the Performance of Imaging-Guided Percutaneous Thoracic Aspiration on Catheter Drainage in Adults
9. ACR Standard for the Performance of Percutaneous Nephrostomy

Nuclear Medicine

1. ACR Standard for Imaging for Radiopharmaceuticals
2. ACR Standard for the Performance of Cerebral Scintigraphy for Brain Death
3. ACR Standard for the Performance of Skeletal Scintigraphy
4. ACR Standard for the Performance of Cardiac Scintigraphy
5. ACR Standard for the Performance of Thyroid Scintigraphy and Uptake Measurements
6. ACR Standard for the Performance of Parathyroid Scintigraphy
7. ACR Standard for the Performance of Pulmonary Scintigraphy
8. ACR Standard for the Performance of Gastrointestinal Scintigraphy
9. ACR Standard for the Performance of Hepatobiliary Scintigraphy
10. ACR Standard for the Performance of Liver/Spleen Scintigraphy
11. ACR Standard for the Performance of Renal Scintigraphy
12. ACR Standard for the Performance of Radionuclide Cystography
13. ACR Standard for the Performance of Scrotal Scintigraphy
14. ACR Standard for the Performance of Infectious and Inflammatory Conditions
15. ACR Standard for the Performance of Tumor Scintigraphy
16. ACR Standard for the Performance of Therapy with Unsealed *Radionuclide* Sources

Radiation Oncology

1. ACR Standard for Radiation Oncology
2. ACR Standard for the Performance of Radiation Oncology Physics for External Beam Therapy
3. ACR Standard for the Performance of High-Dose-Rate Brachytherapy
4. ACR Standard for the Performance of Low-Dose-Rate Brachytherapy
5. ACR Standard for the Performance of Brachytherapy Physics: Manually-Loaded Sources
6. ACR Standard for 3D External Beam Radiation Planning and Conformal Therapy
7. ACR Standard for the Performance of Stereotactic Radiation Therapy/Radiosurgery
8. Standard for Diagnosis and Management for Invasive Breast Carcinoma
9. Standards for Diagnosis and Management of Ductal Carcinoma In-Situ of the Breast (DCIS)
10. ACR Standard for the Performance of Therapy with Unsealed Radionuclide Sources

Ultrasound

1. ACR Standard for Performing and Interpreting Diagnostic Ultrasound Examinations
2. ACR Standard for the Performance of an Ultrasound Examination of the Extracranial Cerebrovascular System
3. ACR Standard for Performance of the Pediatric Neurosonology Examination
4. ACR Standard for the Performance of Peripheral Arterial Ultrasound Examination
5. ACR Standard for Performance of the Peripheral Venous Ultrasound Examination
6. ACR Standard for the Performance of the Thyroid and Parathyroid Ultrasound Examination
7. ACR Standard for the Performance of Breast Ultrasound Examination
8. ACR Standard for the Performance of Abdominal, Renal, or Retroperitoneal Ultrasound Examination in Infants, Children, and Adults
9. ACR Standard for the Performance of Ultrasound Examination of the Female Pelvis
10. ACR Standard for the Performance of Antepartum Obstetrical Ultrasound
11. ACR Standard for the Performance of Ultrasound Evaluation of the Prostate (and surrounding structures)
12. ACR Standard for the Performance of Scrotal Ultrasound Examination

Credentialing

1. ACR Standard for Continuing Medical Education (CME)

Magnetic Resonance Imaging

MRI Monograph

APPENDIX VIII

Radiation Protection Data

Appendix VIII-A

Values of the Radiation Weighting Factor (W_R)

*and the Tissue Weighting Factor (W_T)**

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* Taken from: Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organisation, Nuclear Agency of the Organisation for Economic Co-operation and Development, Pan American Health Organization, World Health Organization. *International basic safety standards for protection against ionizing radiation and for the safety of radiation sources*. Vienna: International Atomic Energy Agency; 1997. (Safety series 115).

