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

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Abbreviations and Acronyms

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

TUSA1

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 wellbeing.

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.