INTERNATIONAL ATOMIC ENERGY AGENCY
UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION
INTERNATIONAL CENTRE FOR THEORETICAL PHYSICS
I.C.T.P., P.O. BOX 586, 34100 TRIESTE, ITALY, CABLE: **CENTRATOM TRIESTE**

H4.SMR/773-24

College on Medical Physics:
Radiation Protection and Imaging Techniques

5 - 23 September 1994

Quality Assurance in Nuclear Medicine

A. Benini

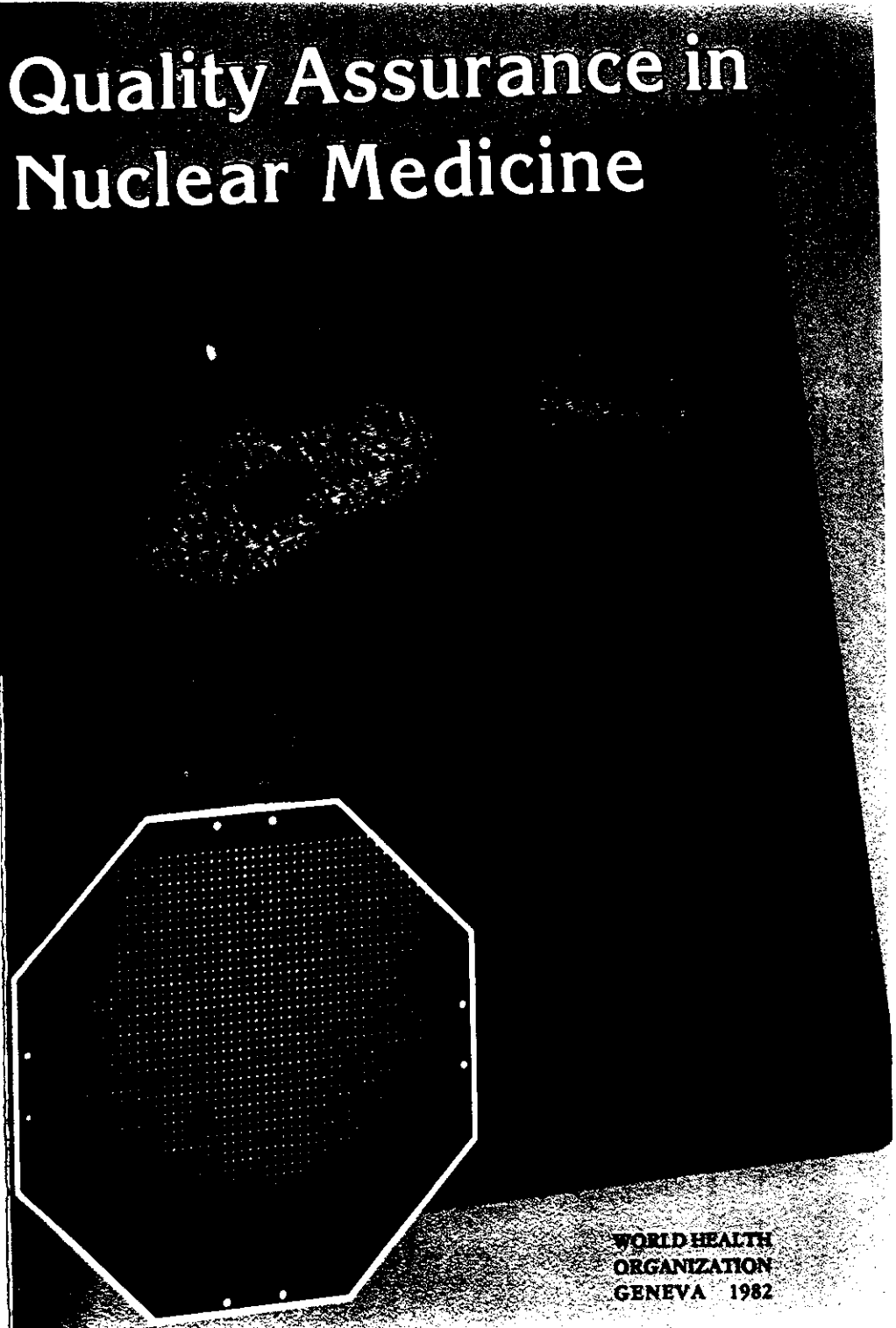
International Atomic Energy Agency
Vienna, Austria

Nuclear medicine offers particular advantages for the diagnosis of a wide range of malignant and nonmalignant diseases. However, to achieve and maintain a high standard of diagnostic reliability, it is essential to institute quality assurance programmes. In a nuclear medicine department, such a programme should cover each stage of the diagnostic process, from the initial decision to perform a chosen diagnostic test to the recording of results and the collection of follow-up data.

This guide, which was prepared following an international expert workshop, summarizes the available information, defines the main components of quality assurance and quality control programmes in nuclear medicine, and describes the organizational and technical methods required for the efficient and effective implementation of such programmes nationally, regionally, and internationally.

This book is addressed to the staff of nuclear medicine facilities and to individual specialists (physicians, radiopharmacists, medical physicists, radiochemists) who wish to ensure good practice in their working environment through quality assurance procedures. It will also be of interest to administrators and other authorities, both national and international, who are concerned with establishing and maintaining standards in nuclear medicine.

Quality Assurance in Nuclear Medicine



WORLD HEALTH ORGANIZATION
GENEVA 1982

The World Health Organization is a specialized agency of the United Nations with primary responsibility for international health matters and public health. Through this organization, which was created in 1948, the health professions of more than 155 countries exchange their knowledge and experience with the aim of making possible the attainment by all citizens of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life.

By means of direct technical cooperation with its Member States, and by stimulating such cooperation among them, WHO promotes the development of comprehensive health services, the prevention and control of diseases, the improvement of environmental conditions, the development of health manpower, the coordination and development of biomedical and health services research, and the planning and implementation of health programmes.

These broad fields of endeavour encompass a wide variety of activities, such as developing systems of primary health care that reach the whole population of Member countries; promoting the health of mothers and children; combating malnutrition; controlling malaria and other communicable diseases including tuberculosis and leprosy; having achieved the eradication of smallpox, promoting mass immunization campaigns against a number of other preventable diseases; improving mental health; providing safe water supplies; and training health personnel of all categories.

Progress towards better health throughout the world also demands international cooperation in such matters as establishing international standards for biological substances, pesticides and pharmaceuticals; formulating environmental health criteria; recommending international non-proprietary names for drugs; administering the International Health Regulations; revising the International Classification of Diseases, Injuries, and Causes of Death; and collecting and disseminating health statistical information.

Further information on many aspects of WHO's work is presented in the Organization's publications.

Cover photograph by courtesy of Autonomous Division of Nuclear Medicine,
Central University Hospital of Vaud, Lausanne, Switzerland.

QUALITY ASSURANCE IN NUCLEAR MEDICINE

Quality Assurance in Nuclear Medicine

A Guide Prepared Following a Workshop Held in Heidelberg, Federal Republic of Germany, 17–21 November 1980, and Organized Jointly by

Institute of Nuclear Medicine, German Cancer Research Centre, Heidelberg, Federal Republic of Germany

Institute of Radiation Hygiene, Federal Health Office, Neuherberg, Federal Republic of Germany

Society for Radiation and Environmental Research, Neuherberg, Federal Republic of Germany

and

World Health Organization, Geneva, Switzerland

WORLD HEALTH ORGANIZATION, GENEVA, 1982

ISBN 92 4 154165 2

TYPESET IN INDIA
PRINTED IN ENGLAND

81 5148 Macmillan Spottiswoode 6500

CONTENTS

1. Introduction

DURING the past few years, the World Health Organization's programme on diagnostic radiology and nuclear medicine has been mainly concerned with improving the coverage of these services and increasing their efficiency. Several of the activities in question, carried out in collaboration with the International Atomic Energy Agency (IAEA), have been devoted to efficacy and efficiency studies and the implementation in clinical practice of quality control and quality assurance in the diagnostic applications of radiation and radionuclides, with the aim of improving diagnostic quality and reducing wastage. This is particularly important for developing countries, in which the resources that can be devoted to health care are limited; the problem is frequently compounded by a lack of well-trained personnel and difficulties in obtaining equipment and radionuclide supplies.

In most countries—even those possessing a considerable number of nuclear medicine facilities—quality control procedures have still not been put into practice in many hospitals and other medical institutions.

Nuclear medicine—a specialty that owes its existence to advances in technology—offers particular advantages for the diagnosis of a wide range of malignant and nonmalignant diseases. However, in order to achieve a high standard of diagnostic reliability at the outset and then maintain it permanently, it is essential to institute *quality assurance programmes*.[1] Such programmes must cover all aspects of the nuclear medicine diagnostic process and include regular quality control tests for the instrumentation, the radiopharmaceuticals, and the methods of evaluating the diagnostic results. A quality assurance programme in a nuclear medicine department should therefore cover each stage of the diagnostic process, from the initial decision to perform a chosen diagnostic test, to the recording of the results, and to the collection of any subsequent follow-up data.

Three main objectives should be envisaged when quality assurance programmes are considered:

[1] For a definition of this term, see Annex 1.

(1) improvement in the quality of the diagnostic information;

(2) use of the minimum amount of radionuclide activity to ensure the production of the desired diagnostic information; and

(3) effective use of available resources.

A number of countries have already commenced quality assurance and quality control programmes in nuclear medicine at the national level. However, most of these programmes have resulted from local initiative and often depend on the particular interest of a few specialists—physicians, medical physicists, radiopharmacists, and radiochemists—concerned with this aspect of radiation medicine.

An international meeting on quality assurance in nuclear medicine[1] was organized by WHO in collaboration with the Institute of Nuclear Medicine of the German Cancer Research Centre, the Institute for Radiation Hygiene of the Federal Health Office, and the Society for Radiation and Environmental Research—all of the Federal Republic of Germany. The present guide, which was prepared following the holding of the meeting, summarizes the available data, defines the main components of quality assurance and quality control programmes, and describes the organizational and technical methods that are required for the efficient and efficacious implementation of such programmes on a national, regional, and international basis.

[1] Another international meeting—a workshop on quality assurance in diagnostic radiology—was held in October 1980. A guide on this subject has been published by WHO as a companion volume to the present publication.