Values of the Radiation Weighting Factor (W_R) and the Tissue Weighting Factor (W_T)

Type and energy range of radiation	Radiation weighting factor, W_R
Photons	1
Electrons	1
Neutrons	
< 10 keV	5
100 keV to 2 MeV	20
2 MeV to 20 MeV	10
> 20 MeV	5
Protons > 2 MeV	5
Alpha particles	20

Tissues or organs	Tissue weighting factor, W_T
Bone surfaces - skin	0.01
Liver - breast - bladder - oesophagus - thyroid - remainder	0.05
Bone marrow (red) - colon - lung - stomach	0.12
Gonads	0.20

Appendix VIII-B

*Sources of Exposure to Ionizing Radiation**

* Taken from: United Nations Scientific Committee on the Effects of Atomic Radiation. *Sources and effects of ionizing radiation*. New York: UN; 1993. (UNSCEAR 1993 Report to the General Assembly).

Natural Sources	Average Annual *Effective Dose* (mSv)
Cosmic rays	0.39
Terrestrial gamma rays	0.46
Radioisotopes in the body (except ***radon***)	0.23
Radon and its ***decay*** products	1.3
Total	2.4

Artificial *Sources*	Average Annual *Effective Dose* (mSv)
Medical ***sources***	0.6
Nuclear explosions	0.01
Nuclear energy	0.0002

Sources for Medical Use	Number
X-ray units (diagnosis)	720,000
X-ray units (therapy)	13,000
Cobalt therapy and caesium units	4,000
Accelerators	1,800
Nuclear medicine clinics	13,000
"Spent" Radioactive ***sources*** (in disuse)	130,000

Annual ***collective dose*** due to diagnostic radiology: 1,600,000 man Sv

Appendix VIII-C

*Threshold Dose Values for Deterministic Effects**

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* Taken from: International Commission on Radiological Protection. 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. *Ann ICRP* 1991 21(1-3).

Threshold *Dose* Values for *Deterministic Effects*

Deterministic Effect	***Dose Equivalent* Threshold (Single Exposure) (Gy)**
Permanent Sterility	
Males	3.5 - 6.0
Females	2.5 - 6.0
Lens Opacity	0.5 - 2.0
Cataracts	5.0
Hematopoietic Depression	0.5

Appendix VIII-D

*Dose Limits**

* Taken from: Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organisation, Nuclear Agency of the Organisation for Economic Co-operation and Development, Pan American Health Organization, World Health Organization. *International basic safety standards for protection against ionizing radiation and for the safety of radiation sources*. Vienna: International Atomic Energy Agency; 1997. (Safety series 115).

Dose Limits

The annual ***effective dose limit*** for ***workers*** in accordance with the *BSS* (*26*) is 20 mSv per year (not to exceed 50 mSv per year averaged over 5 consecutive years), and the annual ***equivalent dose*** to the extremities (hands and feet) or the skin is 500 mSv and to the lens of the eye, 150 mSv. For ***members of the public,*** the annual ***effective dose limit*** has been established at 1 mSv; the ***equivalent dose*** to the extremities is not to exceed 50 mSv, and to the lens, 15 mSv.

In monitoring compliance with these ***limits***, both ***doses***, those generated by external ***sources*** and the committed ***doses*** from ***radionuclide*** intakes into the body, must be taken into account. However, ***doses*** from natural radiation and those incurred by people as patients undergoing medical procedures with radiation ***sources*** should not be included.

In the case of pregnant female ***workers***, once pregnancy is declared and during the rest of gestation, the ***equivalent dose*** to the embryo/fetus should not exceed 1 mSv.

For students between 16 and 18 years of age, the recommended annual ***limits*** are as follows: ***Effective dose,*** 6 mSv; ***equivalent dose*** to the lens, 50 mSv, and to the skin or the extremities, 150 mSv.

Glossary

Absorbed dose
The fundamental dosimetric quantity D, defined as:

$$D = \frac{d\epsilon}{dm}$$

where $d\epsilon$ is the mean energy imparted by ionizing radiation to matter in a volume element and dm is the mass of matter in the volume element. The energy can be averaged over any defined volume, the average dose being equal to the total energy imparted in the volume divided by the mass in the volume. The SI unit of absorbed dose is the joule per kilogram ($J \cdot kg^{-1}$), termed the gray (Gy).

Accelerator
A device that accelerates charged particles (e.g., protons or electrons) to high speed, often used for the production of certain radionuclides or for treatment of radiation therapy patients.

Accident
Any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

Activity
The quantity A for an amount of radionuclide in a given energy state at a given time, defined as:

$$A = \frac{dN}{dt}$$

where dN is the expectation value of the number of spontaneous nuclear transformations from the given energy state in the time interval dt. The SI unit of activity is the reciprocal second (s^{-1}), termed the becquerel (Bq).

