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

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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

Contents

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.