2. Definition of the problem

DIAGNOSTIC procedures can be improved by ensuring optimum instrument performance, by the development of new radiopharmaceuticals, by the introduction of new methods of investigation, and by using a well-designed system of data recording, storage, and retrieval to facilitate efficient and accurate statistical analysis of the data.

When the complexity of nuclear medicine procedures is considered, it is not surprising that performance varies not only with different instruments and different radiopharmaceuticals, but also with nominally identical procedures. This lack of uniformity is due both to variations in the training and experience of staff members—i.e., physicians, physicists, technologists, and technicians—and to changes in the instrument performance and the quality of the radiopharmaceuticals. In order to guarantee the necessary uniformity of diagnostic procedures in nuclear medicine, initial and then *routine tests*[1] are essential. This subsequent performance testing is known as *quality control*[1] and refers to individual components of a diagnostic procedure. *Quality assurance*[1] refers to the entire diagnostic process including the instrumentation, the radiopharmaceuticals, and the diagnostic report. Comparison of nuclear medicine investigation methods on a regional, national, or international level will be of value for both patient and management services and will lead to greater uniformity of diagnostic procedures in nuclear medicine. Such comparisons can be undertaken using tests of overall quality that determine the total performance of a particular procedure. The problem thus commences at the local departmental level, but its logical solution extends to international cooperation.

[1] For definitions of these terms, see Annex 1.

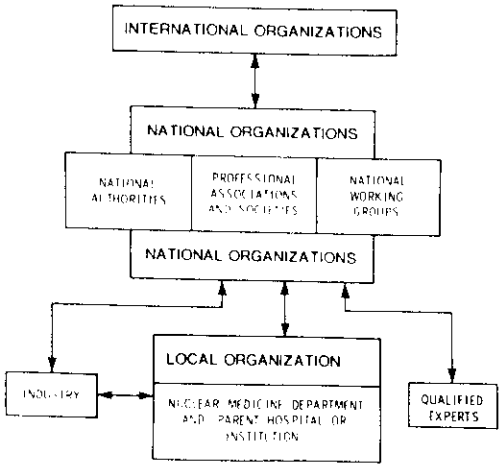
3. Organization of quality assurance programmes

QUALITY assurance programmes should be implemented in all countries that use nuclear medicine procedures, and should take account of the instrumentation, radiopharmaceuticals, and evaluation of the diagnostic results. The organization of such quality assurance programmes and the requirements for training are discussed in sections 3.1–3.7.

3.1 Organizational structure and stages

An organizational structure is essential to the efficient and accurate implementation of a quality assurance programme. Fig. 1 illustrates such a structure and schematically indicates the interactions that should occur between the different components. There should always be two constituent parts: first, the nuclear medicine department, which may be represented by the

Fig. 1. Organizations involved in quality assurance programmes



parent hospital or institution, and, secondly, a national working group that is competent to set reference standards. Such a working group may be formed, and monitored, under the auspices of governmental authorities and/or national professional associations. The types of professional associations or societies vary from country to country, since membership qualifications differ. There are associations solely for nuclear medicine physicians, for medical physicists, or for technologists, as well as associations that do not distinguish between the different categories of nuclear medicine personnel.

Two-way interactions between the national organizations and international organizations—for example, the World Health Organization and the International Atomic Energy Agency (IAEA)—are of particular value. Also, at a lower level, an interaction between industry and nuclear medicine departments can prove to be of great assistance and should be encouraged.

A quality assurance programme may be organized in two stages. Stage 1, which is termed *initial basic* in this guide, is for the control of standards and specifications for the acceptance of instrumentation and radiopharmaceuticals and for the establishment of reference standards for all future measurements. Stage 2, which is termed *routine* herein, is for the assurance of good practice in daily work, and takes into account all aspects of the diagnostic procedures, including instrumentation, radiopharmaceuticals, radiation safety, patient records, and the evaluation of results. Examples of some of these necessary aspects are given in Table 1.

Table 1. Examples of factors to be considered when establishing quality assurance programmes

Organizational stage	Instrumentation	Radiopharmaceuticals
(1) Initial basic	Definition of specifications. Acceptance testing. Initial testing to enable reference values to be defined. Design of record book log-book.	Definition of standards. Licensing registration. Quality assessment.
(2) Routine	Measurement of parameters. Test procedures with selected radionuclide sources and phantoms. Documentation of results in record book log-book.	Acceptance procedures for "ready-for-use" pharmaceuticals. Tests for radiochemical purity, which can be simply applied.

The results of quality control measurements should be compared with reference standards, and if this analysis indicates that any significant departure from the standards has occurred, then appropriate action should be taken to ensure that the performance characteristics are improved. Accurate record-keeping is essential, and a good data-storage and data-retrieval system should be available.

3.2 The nuclear medicine facility

At each stage of the quality assurance programme organization, whether it be initial basic or routine, an appropriate framework should be established to facilitate the implementation of the quality assurance programme. A nuclear medicine facility may consist of a single department or a number of departments in a group of hospitals that are responsible to a single institution. However, regardless of the local administrative arrangements, all departments, when initiating a quality assurance programme, must consider staffing and equipment, the organization of initial basic and routine quality assurance, the analysis of results, and the implementation of follow-up action should the results prove to be unsatisfactory.

3.2.1 *Staffing and equipment*

Responsibility for the safety of the patient and for the quality of the diagnostic process is vested in the nuclear medicine physician in charge, although certain aspects of this responsibility may be delegated to the nuclear medicine scientist—e.g., medical physicist, radiopharmacist, or radiochemist—or to the chief nuclear medicine technician. However in many countries, little attention has so far been paid to the need for and the availability of nuclear medicine scientists. This situation should be rectified and more attention should be paid to the requirements of the quality assurance programme organization. It has been shown that diagnostic efficiency, cost–benefit, and radiation protection practices improve when trained nuclear medicine scientists are among the staff members of the nuclear medicine facility. This category of personnel is of vital importance for the efficient implementation of quality assurance programmes, particularly when specialized instrumentation has to be used.

In hospitals without any qualified medical physicists, radiopharmacists, radiochemists, or other competent scientific personnel, the necessary expertise should be made available by cooperation with other hospitals, institutes, professional associations, or governmental bodies. In this case, the quality assurance programme will rely heavily on external support. The hospital should therefore ensure that the necessary instrumentation and manpower resources will always be available whenever required by obtaining a formal agreement from the external hospital or institute in order to avoid a vague *ad hoc* arrangement.

3.2.2 *Initial basic quality assurance*

Quality control measurements are undertaken to assess whether nuclear medicine instrumentation and radiopharmaceuticals comply with their specifications. The results of initial tests should be recorded as a basis for reference standards. Tests should be repeated annually and also after any major change of components, updating by the manufacturer, or repairs. Since it is essential to maintain long-term overall stability of performance, these initial and basic quality assurance measurements must be very carefully specified, performed, recorded, and evaluated.

3.2.3 *Routine quality assurance*

Routine quality assurance is performed to maintain high standards in all nuclear medicine procedures. Since the measurements are routine, they should be simple and uncomplicated, so that they can be implemented frequently in the initial working period and during periods when a defect is being investigated.

3.2.4 *Analysis of results*

The analysis of quality assurance measurements must be made by a competent person with adequate experience. He should consider the following two aspects:

(1) Is the observed result significantly different from the reference standard obtained initially?

(2) Is the observed result due to errors in the quality control procedure?

If there is no error in the quality control procedure, and the observed result does not represent a significant departure from the reference standard, then routine nuclear medicine studies can proceed. However, if there is a significant change in quality from that achieved at installation of the instrumentation—for example, after repair or after a manufacturer's modification—then corrective measures (*after-repair test*[1]) must be taken before further nuclear medicine studies are carried out. The reference standard refers not only to image quality, but also to patient radiation exposure. If radiopharmaceuticals do not fulfil the required standards, corrective measures must be taken.

3.3 Industry

The interaction between industry and the local nuclear medicine facility, and between industry and national organizations, is shown in Fig. 1. These interactions are highly desirable, since nuclear medicine equipment and radiopharmaceuticals should be manufactured to meet the latest available national or international recommendations for acceptable performance characteristics. It is also important to ensure that, after delivery, documentation for compliance with these standards and regulations should be made available by the manufacturer. The manufacturer should also be encouraged to assist the customer with the implementation of *acceptance inspection (acceptance tests)*,[1] since this has the advantage of ensuring that the manufacturer will participate to some extent in the tests, and therefore will not dispute the results even if they prove that his equipment does not comply with the agreed specifications.

[1] For definitions of these terms, see Annex 1.

3.4 National organizations

The links that can be developed between national organizations and the local nuclear medicine facility are summarized in Fig. 1. The responsibilities of national authorities vary from country to country and there is no standard international pattern for equipment assessment, radiation protection and radioactive waste disposal, licensing of nuclear medicine staff, approval for the use of radiopharmaceuticals, etc. There is also no overal pattern determining the role of professional associations and societies in individual countries. However, a national working group may be organized and sponsored by national authorities and/or professional associations or societies that can assist with such aspects of quality assurance programmes as:

(1) Provision of assistance and coordination mechanisms in setting up local quality assurance programmes.

(2) Provision of nuclear medicine scientist(s) and equipment for either the entire or specific parts of the quality assurance programme in nuclear medicine facilities which are unable to undertake a quality assurance programme using their own local resources.

(3) Provision of a monitoring service, on a random basis, to afford a consistency check on local quality assurance programmes.

(4) Assistance with record-keeping, including advice on data storage and retrieval systems, so that accurate patient data records can continue to be available for statistical analysis (possibly on a national basis).

(5) Provision of calibration services for equipment used in local quality assurance programmes.

(6) Dissemination of guidelines, codes of practice, regulations, requirements, etc., which are generated by national authorities, professional associations and societies, and international bodies.

(7) Assistance with the performance of initial basic quality assurance tests when this is requested by a nuclear medicine facility.

(8) Assistance in the preparation of national guidelines, codes of practice, regulations, requirements, etc., with special reference to legislation and to related legal obligations placed on the nuclear medicine facility and its parent hospital or institute.

It is also recommended that when national authorities are introducing legislation related to nuclear medicine, there should be a dialogue between these authorities and the nuclear medicine experts in the field, so that realistic and meaningful legislation is enacted.

3.5 Professional associations and societies

Since quality assurance programmes are currently undertaken on a voluntary basis, the professional associations and societies can and should play an important role by:

(1) explaining to their members the importance of a quality assurance programme for a nuclear medicine facility;

(2) strongly supporting the adoption of quality assurance programmes;

(3) providing guidelines, codes of practice, regulations, etc., either directly to the nuclear medicine facility or via a national working group; and

(4) supporting the idea of national working groups in each country, which can operate as indicated in section 3.4.

