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*).