Alpha particle
A nucleus of Helium ($^{4}_{2}$ He).

Annual Limit on Intake (ALI)
The intake by inhalation, ingestion or through the skin of a given radionuclide in a year by the reference man which would result in a committed dose equal to the relevant dose limit. The ALI is expressed in units of activity.

Authorization
A permission granted in a document by the regulatory authority to a legal person who has submitted an application to carry out a practice or any other action described in the general obligations for practices of the BSS. The authorization can take the form of a registration or a license.

Average mammary glandular dose
The theoretical average absorbed dose, D_g, in the mammary gland which, for purposes of mammography, can be calculated from:

$$D_g = D_{gN} X_a$$

where D_{gN} is the average absorbed dose in the mammary gland resulting from an incident exposure in air of 2.58×10^{-4} C·kg^{-1} and X_a is the incident exposure in air, and where for X ray tubes with molybdenum targets and molybdenum filters operating at 0.3 mm Al half-value layer and for a tissue composition of 50% adipose tissue and 50% gland, D_{gN} can be inferred from the following:

Breast thickness (cm)	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0
D_{gN}	2.2	1.95	1.75	1.55	1.4	1.25	1.15	1.05	0.95

D_{gN} is expressed in mGy per 2.58×10^{-4} C·kg^{-1}.

Beta particle
Negatively or positively charged electron, emitted during a radioactive decay process.

Collective dose
An expression for the total radiation dose incurred by a population, defined as the product of the number of individuals exposed to a source and their average radiation dose. The collective dose is expressed in man-sieverts (man·Sv).

Committed (effective) dose
An expression for the total radiation dose resulting from an incorporated radioactive substance in the body over an integration time taken as 50 years for adults and 70 years for children.

Computerized tomography (CT) scanner
Equipment for image acquisition using X rays with a computer system for tomographic reconstructions.

Contamination
The presence of radioactive substances in or on a material or the human body or other place where they are undesirable or could be harmful.

Controlled area
A controlled area is any area in which specific protection measures and safety provisions are or could be required for:

a) controlling normal exposures or preventing the spread of contamination during normal working conditions; and
b) preventing or limiting the extent of potential exposures.

Cosmic rays
Stream of atomic nuclei of heterogeneous extremely penetrating character that enters the earth's atmosphere from outer space at speeds approaching that of light.

Decentralization
Transfer of the decision-making process from the central to the local level.

Decontamination
The removal or reduction of contamination in or on materials, persons or the environment by a physical or chemical process.

Deterministic effect
A radiation effect for which generally a threshold level of dose exists above which the severity of the effect is greater for a higher dose.

Detriment
The total harm that would eventually be experienced by an exposed group and its descendants as a result of the group's exposure to radiation from a source.

Dose
A measure of the radiation received or "absorbed" by a target. The quantities termed absorbed dose, organ dose, equivalent dose, effective dose, committed equivalent dose or committed effective dose are used, depending on the context. The modifying terms are often omitted when they are not necessary for defining the quantity of interest.

Dose limit
The value of the effective dose or the equivalent dose to individuals from controlled practices that shall not be exceeded.

Effective dose
The quantity E, defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_T W_T \cdot H_T$$

where H_T is the equivalent dose in tissue T and W_T is the tissue weighting factor for tissue T. From the definition of equivalent dose, it follows that:

$$E = \sum_T W_T \cdot \sum_R W_R \cdot D_{T,R}$$

where W_R is the radiation weighting factor for radiation R, and $D_{T,R}$ is the average absorbed dose in the organ or tissue T. The unit of effective dose is $J \cdot kg^{-1}$, termed the sievert (Sv).

Electrometer
Device sensitive to small flows of electrical charge used with an ionization chamber for dosimetry purposes.

Electron
Atomic particle negatively charged.

Emergency plan
A set of procedures to be implemented in the event of an accident.

Employer
A legal person with recognized responsibility, commitment and duties towards a worker in his or her employment by virtue of a mutually agreed relationship. (A self-employed person is regarded as being both an employer and a worker.)

Entrance surface dose
Absorbed dose in the center of the field at the surface of entry of radiation for a patient undergoing a diagnostic radiology examination, expressed in air and with backscatter.