3.6 International bodies

At the international level the promotion of quality assurance programmes can be achieved by:

(1) recommendations for adequate quality assurance programmes and their wide dissemination;

(2) promotion of interlaboratory comparison programmes;

(3) adoption of reference standards; and

(4) coordination of activities related to quality assurance programmes.

3.7 Training requirements

A major objective of routine quality assurance is to introduce good practice for all aspects of nuclear medicine procedures. Thus, initial training and continuing education are necessary for all personnel undertaking nuclear medicine procedures regardless of any previous generalized teaching they may have received in the application of radionuclides in medicine.

This training should include an adequate grounding in the physics of radionuclides, radiation protection, and the importance of quality assurance. Three standards of training can be considered.

Standard A. A basic training requirement for those who have responsibilities for the operation of equipment or for radiopharmaceutical preparations. This standard of training would be required by nuclear medicine technicians, technologists, etc. The training could consist of a series of locally held workshops of two days' duration on various aspects of quality assurance - e.g., quality assurance of gamma cameras. During each workshop, one day should be devoted to practical demonstrations and equipment handling. The training syllabus should be modified according to the particular needs of the participants - for example, it should not be identical for both the radiopharmacists and the personnel responsible for operating the equipment, such as gamma cameras. The syllabus will also need to be modified in accordance with the different legal requirements of the various countries, which should be clearly stated and elucidated. The general framework of work-

shop topics should include:

(1) radiation protection and the handling of radionuclides in a "hot" laboratory, including waste disposal;

(2) radiopharmaceuticals;

(3) activity meters (radionuclide "dose" calibrators) and radionuclide counting equipment;

(4) gamma cameras;

(5) rectilinear scanners;

(6) *in vitro* procedures; and

(7) computer interfaces.

The training should also include familiarization with workshop manuals and nuclear medicine procedure manuals, all of which should be periodically reviewed and updated.

Standard B. An advanced training requirement for physicians, physicists, and radiochemists. This advanced training, in addition to the basic training requirements of standard A, should provide current information on the performance of nuclear medicine instrumentation and on quality control measurements. It could be achieved through the medium of both national and international symposia and seminars sponsored by professional associations. During this training, special reference should be made to the problem of reducing the amount of radiation to which personnel and patients are exposed, while still maintaining good diagnostic results.

Standard C. A continuing education for physicians, physicists, radiopharmacists and radiochemists who have operational responsibilities in a nuclear medicine facility. This continuing educational process can be achieved by:

(1) attendance at appropriate scientific meetings;

(2) participation in interlaboratory comparison studies, sponsored by professional associations and societies and national authorities, which can be carried out at either a national or an international level; and

(3) participation in certification and accreditation programmes, where these exist.

The basic, advanced, and continuing education of radiopharmacists and radiochemists is also discussed in Chapter 5.

* *
*

Further reading

The following references are recommended for further reading: *4*, *5*, *15*, *16*, *33*, *34*, *36*, and *38*.

4. Quality control of nuclear medicine instrumentation

4.1 General principles

QUALITY assurance refers collectively to all aspects of a nuclear medicine programme that may contribute directly or indirectly to the quality of the results obtained. Quality control, on the other hand, refers to individual aspects of the nuclear medicine programme and may be used in relation to specific instruments and their performance. This chapter is restricted to a discussion of quality control and the tests which need to be carried out for each class of instrument to ensure optimum performance. The tests recommended, and their frequencies, should provide acceptable quality control of nuclear medicine instrumentation. In the formulation of the recommendations included in this chapter, the document "Quality control schedules for nuclear medicine instrumentation" prepared by a 1979 IAEA advisory group on the quality control of *in vivo* radionuclide procedures (*21*) has been used as a basis and much of its content has been incorporated into the present text.

4.2 Quality control factors

4.2.1 *Choice of instruments*

The choice of instrument is governed by the type of procedure to be undertaken, but the choice of a particular manufacturer's model must be determined in large part by the experience of local users, by referral to any available comparative results, and by considerations of cost. Full technical specifications of performance should be sought from the manufacturer when quotations are requested, and the quotations should be compared not only in terms of price, but also in terms of the instruments' ability to satisfy performance requirements. Accessories to be supplied should include both operation and service manuals (appropriately updated), and care should be taken to determine which *optional* accessories are really necessary. Extension boards may be required for servicing electronics units and should be provided at the time of initial installation.

Appropriate radionuclide sources, phantoms, and other devices will be required for quality control and should be purchased with the instrument. The

provision of servicing, including spare parts, should be scheduled for the proposed lifetime of the instrument, and manufacturers' service contracts should be considered—especially if only minimal technical assistance is available at the nuclear medicine facility.

4.2.2 *Siting and precautionary maintenance*

The siting of an instrument should take into account background radiation levels, electrical power supply requirements, and environmental factors.

Background radiation levels should be considered in relation to the storage and movement of radioactive materials, including the movement of patients receiving such materials, and in relation to any nearby X-ray equipment. Such considerations are especially pertinent to the siting of radionuclide activity meters and counting systems for radionuclide measurements *in vitro*, but they also have a bearing on the location and permitted viewing angles of imaging instruments.

Electrical power supplies must match instrument specifications as regards both voltage and frequency, and a properly shielded power line with earth connexion is essential. Protective devices, such as dropout relays, voltage surge suppressors, and voltage regulators, should be provided to guard against power defects.

Environmental factors, such as temperature, humidity and cleanness of air with freedom from dust, smoke, etc., are of great importance, and air filters (if fitted) should be changed regularly. There must be rigorous inspection of the mechanical parts of the equipment that involve the safety of the patient. The importance of performing simple precautionary maintenance, including cleaning, should be stressed to all nuclear medicine staff.

4.2.3 *Acceptance and reference testing*

The carrying out of acceptance tests on receipt of a new instrument is the most critical step towards the achievement and maintenance of high-quality performance. Great care should be taken when conducting acceptance tests. It is necessary to establish, during the negotiations for the purchase of the equipment, the mechanism by which acceptance testing will be undertaken. If specialized equipment is required, the appropriate arrangements must be made. For any major instrument, a nominated representative of the manufacturer should be present during installation and acceptance testing and should be able to take remedial action if technical specifications are not met. Otherwise, the purchaser will have to carry out the acceptance tests on his own and this might lead to problems if remedial action is required. An instrument that fails to operate correctly at installation has a great likelihood of never being satisfactory. However, the purchaser has some insurance against this event's occurring if he withholds full payment until after successful completion of the acceptance tests. This procedure has already been adopted in some countries and has proved effective. It is recommended that more purchasers insist on such an arrangement.

Acceptance tests also constitute the initial *reference tests*,[1] and the results may be used for comprehensive assessments of future performance. Such reference tests should be repeated after any major failure and subsequent repair, or when an instrument is moved to a new site.

4.2.4 *Routine testing*

Routine quality control tests are those which should be carried out regularly to ensure that each instrument produces optimum performance with respect to its current potentialities, and to determine the rate and extent of its deterioration with time. Such tests fall into two categories:

(1) *daily (operational) tests*, to be undertaken whenever an instrument is to be used; and

(2) *longer-period tests*, to be undertaken weekly, monthly, quarterly, etc., the frequency varying according to the rate of failure of the individual instrument.

Tests should in any case be simple and uncomplicated, and designed to be completed—according to a defined sequence—in a short period of time, such as 15 minutes, by an experienced person. If relevant, daily tests should include recordings of the ambient temperature and humidity and the power supply voltage.

It should be realized that test schedules represent a compromise between what is ideal and what is feasible in a facility that has service functions. It is essential that all personnel should be on the alert for instrument malfunction and the presence of artefacts, and that appropriate additional tests should be carried out whenever results are suspect.

4.2.5 *Instrument records*

A good data-recording system is essential for monitoring the operational quality control and servicing requirements of each instrument, and all entries should be signed. Instrument records are discussed in detail in section 6.2.

4.3 Performance test requirements for activity meters (radionuclide "dose" calibrators)

The correct term for this equipment is activity meter, but the term "dose" calibrator is also still in use. Quality control of these instruments must include consideration of background radiation, linearity of the activity response, and the accuracy and precision of the measurements for radionuclides in current use.

---

[1] For a definition of this term, see Annex 1.

4.3.1 *Radiation source requirements*

Sealed, low-energy, medium-energy, and high-energy gamma radiation sources (vial-type) calibrated to ±5 % *overall uncertainty*[1] are required. These may be supplied by local, national, or other secondary standard laboratories. Table 2 lists suitable sources.

Table 2. Examples of radiation sources that are suitable for use in performance tests of activity meters

Radio-nuclide	Principal photon energies	Half-life	Activity	
			SI units	Non-SI units
^{57}Co	0.122 MeV	271 days	37 MBq	1 mCi
^{133}Ba	0.081, 0.356 MeV	10.7 years	9.3 MBq	250 μCi
^{137}Cs	0.662 MeV	30.1 years	3.7 MBq	100 μCi
^{60}Co	1.173, 1.332 MeV	5.3 years	1.8 MBq	50 μCi

An uncalibrated, sealed, medium-energy gamma radiation source of approximately 3.7 MBq (100 μCi) with a long half-life is also required for daily or operational tests, but one of the calibrated sources may be used as an alternative.

Unsealed radionuclide sources in solution are also required—for example, ^{99m}Tc, ^{113m}In, ^{131}I—as well as sample vials, syringes, pipettes, holders for sources, and remote handling devices for the sealed and unsealed sources.

4.3.2 *Acceptance and reference testing*

The instrument should first be physically inspected and then the series of tests listed in Table 3 should be performed.

Table 3. Acceptance and reference tests for activity meters*

Test to check
(1) Precision and accuracy for standard measurement geometry with a calibrated, sealed gamma radiation source.
(2) Linearity of the activity response, with ^{99m}Tc or ^{113m}In in solution.
(3) Leakage of radiation shielding.
(4) Background recording under the most sensitive operating conditions in current use—i.e., in the lowest activity range for the radionuclide with the lowest specific gamma radiation constant.
(5) ^{99}Mo breakthrough option (if applicable) with ^{99}Mo, ^{99m}Tc in solution.
(6) Evaluation (or confirmation) of the calibration factors for nonstandard measurement geometries, with appropriate radionuclides in solution.