Equivalent dose
The quantity $H_{T,R}$, defined as:

$$H_{T,R} = D_{T,R} \cdot W_R$$

where $D_{T,R}$ is the absorbed dose delivered by radiation type R averaged over a tissue or organ T and W_R is the radiation weighting factor for radiation type R. When the radiation field is composed of different radiation types with different values of W_R, the equivalent dose is:

$$H_T = \sum_R W_R \cdot D_{T,R}$$

The unit of equivalent dose is $J \cdot kg^{-1}$, termed the sievert (Sv).

Exposure
The act or condition of being subject to irradiation. Exposure can be either external exposure (irradiation by sources outside the body) or internal exposure (irradiation by sources inside the body). Exposure can be classified as either normal exposure or potential exposure; either occupational, medical or public exposure; and, in intervention situations, either emergency exposure or chronic exposure. The term exposure is also used in dosimetry to express the amount of ionization produced in air by ionizing radiation (see average mammary glandular dose).

Gamma camera
Medical device utilized in nuclear medicine to determine and display the distribution of a radioisotope(s) incorporated in the patient. It is made up of a detector(s), collimators appropriate to the energy of the isotopes utilized, a system for archiving analogical or digital images for static and dynamic studies and a data processing system.

Gamma rays (gamma radiation)
Electromagnetic radiation emitted by atomic nuclei.

Gantry
Part of the support of a radiation emitting or radiation detector unit that normally encloses the source of radiation or the detectors.

Guidance level for medical exposure
A value of dose, dose rate or activity selected by professional bodies in consultation with the regulatory authority to indicate a level above which there should be a review by medical practitioners in order to determine whether or not the value is excessive, taking into account the particular circumstances and applying sound clinical judgement.

Half-life
Time in which the activity of a radionuclide decreases to half its initial value.

Half-value layer
Term used to express the quality of a photon beam of low and medium energy. It corresponds to the thickness of a material which reduces the radiation beam intensity to its half.

Intervention
Any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident.

Intervention level
The level of avertable dose at which a specific protective action or remedial action is taken in an emergency exposure situation or a chronic exposure situation.

Ionization
Any process that produces ion pairs.

Ionization (ion) chamber
A device for the detection of ionizing radiation or for measurements of dose and/or dose rate.

Ionizing radiation
For the purposes of radiation protection, radiation capable of producing ion pairs in biological material(s).

Isotopes
Nuclides that have the same atomic number but different mass number.

Kerma
Quotient K defined by as:

$$K = \frac{dE_{tr}}{dm}$$

being dE_{tr} is the sum of the initial kinetic energies of all charged ionizing particles liberated by uncharged ionizing particles in a material of mass dm. The SI unit of kerma is the joule per kilogram ($J \cdot kg^{-1}$), termed gray (Gy).

Kernel
Mathematical algorithm generally used in image reconstruction software programs.

Klystron
In a medical linear accelerator, component of the power supply circuit.

Levels of care
A stratified form of health service organization and delivery, the purpose of which is to achieve a balance in the quantity, variety, and quality of the health care services available to the population. This stratification is achieved through a deliberate process of re-organization aimed at combining health care programs, personnel, and technologies in a way that they are distributed and shared equitably by all users of health services. Functionally, levels of care correspond to sets of services. The least-complex service—the "primary care level"—comprehends the most basic activities of the health services system.

The other levels, or sets of services—generally termed "secondary", "tertiary," etc.—comprise services of increasing complexity and varying degrees of specialization.

License
An authorization granted by the regulatory authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the licensee.

Limit
The value of a quantity used in certain specified activities or circumstances that must not be exceeded.

Local health systems
Interrelated group of health resources, from within and outside the health sector, responsible for the health of a population in a defined geographic environment

Magnetron
In a medical linear accelerator, component of the power supply circuit.

Medical exposure
Exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

Member of the public
In a general sense, any individual in the population except, for the purposes of the BSS, when subject to occupational or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, the representative individual in the relevant critical group.

Natural sources
Naturally occurring sources of radiation, including cosmic radiation and terrestrial sources of radiation.

Neutron
Atomic particle without electric charge, with a mass approximately equal to that of the proton.

Normal exposure
An exposure which is expected to be received under normal operating conditions of an installation or a source, including possible minor mishaps that can be kept under control.