* With the exception of test 6 (an acceptance test only), all tests are both acceptance and reference tests.

[1] For a definition of this term, see Annex 1.

4.3.3 *Routine testing*

Routine testing is divided into classes according to the desired frequency at which the test should be undertaken (see Table 4).

Table 4. Routine tests for activity meters

Frequency of the test	Test
Daily (operational)	(1) Reproducibility test with an uncalibrated, sealed, medium-energy gamma radiation source with a long half-life.
	(2) Background test under operating conditions for radionuclides in use.
Longer period:	
(A) Weekly	(1) Background test under the most sensitive operating conditions in current use—i.e., in the lowest activity range for the radionuclide with the lowest specific gamma radiation constant.
(B) Quarterly	(2) Test of the linearity of the activity response, with ^{99m}Tc or ^{113m}In in solution.
	(3) Test of accuracy and reproducibility for standard measurement geometry, with calibrated, sealed gamma radiation sources.

4.4 Performance test requirements for manual and automatic counting systems for gamma radiation measurements *in vitro*

Quality control checks of counting systems for gamma radiation measurements must include tests for the following features: the performance of their analyser, scaler, and/or ratemeter; the linearity of energy response, energy resolution, sensitivity for radionuclides in current use; counting precision; background; and the linearity of the count-rate. When appropriate, tests on multichannel systems must be carried out on each individual electronic channel. It should be noted that some of the tests enumerated in this section will not be applicable to systems with elective, preset operating conditions.

4.4.1 *Radiation source requirements*

Sealed gamma radiation sources (rod-type or tube-type) calibrated to ±10 % overall uncertainty are required, and could be supplied by local, national, or secondary standard laboratories. Table 5 lists suitable sources.

Table 5. Examples of radiation sources that are suitable for use in performance tests

Radio-nuclide	Principal photon energies	Half-life	Activity	
			SI units	Non-SI units
^{129}I	0.029, 0.030 MeV	1.57×10^7 years	3.7 kBq	0.1 μCi
^{137}Cs	0.662 MeV	30.1 years	3.7 kBq	0.1 μCi

Unsealed radionuclide sources in solution are also required—for example, ^{125}I, ^{99m}Tc, ^{113m}In, ^{131}I—as well as sample vials, pipettes, etc.

4.4.2 *Acceptance and reference testing*

The instrument should first be physically inspected and then the series of tests listed in Table 6 should be performed.

Table 6. Acceptance and reference tests for manual and automatic counting systems for gamma radiation measurements *in vitro**

Test to check:
(1) Performance of the scaler and/or ratemeter, with a 50-Hz or 60-Hz test facility.
(2) Energy calibration of the analyser, with a calibrated, sealed ^{137}Cs radiation source.
(3) Linearity of the energy response and the zero-offset of the energy calibration of the analyser with calibrated, sealed ^{129}I and ^{137}Cs radiation sources and at least one other radionuclide.
(4) Sensitivity with calibrated, sealed ^{129}I and/or ^{137}Cs radiation sources.
(5) Counting precision, using the chi-square test, with calibrated, sealed ^{129}I and/or ^{137}Cs radiation sources.
(6) Leakage of radiation shielding, with radionuclides in common use.
(7) Integral background above a specified threshold—for example, 20 keV.
(8) Present analyser peak settings for the appropriate radionuclides, if applicable.
(9) Linearity of the count-rate, with ^{99m}Tc or ^{113m}In in solution.
(10) Dependence of the response on volume, the position of sample, the nature of container, etc., with appropriate radionuclides in solution; evaluation of their significance.
(11) Energy resolution (FWHM—full width at half maximum) with a calibrated, sealed ^{137}Cs radiation source.

* With the exception of test 10 (an acceptance test only), all tests are both acceptance and reference tests

4.4.3 *Routine testing*

Routine testing is divided into classes according to the desired frequency at which the test should be undertaken (see Table 7).

4.5 Performance test requirements for single- and multi-probe counting systems for gamma radiation measurements *in vivo*

Quality control of counting systems for gamma radiation measurements *in vivo* must include aspects similar to those already mentioned for quality control of systems for measurements *in vitro* (see section 4.4). However, for *in vivo* measurements collimator characteristics are more relevant than the dependence of the results on the volume and position of the sample, the nature of container, etc. In addition, the performance of strip-chart recorders may have to be included. Also, tests on multi-probe systems, when appropriate, must be undertaken on each individual probe and its associated electronic

Table 7. Routine tests for manual and automatic counting systems for gamma radiation measurements *in vitro*

Frequency of test	Test
Daily (operational)	(1) Sensitivity test with calibrated, sealed ^{129}I and/or ^{137}Cs radiation sources.
	(2) Test of the analyser energy peak setting for the radionuclide in use.
	(3) Background test under operating conditions for the radionuclide in use.
Longer period:	
(A) Weekly	(1) Test of the performance of the scaler and/or ratemeter, with a 50-Hz or 60-Hz test facility.
	(2) Energy calibration of the analyser with a calibrated, sealed ^{137}Cs radiation source (where applicable).
	(3) Test of the integral threshold—for example, 20 keV.
(B) Monthly	(4) Chi-square test of counting precision with calibrated, sealed ^{129}I and/or ^{137}Cs radiation sources.
(C) Half-yearly	(5) Test of the linearity of energy response and zero-offset of energy calibration of the analyser, with calibrated, sealed ^{129}I and ^{137}Cs radiation sources and at least one other radionuclide.
	(6) Test of the energy resolution (FWHM—full width at half maximum) with a calibrated, sealed ^{137}Cs radiation source.
	(7) Confirmation of the preset analyser energy peak settings for appropriate radionuclides.
	(8) Test of the linearity of the count-rate with ^{99m}Tc or ^{113m}In in solution.

channel, and the possible requirement to equalize probe sensitivities must be taken into account.

4.5.1 *Radiation source requirements*

A sealed, medium-energy gamma radiation source (disc-type or rectangular-type) calibrated to $\pm 10\%$ overall uncertainty is required, and could be supplied by local, national, or secondary standard laboratories. Table 8 lists suitable sources.

Unsealed radionuclide sources in solution—for example, ^{99m}Tc, ^{113m}In, ^{113}I—as well as mountings for calibrated sources and for point sources, sample vials, pipettes, etc., are also required. (N.B.: A system without a scaler should be coupled to an external scaler for certain of the tests.)

Table 8. Examples of radiation sources that are suitable for use in performance tests

Radionuclide	Principal photon energies	Half-life	Activity	
			SI units	Non-SI units
^{137}Cs	0.662 MeV	30.1 years	370 kBq	10 μCi
^{133}Ba	0.356, 0.081 MeV	10.8 years	370 kBq	10 μCi

4.5.2 *Acceptance and reference testing*

The instrument should first be physically inspected and then the series of tests listed in Table 9 should be performed.

Table 9. Acceptance and reference tests for single- and multi-probe counting systems for gamma radiation measurements *in vivo**

Test to check:
(1) Performance of the scaler and or ratemeter with a 50-Hz or 60-Hz test facility.
(2) Energy calibration of the analyser with a calibrated, sealed ^{137}Cs or ^{133}Ba radiation source.
(3) Linearity of the energy response and zero-offset of energy calibration by the analyser, with a calibrated, sealed ^{137}Cs or ^{133}Ba radiation source.
(4) Energy resolution (FWHM—full width at half maximum) with a calibrated, sealed ^{137}Cs or ^{133}Ba radiation source.
(5) Sensitivity with a calibrated, sealed ^{137}Cs or ^{133}Ba radiation source.
(6) Counting precision, using the chi-square test, with a calibrated, sealed ^{137}Cs or ^{133}Ba radiation source.
(7) Leakage of radiation shielding, with radionuclides in common use.
(8) Integral background above a specified threshold—for example 50 keV.
(9) Confirmation of the present analyser energy peak settings for appropriate radionuclides, if applicable.
(10) Linearity of the count-rate with ^{99m}Tc or ^{113m}In in solution.
(11) Evaluation of the field of view of the collimator at different distances, with the appropriate radionuclides as point sources.
(12) Strip-chart recorder speed.
(13) Strip-chart recorder response time.
(14) Linearity with respect to the ratemeter output.

* With the exception of test 11 (an acceptance test only), all tests are both acceptance and reference tests.

4.5.3 *Routine testing*

Routine testing is divided into classes according to the frequency at which the test should be undertaken (see Table 10).

4.6 Performance test requirements for rectilinear scanners

Quality control schedules for rectilinear scanners must include aspects similar to those mentioned for counting systems in gamma radiation measurements *in vivo*. In addition, they must include mechanical parameters, such as scanning speed and line spacing, and display functions, such as background subtraction, contrast enhancement, colour recording and photo-recording. Attention must also be given, when appropriate, to the characteristics of each available collimator. When appropriate, tests on dual-probe scanners must be carried out on each individual probe and its associated electronic channel, as well as on the summed outputs from both channels.

Table 10. Routine tests for single- and multi-probe counting systems for gamma radiation measurements *in vivo*

Frequency of test	Test
Daily (operational)	(1) Test of the mechanical safety of probe and collimator mountings.
	(2) Test of the analyser energy peak setting for radionuclides in use.
	(3) Equalization of probe relative sensitivities, if applicable.
	(4) Background test under operating conditions for the radionuclide in use.
	(5) Test of the strip-chart recorder pen function.
Longer period:	
(A) Weekly	(1) Sensitivity test with calibrated, sealed ^{137}Cs or ^{133}Ba radiation source.
	(2) Performance test of the scaler and or ratemeter with 50-Hz or 60-Hz test facility.
	(3) Energy calibration of the analyser with calibrated, sealed ^{137}Cs or ^{133}Ba radiation source.
	(4) Test of the integral background above a specified threshold—for example, 50 keV.
(B) Monthly	(5) Chi-square test of counting precision with calibrated, sealed ^{137}Cs or ^{133}Ba radiation source.
(C) Quarterly	(6) Test of the linearity of energy response and zero-offset of energy calibration of the analyser with calibrated, sealed ^{137}Cs or ^{133}Ba radiation source, and at least two other radionuclides.
	(7) Test of the energy resolution (FWHM—full width at half maximum) with calibrated, sealed ^{137}Cs or ^{133}Ba radiation source.
	(8) Test of the strip-chart recorder linearity.
	(9) Test of the strip-chart recorder response time.
(D) Half-yearly	(10) Confirmation of present analyser energy peak settings for appropriate radionuclides, if applicable.
	(11) Test of the linearity of count-rate with ^{99m}Tc or ^{113m}In in solution.
	(12) Test of the strip-chart recorder chart speed.

(N.B.: Some of the tests mentioned in this section may not be applicable to systems with elective, preset operating conditions.)

4.6.1 *Radiation source requirements*

A sealed, disc- or rectangular-type medium-energy gamma radiation source (for example, ^{137}Cs, calibrated to $\pm 10\,\%$ overall uncertainty), with an activity of about 370 kBq (10 μCi), is required. This could be supplied by local, national, or secondary standard laboratories.

Unsealed radionuclide sources in solution are also required—for example, ^{99m}Tc, ^{113m}In, ^{131}I—as well as a mounting for the calibrated source.

In addition, an emission-type, step-wedge phantom and an emission-type, *total-performance phantom*[1] are required. However, a step-wedge phantom of the transmission type could be used as an alternative to the emission-type, step-wedge phantom, but the results are less informative. A rectilinear scanner

[1] For a definition of this term, see Annex 1.

with scaler should be coupled to an external scaler for some of the following tests.

4.6.2 *Acceptance and reference testing*

The instrument should first be physically inspected and then the series of tests listed in Table 11 should be performed.

Table 11. Acceptance and reference tests for rectilinear scanners*

Test to check:
(1) Performance of the scaler and or ratemeter with a 50-Hz or 60-Hz test facility
(2) Energy calibrations of the analyser with calibrated, sealed ^{137}Cs radiation source and with *collimator removed*.
(3) Linearity of energy response and zero-offset of energy calibration of the analyser with calibrated, sealed ^{137}Cs radiation source and at least two other radionuclides. Test must be undertaken with *collimator removed*.
(4) Energy resolution (FWHM—full width at half maximum) with calibrated, sealed ^{137}Cs radiation source and with *collimator removed*.
(5) Sensitivity with calibrated, sealed ^{137}Cs radiation source and with *collimator removed*.
(6) Counting precision, using chi-square test, with calibrated, sealed ^{137}Cs radiation source and with *collimator removed*.
(7) Integral background above a specified threshold—for example, 50 keV.
(8) Leakage of radiation shielding, with radionuclides in common use.
(9) Confirmation of preset analyser energy peak settings for the appropriate radionuclides.
(10) Count-rate losses with ^{99m}Tc or ^{113m}In in solution, and with *collimator removed*.
(11) Evaluation of relative sensitivity of collimator in air, with appropriate radionuclide in solution as a line source or flood source, whichever is available.
(12) Background subtraction facility using a chosen radionuclide in solution with a step-wedge phantom.
(13) Contrast enhancement facility using a chosen radionuclide in solution with a step-wedge phantom. (N.B.: Contrast enhancement should be used with caution and is not recommended unless the raw data can be retained for display.)
(14) Performance of scanner drive mechanism.
(15) Total performance for all collimators with appropriate radionuclides in solution, in a total-performance phantom.

* A photodensitometer is highly desirable for use with tests 12 and 13 when film density measurements are required.

4.6.3 *Routine testing*

Routine testing is divided into classes according to the frequency at which the test should be undertaken (see Table 12).

4.7 Performance test requirements for gamma cameras

Quality control to ensure optimum performance will determine the rate and extent of instrument deterioration with time, and is especially important for gamma cameras because of the electronic complexity of this instrument, which is now the basic tool of choice in radionuclide imaging. In particular,

Table 12. Routine tests for rectilinear scanners

Frequency of test	Test
Daily (operational)	(1) Test of the mechanical safety of the probe and collimator mountings. (2) Test of the analyser energy peak setting for radionuclide in use. (3) Test of the tapper function with a 50-Hz or 60-Hz test facility. (4) Background test under operating conditions for the radionuclide in use.
Longer period:	
(A) Weekly	(1) Test of the performance of the scaler and or ratemeter with a 50-Hz or 60-Hz test facility. (2) Energy calibration of the analyser with a calibrated, sealed ^{137}Cs radiation source and with *collimator removed*. (3) Test of the sensitivity with calibrated, sealed ^{137}Cs radiation source and with *collimator removed*. (4) Test of the integral background above a specified threshold—for example, 50 keV. (5) Test of the system's linearity with a step-wedge phantom. (6) Total-performance test with chosen radionuclide in solution with a total-performance phantom.
(B) Monthly	(7) Chi-square test of counting precision with calibrated, sealed ^{137}Cs radiation source and with *collimator removed*.
(C) Quarterly	(8) Test of the linearity of energy response and zero-offset of energy calibration of the analyser, with calibrated, sealed ^{137}Cs radiation source and at least two other radionuclides. Test must be undertaken with *collimator removed*. (9) Test of the energy resolution (FWHM—full width at half maximum) with calibrated, sealed ^{137}Cs radiation source and with *collimator removed*.
(D) Half-yearly	(10) Confirmation of preset analyser energy peak settings for the appropriate radionuclides. (11) Test of the background subtraction facility using a chosen radionuclide in solution with a step-wedge phantom. (12) Test of the contrast enhancement facility using a chosen radionuclide in solution with a step-wedge phantom. (N.B.: Contrast enhancement should be used with caution and is not recommended unless the raw data can be retained for display.) (13) Test of the performance of the scanner drive mechanism.

quality control tests must consider the correct setting of the analyser energy peak and window controls, energy resolution, intrinsic spatial resolution, uniformity, sensitivity, spatial linearity and distortion, count-rate performance, and display parameters. (N.B. The test procedures must be used without any electronic or mechanical modification.) The control settings should be those normally used in clinical practice and must not be specially readjusted for the measurement of specific parameters. If not otherwise stated, measurements should be performed for count-rates not exceeding 10^4 counts per second for gamma cameras built during or after 1975, and 5×10^3 counts per second for gamma cameras built prior to 1975. All measurements should be performed with a $\pm 10\%$ window centred on the energy peak, and it should be noted that some acceptance tests require a multichannel analyser. Needless

removal of collimators should be avoided and great care should be taken to avoid damage to the crystal during tests undertaken with the collimator removed. Except during such tests, the detector head should always carry a collimator to provide mechanical and thermal protection to the crystal.

4.7.1 *Radiation source requirements*

Unsealed radionuclides in solution are required—for example, ^{99m}Tc, ^{131}I, ^{67}Ga and ^{111m}In. In addition, a mounting is required for a point source.

4.7.2 *Phantom requirements*

The phantom requirements for performance tests on gamma cameras are given in Table 13.

Table 13. Phantom requirements

Phantom	Comments
(1) Flood-field phantom according to IEC (*21*)	See section 7.1(1) for IEC (*22*) phantom. A ^{57}Co disc flood-field phantom (see section 7.1(2)) may be used in addition for uniformity measurements, but only after ensuring that no significant ^{60}Co contamination is present.
(2) Orthogonal hole transmission pattern phantom.	The Ortho Test (Smith orthogonal hole—SOH) phantom (see section 7.2(1)) is recommended as the most appropriate phantom but other phantoms, such as the OHP (BRH) phantom (see section 7.2(2)), may be used as an alternative.
(3) IEC (*21*) count-rate performance phantom	See section 7.3.
(4) NEMA (*32*) resolution and linearity phantom.	See section 7.4.
(5) Step-wedge phantom.	See section 7.5. This is an optional phantom.
(6) Total-performance phantoms	See section 7.6. These are optional phantoms.

4.7.3 *Acceptance and reference testing*

The acceptance tests recommended in this section follow in part the recommendations of the American Association of Physicists in Medicine (AAPM), the International Electrotechnical Commission (IEC), and the National Electrical Manufacturers' Association (NEMA), for some of the performance parameters. However, it should be emphasized that in a nuclear medicine facility in which the recommendations given in this guide cannot be fulfilled, the scheme of acceptance testing recommended by AAPM (*1*) should be considered. This statement is not intended to allow nuclear medicine facilities to escape any of their obligations with regard to quality assurance and quality control, but only to recognize the reality of some unusual

situations in which facilities are rather basic with regard to ancillary equipment and manpower and their access to technical expertise is limited.

The purchase contract for a gamma camera should include a clause stating that the instrument must meet specified performance criteria, and that the manufacturer will conduct measurements of the performance parameters to the satisfaction of the user. Acceptance testing is undertaken to ensure that the instrument does in fact meet the manufacturer's specifications and therefore must be completed as soon as the instrument is installed and operational, and before patient studies are initiated. As stated earlier in this guide, all results should be carefully recorded and stored in such a way that the portion concerning acceptance *and* reference data should be readily available for routine quality control.

Table 14 lists the necessary acceptance and reference tests for gamma cameras that should be performed after a physical inspection of the instrument. Advice on how such an inspection should be conducted is given by AAPM (*1*).

Table 14. Acceptance and reference tests for gamma cameras

Test to check:
(1) The analyser energy peak and window settings for radionuclides in common use, in either point-source configuration (with *collimator removed*) or flood-source configuration.
(2) Measurement of intrinsic energy resolution with ^{99m}Tc according to NEMA (*32*).
(3) Measurement of intrinsic spatial resolution with ^{99m}Tc according to NEMA (*32*).
(4) The uniformity of response for radionuclides in common use, in flood-source configuration with a parallel hole collimator appropriate to the radionuclide used. The output should be visually inspected and the reference images stored. If possible, numerical evaluation by computer should be undertaken, according to IEC recommendations. In case of vital inspection only, the count density should exceed 5000 counts cm^{-2}, otherwise the IEC specifications should be followed.
(5) Measurement of sensitivity according to IEC (*22*).
(6) Measurement of intrinsic spatial linearity and distortion with ^{99m}Tc according to NEMA (*32*).
(7) Measurement of count-rate characteristics according to IEC (*22*) with a chosen radionuclide.
(8) The multiple window spatial registration, if applicable.
(9) Confirmation of present analyser energy peak and window settings for appropriate radionuclides in point-source configuration (with *collimator removed*) or in flood-source configuration.
(10) *Optional test*: The contrast with a chosen radionuclide in flood-source configuration using a step-wedge phantom.
(11) *Optional test*: Total performance, using a chosen radionuclide in solution with a total-performance phantom.

4.7.4 *Routine testing*

Routine testing is divided into classes according to the frequency at which the test should be undertaken (see Table 15).