Nuclide
Atomic species characterized by its mass number, atomic number and nuclear energy level.

Occupational exposure
All exposures of workers incurred in the course of their work, with the exception of exposures excluded from the BSS and exposures from practices or sources exempted by the BSS.

Organ dose
The mean absorbed dose D_T in a specified tissue or organ T of the human body.

Penetration ratio
Term used to express the quality of high energy photon beams. It corresponds to the ratio of absorbed dose at two different depths using either a constant source-surface distance or a constant source-detector distance, depending on the irradiation conditions.

Phantom
An object used to simulate the absorption and scatter characteristics of the patient's body for radiation measurement or image quality assessment purposes.

Photon
A *quantum* of electromagnetic radiation that has the energy $h \cdot \nu$ where the h is Planck constant and ν the frequency.

Pixel
In a digital image it corresponds to the smallest area which contains information.

Planning target volume
A geometrical concept used in radiotherapy for planning treatment with consideration of the net effect of movements of the patient and of the tissues to be irradiated, variations in size and shape of the tissue, and variations in beam geometry such as beam size and beam direction.

Potential exposure
Exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

Practice
Any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.

Proton
Atomic particle positively charged; the nucleus of the hydrogen atom.

Public exposure
Exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation but including exposure from authorized sources and practices and from intervention situations.

Quality assurance (QA)
All those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily complying with agreed standards.

Quality control (QC)
It is a part of quality assurance. The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured and controlled.

Qualified expert
An individual who, by virtue of certification by appropriate boards or societies, professional licenses or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, radiation protection, occupational health, fire safety, quality assurance or any relevant engineering or safety specialty.

Radiation generator
Device capable of generating radiation, such as x rays, neutrons, electrons or other charged particles, which may be used for scientific, industrial or medical purposes.

Radioactive decay
Exponential decrease of the activity of a radioactive substance; its transformation in its daughter products.

Radioactive waste
Material, whatever its physical form, remaining from practices or interventions and for which no further use is foreseen I) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements, and ii) exposure to which is not excluded from the BSS.

Radioactivity
Activity synonym.

Radioisotope
An isotope which is radioactive.

Radionuclide
A nuclide which is radioactive.

Radionuclide calibrator
Equipment made up of a detector system and an activity counter, utilized in nuclear medicine to calibrate different isotopes of common use.

Radionuclide generator
Device containing a relatively long-lived parent radionuclide solution from which a short-lived daughter can be separated by elution in the nuclear medicine laboratory. Examples: ^{99}Mo - ^{99m}Tc for diagnosis and ^{188}W - ^{188}Re for therapy.

Radon
The isotope ^{222}Rn of the element of atomic number 86.

Reference level
Action level, intervention level, investigation level or recording level. Such levels may be established for any of the quantities determined in the practice of radiation protection.

Regulatory authority
An authority or authorities designated or otherwise recognized by a government for regulatory purposes in connection with protection and safety.

Risk
A multiattribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

Sealed source
Radioactive material that is permanently sealed in a capsule or closely bounded and in a solid form. The capsule or material of a sealed source shall be strong enough to maintain leaktightness under the conditions of use and wear for which the source was designed, also under foreseeable mishaps. Examples: ^{60}Co in radiation therapy and ^{192}Ir in brachytherapy.

Shielding
Material or structure the purpose of which is to reduce or attenuate a beam of ionizing radiation.

Source
Anything that may cause radiation exposure, such as by emitting ionizing radiation or releasing radioactive substances or materials.

SPECT and PET
Equipment for image acquisition in nuclear medicine, with a computer system for tomographic reconstructions. The SPECT (single photon emission computed tomography) uses photons, the PET (positron emission tomography) uses positrons.

Stochastic effects
Radiation effects, generally occurring without a threshold level of dose, the probability of which is proportional to the dose and the severity of which is independent of the dose.

Supervised area
Any area not designated as a controlled area but for which occupational exposure conditions are kept under review even though specific protective measures and safety provisions are not normally needed.

Unsealed source
A source that does not meet the definition of a sealed source.

Worker

Any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and a worker.)

X rays

Electromagnetic radiation produced bombarding a substance with electrons accelerated to high velocity.

Pan American Health Organization
World Health Organization