Table 15. Routine tests for gamma cameras

Frequency of test	Test
Daily (operational)	(1) Test of the safety of the detector head and collimator mountings. (2) Test of the analyser peak and window settings for the radionuclide in use, in point-source configuration or flood-source configuration. (3) Test of the function of oscilloscopes and hard-copy devices. (4) Test of the uniformity, linearity, sensitivity, and resolution of the response for ^{99m}Tc with an orthogonal hole transmission pattern (OHTP) phantom and a point source at a large distance (with *collimator removed*). The Ortho Test (SOH) phantom (see section 7.2(1)) is recommended as the most appropriate phantom, but other phantoms such as the OHTP (BRH) phantom (see section 7.2(2)) may be used as an alternative. If this test, which may constitute a further reference test when first performed, shows good stability of the instrument, its frequency may be reduced to weekly. The system uniformity may then be checked daily and operationally with ^{99m}Tc in solution in a flood-field phantom or, less recommendably, with a ^{57}Co flood source, with an appropriate collimator. The interposition of scattering material 20 cm thick between the flood-source and the collimator is recommended. If ^{99m}Tc is not available, a corresponding test must be carried out with a radionuclide in common use. The hole diameter and spacing of the orthogonal hole transmission pattern phantom should be approximately equal to the intrinsic resolution of the gamma camera. (5) Background test under operating conditions for the radionuclides in use. (6) Test of the film developer temperature, if applicable.
Longer period	
(A) Weekly	(1) *Optional test*: Test of contrast with chosen radionuclide in flood-source configuration and step-wedge phantom. (2) *Optional test*: Total-performance test with chosen radionuclide in solution in total-performance phantom.
(B) Half-yearly	(3) Measurement of count-rate characteristics according to IEC (*22*). (4) Test of the multiple window spatial registration according to the AAPM (*1*). (5) Test of the uniformity for a chosen radionuclide, with the radionuclide in solution in a scattering phantom, with appropriate collimator, according to IEC protocol (*22*).

4.7.5 *Tests for whole body attachment*

If the gamma camera has a whole body attachment then the additional tests listed in Table 16 should be undertaken.

Table 16. Acceptance, reference and routine tests for gamma camera whole body attachment

Test
(1) Test that the collimator axis is perpendicular to the scanning plane. (*This should be performed daily.*)
(2) Perform a total scan with a flood source fixed to the collimator outer face. Verify that the image is uniform and undistorted, and if there is more than a single page, verify that there is no image overlapping. (*This should be performed weekly.*)

4.8 Preliminary proposals for the test requirements for single photo emission computed tomographic systems using rotating cameras

Special consideration should be given to the camera detector head and should include the following aspects:

(1) spatial linearity and uniformity;

(2) interaction between external magnetic fields and photomultiplier gain, depending on the angulation of the detector head; and

(3) maintenance of optical coupling between photomultiplier and crystal throughout all movements.

Requirements for mechanical drive mechanisms should include:

(1) control, such that the collimator axis lies in the plane defined by the rotation of the geometric centre of the detector, and that it crosses through the rotational axis;

(2) control constancy of the radius measured from the rotational axis to the detector's geometric centre during movement; this is important with single plane converging collimators;

(3) for continuous movement: control of rotation speed constancy; and

(4) for stepwise movement: control of constancy of angular increment displacement and measurement time at each step.

Some phantoms will be required for certain tests. These will include:

(1) a phantom for testing uniformity—for example, a cylindrical uniformly distributed source;

(2) a phantom for testing longitudinal resolution—for example, a point source immersed in a scattering medium; and

(3) a phantom for the total-performance test: this phantom (see section 7.7) should consist of a cylinder with an outer shell containing a uniformly distributed source of low-activity concentration; the phantom should also contain "hot" and "cold" rods placed asymmetrically within the inner cylindrical source, with their long axes parallel to the long axis of the phantom.

For the testing of the camera–computer interface the following procedures are required:

(1) test that a point source on the rotational axis is always positioned in the centre of a specified frame pixel;

(2) ensure that the size of the object is consistent with the reconstruction area; and

(3) ensure that no pixel count overflow occurs during data acquisition.

Image quality tests should be performed to test the following:

(1) spatial resolution—i.e., edge response (*a*) for different radii within the reconstruction plane, and (*b*) along the rotational axis;

(2) uniformity;

(3) spatial linearity of the total system;

(4) signal-to-noise ratio for different information densities and reconstruction procedures; and

(5) extent of image artefacts.

4.9 Preliminary proposals for performance test requirements for data-processing systems

4.9.1 *Acceptance testing*

It is recommended that all the manufacturer's specifications should be checked, since many defects may exist.

Tests should include an evaluation of the following:

(1) dead time;

(2) count-rate performance, with special reference to high count-rate images for misplaced data;

(3) differential and integral linearity;

(4) energy window, if applicable;

(5) list mode acquisition and particularly the accuracy of information timing;

(6) frame mode acquisition;

(7) time per frame;

(8) time between frames for all proposed frame sizes; and

(9) physiological triggers and gated acquisition.

Software tests should include evaluations of the following:

(1) contents and areas for regions of interest, particularly for irregular regions;

(2) time-activity curves, especially at high count rates and when images with different framing intervals are used;

(3) acquisition: this should be tested for data loss when some other process is involved—e.g., writing to magnetic tape;

(4) stability of system when lights, motors, etc., are switched on and off in adjacent rooms;

(5) stability in the event of mechanical shock;

(6) blockages on disc packs;

(7) results of adding, subtracting, multiplying, and dividing known time-activity curves; and

(8) small programme routines to check the existence of utilities such as editors, compilers, subroutines and means to incorporate a user programme.

System testing is also important, and while the installation engineer is present a simulated, gated, dynamic study should be performed. If relevant, deconvolution, blood background subtraction, etc., should be tested after the performance of a renogram.

The validation of protocols and new software products must also be considered. This can be achieved in two ways:

(1) The establishment of a tape library of validated clinical cases, so that the results of new protocols can be compared with *probable* values in the library.

(2) The establishment of a library of simulated cases for which, in principle, "true" values would exist. In the case of an ejection fraction, great care must be taken with background simulation, since the value of the ejection fraction is very dependent on this parameter.

A complete set of manuals should be provided, and should include: an installation guide; a well-illustrated hardware guide with a section on each hardware device; a user manual containing all routine programmes and protocols; a design manual with details of all algorithms used; a maintenance manual with details of all test procedures and programmes; and, most important, a list of all the available manuals and their date of publication or revision.

4.9.2 *Routine testing*

In this section it is assumed that a properly working system has been installed and accepted, and therefore the routine tests applied are designed to

Table 17. Routine tests for data-processing systems

Frequency of test	Test
(A) Weekly	The standard routine test proposed is one of uniformity. A uniformity image should be obtained, as in the routine testing of gamma cameras (see section 4.7.4). The following observations should be made: (1) Total count in standard time. Is this correctly related to that for the gamma camera alone? (2) Dimensions of image. Have they changed? (3) Position of image. Has it changed? (4) Integral uniformity of image—i.e., the number of pixels > 5%, > 10%, > 15%, etc., from the mean. Has it changed? (5) Differential uniformity of the image. (6) Differential linearity of the image, in both axes—including zoom capability, if applicable. (7) Presence of events outside the field of view of the camera. (8) Presence of "hot" spots. A further routine test for systems with magnetic tape, floppy disc, or similar recording facility, is to read an old test pattern, to write it, and to read it back again observing any losses.
(B) Quarterly	These tests should include: (1) Test of count-rate performance according to IEC (22). (2) Test of display contrast. (3) Test of spatial resolution. (4) For systems with *energy encoding*, tests of linearity, window width, and spatial alignment of images from different windows.

establish whether a change has occurred in the system. The components which may change (apart from any due to a catastrophic breakdown), and for which quality control tests are appropriate, are primarily those of the interface, the display, and the magnetic storage devices. Also, it is emphasized that the recommendations of the manufacturer should be followed, otherwise guarantee and warranty agreements might be invalidated.

Routine tests, divided into classes according to the frequency at which the test should be undertaken, are given in Table 17.

The importance of regular maintenance—as recommended by the manufacturer—including visual checks on all moving parts, such as disc packs or a printer, is stressed. Most manufacturers of systems that include discs provide a programme for the detection of bad blocks, and this should be run at regular intervals—for example, weekly. Cleanliness is important, and disc packs, magnetic tape heads and disc air filters should be cleaned at regular intervals. The last-named are especially important, since dust can rapidly destroy the discs. Also, cigarette smoke is reported to be even more dangerous to the discs than dust.

* *
*

Further reading

The following references, which have not been explicitly quoted in Chapter 4, are recommended for further reading: *5*, *15*, *21*, *23*, *24*, *34*, *38*, and *39*.

5. Quality control of radiopharmaceuticals

THE purpose of quality assurance in radiopharmacy is to ensure that only safe and effective radiopharmaceuticals of uniform quality are administered in the prescribed dose. *Quality* is not a uniquely defined term, and a product of a given quality may be acceptable under one set of circumstances but unacceptable under another. The safety and efficacy of radiopharmaceuticals must never be regarded as a static field of interest. Thus, to continue to obtain the best available nuclear medicine diagnostic information requires continuing development of radiopharmaceuticals, taking into account new technology. It should also be noted that it is an integral part of quality assurance to replace, wherever possible, established radiopharmaceuticals by newer ones that give better information or cause a lower radiation dose to the patient. Since quality is never established by analytical quality control for radiopharmaceuticals in routine use, it is very important to incorporate quality procedures into the total process of production and handling. As for other pharmaceuticals, the level of quality is primarily established by two procedures:

(1) setting standards for the product; and
(2) the manufacturing and handling process.

The methods used to establish the level of quality will, of course, vary from country to country, and will depend on local conditions for example, regulations, manpower resources, and the stage of development of nuclear medicine facilities. However, it would be a great advantage if internationally accepted standards and methodology could be agreed upon and implemented.

5.1 Classes of radiopharmaceutical

Quality control programmes in radiopharmacy depend on the types of radiopharmaceutical used. These have been grouped into four separate classes of product in the following sections (5.1.1–5.1.4).

5.1.1 "*Ready-for-use*"

This class of radiopharmaceuticals refers to products which are delivered to the nuclear medicine facility by the producer and are ready for immediate administration to the patient. They may be radionuclides in simple ionic form, such as ^{201}Tl, or a labelled compound, such as [^{131}I] Hippurate.

5.1.2 *Radionuclide generators and kits*

Radionuclide generators (e.g., ^{99}Mo–^{99m}Tc) and kits (e.g., Sn-phosphate compounds) are delivered to the nuclear medicine facility by a commercial producer. The final product for administration to the patient is only partly manufactured by the commercial organization and requires subsequent handling by the user.

5.1.3 "*Home-made*"

The classification "home-made" radiopharmaceutical is reserved for products derived from raw materials, either radioactive or nonradioactive, within the hospital or institute. These include cyclotron-produced radionuclides, such as positron emitters, and laboratory-prepared pharmaceuticals, such as colloids.

5.1.4 *Autologous labelled*

Autologous radiopharmaceuticals are produced by the radioactive labelling of materials from the patient—for example, cells or metabolic compounds.

5.2 Organization of quality control

The quality of a product is the sum of the characteristics that determine the extent to which it will satisfy the expectation or needs of the user. It is therefore necessary to determine which characteristics are of interest to the user and the patient.

Quality control is a continuous process that commences with the design of the product and the specification of the raw materials from which it is derived, and extends to a determination of the degree to which the user's requirements and the patient's interests are satisfied. Specifications (i.e., standards) for all radiopharmaceuticals must be established from development work—including clinical trials—in order to maintain a uniform quality in radiopharmacy. For nonradioactive pharmaceuticals, standards may be published in pharmacopoeias, and a number of these reference works also describe "ready-for-use" radiopharmaceuticals and some ^{99m}Tc-labelled compounds. A method for setting standards other than by publication in a pharmacopoeia is to require the producer to submit product documentation to an appropriate national authority. Approval can be granted in the form of a product licence,

in which the required product quality is stated. For radiopharmaceuticals not standardized in either of these ways (i.e., pharmacopoeia or product licence), the physician in charge will have to establish his own specifications in accordance with general pharmaceutical rules, and also perhaps in cooperation with local or national authorities. It is then expected that manufacturers will produce radiopharmaceuticals in accordance with a system referred to as GMP (good manufacturing practice), to ensure that every individual product batch conforms to set standards. In many countries, a legal system has been established that requires commercial manufacturers to obtain a licence to produce radiopharmaceuticals, and this allows the authorities to conduct factory inspections and undertake independent quality control analyses.

Because of the special properties of radiopharmaceuticals and their handling procedures, the user is in a very different situation from that in which he is placed when dealing with nonradioactive pharmaceuticals. Radioactive decay makes the patient dosage specification more complicated and the final preparation by the user of material from radionuclide generators and kits (see section 5.1.2) divides the responsibility between the commercial manufacturer and the user. It is therefore useful to apply a modified GMP system that describes guidelines for good practice in the final preparation and dispensing of radiopharmaceuticals. This is termed GRP (good radiopharmaceutical practice) and its elements are:

- personnel,
- premises,
- equipment,
- documentation,
- analytical quality control, and
- radiation safety.

The amount of handling that has to be undertaken at an individual hospital depends on the classes of radiopharmaceutical used, but the major part of any hospital's quality control programme must deal with that part of the preparation that is actually undertaken on the premises. Much will depend, of course, on the quality of the radiopharmaceuticals received from outside the hospital, but (as previously mentioned) the standards laid down by pharmacopoeias and in product licences will largely fulfil the quality requirements. Therefore, in general, "ready-for-use" radiopharmaceuticals, generators, and kits are expected to be of the requisite quality for their intended use—*if* stored, prepared, and dispensed in accordance with the manufacturer's recommendations. Examples of quality control programmes that might be considered useful for the different classes of radiopharmaceuticals are given in sections 5.2.1–5.2.4.

5.2.1 "*Ready-for-use*"

When a radiopharmaceutical has been selected for a given procedure the quality control programme must ensure that the same product is ordered and received each time, and a written instruction sheet specifying all the relevant

details should be available. A careful comparison of the details on the written specification sheet, the label, and the package documentation of the product received is essential. It should also be verified that there have been no changes in the manufacturer's specifications since the control procedure was set up. This kind of simple receiving control mechanism should also include a visual inspection using proper radiation protection measures. The product must then be properly stored from both pharmaceutical and radiation protection standpoints. When the prescribed dose is dispensed, a control of the actual activity of the dose[1] should be made using either an activity meter (see section 4.3) or another suitably calibrated instrument. No other analytical quality control should be required.

5.2.2 *Radionuclide generators and kits*

In the case of this material, the bulk of radiopharmaceutical preparation is undertaken at the hospital and this places part of the responsibility on the user, and therefore analytical quality control testing must be undertaken by the user. Such testing may be carried out either as a routine check on the preparation before it is released for use, or as a continuous control of all the methods that constitute the radiopharmacy production and issue system. The parameters that are controlled will be limited to those affected by the handling and storage conditions at the hospital and by transport of the material—as in the case of generators. The following example refers to ^{99}Mo - ^{99m}Tc but the same principles will equally apply to other systems, such as ^{113}Sn - ^{113m}In.

For ^{99m}Tc-pertechnetate the elution yield from the generator should be calculated as an indicator of whether the generator is working properly. ^{99}Mo is a possible impurity, and when it occurs will be primarily due to incorrect mounting of the generator by either manufacturer or user, or possibly after transport damage. ^{99}Mo-breakthrough is easily controlled by measuring the ^{99m}Tc-pertechnetate sample with and without lead shielding. Testing of the first eluate is the most relevant. Aseptic technique control may also be undertaken by testing the last eluate for microbial contamination, but such a test can only reveal a grossly faulty system and therefore it can only be used in methods control and not as a test prior to the issue of individual patient doses.

For ^{99m}Tc radiopharmaceuticals prepared with kits, the system of GRP has been designed with the purpose of ensuring that the radiopharmaceutical will fulfil specifications *if* prepared according to instructions. It is also noted that problems associated with the biological distribution of such pharmaceuticals were probably more frequent before the introduction of "one-step" kits. Compatibility between generators and kits may have to be considered when a procedure is specified, and a radiochemical purity test may also have to be incorporated into the procedure to control quality. A number of manufacturers of kits recommend that the ^{99m}Tc solution required for the

[1] "Dose" is used in the context of "pharmaceutical dose" and does not refer to "dose in rads or cGy". The specification of the radioactive content is given in terms of "activity in MBq or μGi".

preparation of the radiopharmaceuticals should contain no oxidizing substances, but they do not recommend a suitable test. However, the most commonly used method is to test the compatibility of the reagents using a radiochemical purity test on the ^{99m}Tc-labelled product. The necessity for radiochemical purity testing of kit-prepared compounds depends very much on the type of radiopharmaceutical and the method of manufacture. There is no consensus among radiopharmacists. Some consider it necessary to use purity testing as a criterion prior to issue of the material for patient administration, whereas others maintain that purity testing need only be used for each new batch preparation made with the kit. Also, certain centres which have undertaken purity testing over a long period of time will now only apply purity tests when elements of the manufacturing process are changed—for example, when a new type or size of generator is used, or when a new technician is employed on the staff. Radiochemical purity testing may be of additional use when there are doubts concerning an image and the possibility arises that the observed image abnormalities might be attributable to a defect in the radiopharmaceutical. It is also useful if the stability of the ^{99m}Tc-labelled compound is to be studied. Finally, it should be noted that a simple and reliable chromotographic test will take only a few minutes to carry out, but a complete evaluation of the quality of a radiopharmaceutical needs more elaborate and time-consuming tests.

5.2.3 *"Home-made"*

With "home-made" radiopharmaceuticals the hospital must guarantee all aspects of product quality, including:

- radionuclide purity,
- specific activity,
- radioactive concentration,
- pH,
- isotonicity,
- particle size (if relevant),
- sterility, and
- apyrogenicity.

Since it is not possible to enter into full details of all the above aspects in this guide, reference is made to relevant publications (see page 43).

When considering whether a given radiopharmaceutical or a preparation kit should be prepared in the hospital or be supplied from an outside source, it is most important that all aspects of quality, safety, and economy should be considered. The "home-made" product may require more qualified staff, more elaborate facilities, and more quality control work. However, raw materials are much cheaper than preparation kits and the delivery of preparations may not be affected by transport problems. In a consideration of all these factors, the overriding priority will be to make the maximum use of existing resources.

5.2.4 *Autologous labelled*

This class of radiopharmaceuticals presents the same problems as the "home-made" class, but there may also be rather simple procedures to be carried out, as with the kit preparations. In addition, although the preparation of the materials from the patient presents special problems, other important factors—such as control of the separation and viability of cells and of the aseptic techniques, and the minimization of the risk of infection to personnel—must be considered.

5.3 Quality control in hospitals

5.3.1 *Premises*

Most handling of radiopharmaceuticals requires the use of aseptic techniques. For a sterile product, environmental factors such as air quality must be controlled. Special requirements for radiation protection and for hygiene may be required. Such considerations require the installation of special ventilation systems, including fume hoods and laminar-air-flow cabinets, and these must be regularly controlled with regard to air-flow velocity and directions and the effectiveness of the filter. All premises should be regularly monitored for contamination in accordance with national and international regulations, and instruments such as autoclaves and dry-heat sterilizers must be checked with spore samples for sterilizing effectiveness.

5.3.2 *Equipment*

To perform quality control in a hospital environment, various instruments are required, according to the class of radiopharmaceutical used. For "ready-for-use" radiopharmaceuticals (see section 5.1.1) an activity meter is required (see section 4.3). For radionuclide generators and kits, the following items are required:

— activity meter,
— equipment for radiochromatography, including measuring instruments, such as a well counter, gamma camera, or chromatograph scanner,
— microscope for control of particles, and
— equipment for sterility testing.

For "home-made" radiopharmaceuticals a fully equipped analytical chemistry laboratory is required. For autologous labelled biological material additional equipment may be required for staining cells and for the separation of proteins; a special microscope may also be needed.

5.3.3 *Documentation*

Written instructions for the preparation and dispensing of radiopharmaceuticals should always be available and should be routinely reviewed and kept up to date. Vials and syringes containing radiopharmaceuticals which are issued from the "hot" laboratory must be labelled with the following information:

radionuclide,
compound,
radioactivity at the time and date of calibration, and
volume.

The issue of radioactive material from the "hot" laboratory must be recorded, and the administration of radioactivity to a patient must also be registered, including identification of the patient.

5.3.4 *Responsibilities of the hospital and the manufacturer*

The commercial producer of "ready-for-use" radiopharmaceuticals and of semimanufactured radiopharmaceuticals is entirely responsible for the data given in the specification, which should have been accepted by the appropriate national authority. For generators and kits, the hospital (as user) shares in the responsibility for the final preparation performed in the hospital laboratory. For the radioactive material used for labelling "home-made" pharmaceuticals or for labelling autologous materials, the commercial supplier remains responsible for the specification of all delivered radioactive material. If labelling procedures are specified by the commercial producer, he remains responsible for the final quality of the product, *provided that these instructions have been correctly followed.*

Radiopharmaceutical scientists should be involved in all stages of the procedure to ensure the quality of the final product. If only "ready-for-use" radiopharmaceuticals, generators, and kits are employed, then quality assurance within the hospital can be delegated to a trained technician.

5.4 Training

Training requirements have already been discussed in section 3.7, and three standards of training—A, B, and C—were defined: basic training (A); advanced training (B); and continuing education (C). These three training standards will now be defined for radiopharmaceutical scientists in particular, but it is emphasized that such educational measures are also necessary for the technician involved in radiopharmaceutical preparation, as well as for the nuclear medicine physician.

Standard A is a basic training of short duration and is suitable for technicians. It should be implemented through additional continuous training within the department, and in the laboratory, under the supervision of the competent person in charge of the hospital preparation of radiopharmaceuticals.

Standard B is advanced training in seminar format and is suitable for the education of physicians. The main content of this training is information on

preparation procedures and on instructions for reporting adverse radiopharmaceutical reactions.

Standard C is continuing education and training and is recommended for radiopharmaceutical scientists. The duration of these courses differs at present in various countries, but it is recommended that in future they should be more standardized in content, duration, and format. Since the development and improvement of the preparation procedures and of the quality control measures is an ongoing process, these postgraduate courses should be repeated at regular intervals. They should concentrate on problems such as the handling of radiopharmaceuticals, radiation hygiene, new prescriptions, and regulations.

Finally, it is emphasized that training within the department—i.e., in-house training—is very important for all personnel concerned with radiopharmaceuticals, including technicians and physicians. It is also noted that since, in some countries, a radiochemist is in charge of the laboratory responsible for the preparation of radiopharmaceuticals, he should also be well trained in radiopharmacy.

5.5 Surveillance of the total system

The quality of the radiopharmaceutical, after administration to the patient, can be observed by physicians during and after the nuclear medicine procedure.

5.5.1 In vivo *instability*

During the interpretation of images the physician should be aware of false biological distributions such as:

- accumulation of free pertechnetate in the thyroid gland and/or stomach after application of ^{99m}Tc-labelled compounds;
- accumulation in the lungs after application of ^{99m}Tc- or ^{113m}In-labelled compounds; and
- accumulation in the liver after application of labelled macroaggregates for lung scanning.

5.5.2 *Radiopharmaceutical defects*

Radiopharmaceutical defects detected by quality control procedures or by observation should be reported to the manufacturer, as well as to any relevant national, regional, or international committee which may have been set up to monitor and record such defects.

5.5.3 *Adverse reactions*

Unexpected adverse reactions—such as pyrogenic, vasovagal and allergic—should be reported to the manufacturer, and to any relevant national, regional, or international committee. Occurrence of these events must be fully documented.

* *
*

Further reading

The following references are recommended for further reading, as an aid for training and education, and also to gain a knowledge of the existing state of the art: *3, 6, 11, 17, 19, 25, 28, 35, 40, 42, 44*, and *45*.

6. Records and evaluation of results, with special reference to quality assurance

6.1 Patient records

RECOMMENDATIONS for the minimum requirements for a patient record are given in schematic form in Fig. 2, and where additional explanations are given, these are indicated by the relevant section numbers, 6.1.1–6.1.5. The symbol → [PDR] indicates a requirement to transfer information to the patient's data record (PDR), and the dotted lines (as distinct from the solid lines) indicate that a different course of action must be taken from that which was originally envisaged.

"Faulty performance" in Fig. 2 could be caused by a change in the clinical condition of the patient during the study, instrument failure, or an error occurring during administration of the activity.

It is also noted that the following references contain data relevant to patient records. Rhodes (*36*) discussed acceptable working standards for quality assurance within a framework of:

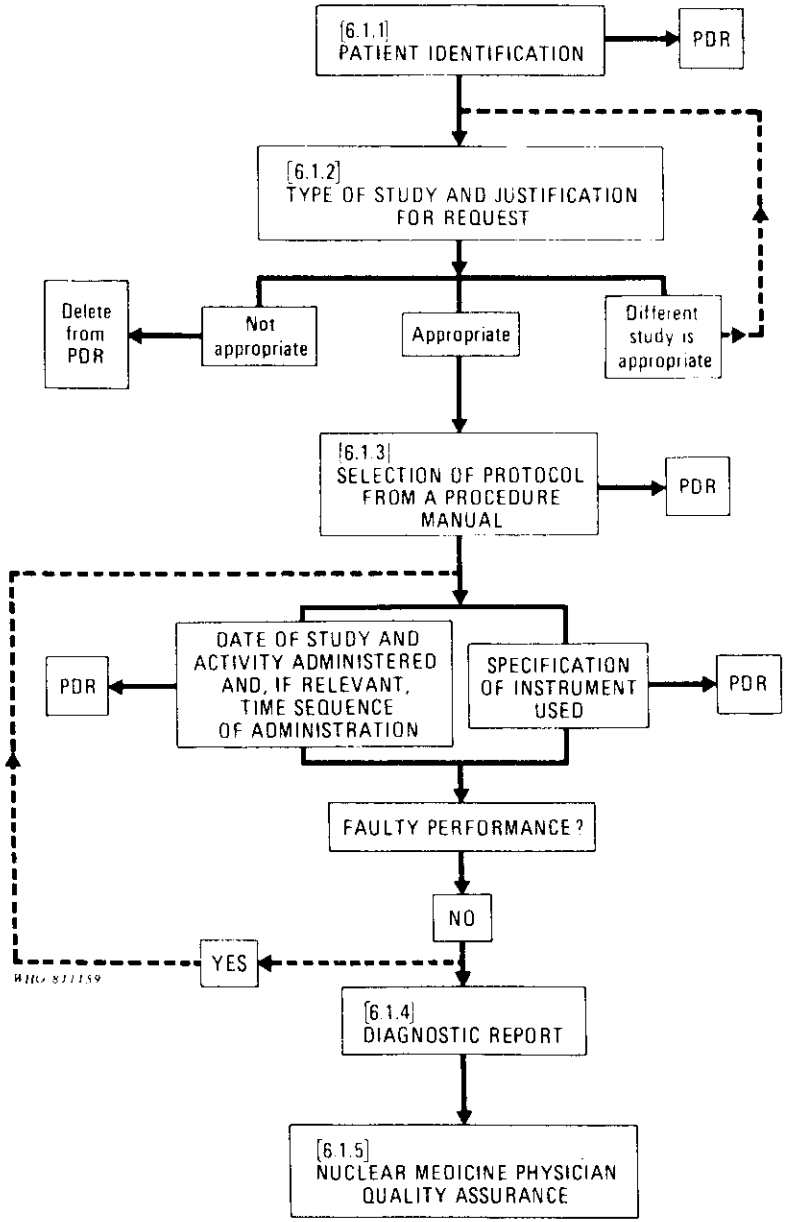
- measure,
- evaluate,
- apply criteria,
- take action,
- inform,
- remedy problem, and
- keep records.

Rollo (*38*) subdivided recommendations for quality control programmes into:

- materials,
- methods, and
- record-keeping;

and illustrated an example of a request/report form and a patient study sheet for scintillation gamma-camera studies. Paras (*33*), when discussing quality assurance in nuclear medicine, also referred to record-keeping but his remarks are directed towards instrument log-book records, some of which are also relevant to the patient record.

Fig. 2. Specification of patient record requirements



Apart from the works mentioned above, very little has been published on guidance for the design and processing of nuclear medicine patient records relating to quality assurance, unlike those designed for the processing of patient records relating to the treatment of cancer or the incidence of cancer. However, where such hospital cancer registries exist it might well be possible to extend their use to accommodate nuclear medicine patient records.

6.1.1 *Patient identification*

Table 18 lists the recommended minimum requirements for the patient identification record.

Table 18. Patient identification record

Data requirement
(1) Patient's name, including surname and given name(s).
(2) Date of birth.
(3) National reference number, if any.[a]
(4) Sex.
(5) Address.
(6) Name of referring physician.
(7) Name of nuclear medicine physician.
(8) Hospital case number.

[a] Some countries have a system of reference numbers that pertain to one person only and are not duplicated for any other persons. Such numbers can be extremely useful in tracing hospital patients for subsequent follow-up (see section 6.1.5). Countries that have national systems include the *Scandinavian* countries (in *Denmark* the reference number is called the Person's Number and is a 10-digit number with the first 6 digits representing the date of birth); the *United Kingdom*, in which every person is allocated a unique National Health Service Number and patient-tracing can be achieved through a central registry; *Poland*, which (since 1978) allocates a number at birth; and the USA, in which a Social Security Number is allocated once the person has reached 15–16 years of age.

6.1.2 *Type of study and justification for request*

It is the responsibility of the nuclear medicine physician to ensure that the study requested by the referring physician is justified. For example, special attention must be paid to the medical justification for studies requested for children and for pregnant women. The nuclear medicine physician must control the use of radionuclides within his department.

A similar situation may also arise when the study originally requested by the referring physician is not considered to be an appropriate study by the nuclear medicine physician—for example, a request for a radionuclide investigation for suspected gallstones, when a more appropriate hepato-biliary study could be undertaken using ultrasound equipment.

6.1.3 *Selection of protocol*

It is recommended that a procedure manual should be made available for each type of study. This manual should be reviewed at least annually and any changes to the original manual should be dated and initialled by the nuclear medicine physician or physicist who institutes the changes.

Table 19 lists the minimum requirements for such a procedure manual, which nuclear medicine centres might wish to expand. Also, the centres are left to design their own format for their own records since a standard format is not considered to be an advantage.

Table 19. Procedure manual requirements

Data requirement
(1) *Name of study*—enter in PDR.
(2) *Rationale of study*—i.e., "How it works", the physiological and pharmacological basis for the study.
(3) *Previous relevant history of the patient*—e.g., iodine premedication, application of X-ray contrast media, previous radionuclide study.
(4) *Preparation of the patient*—including details of any premedication.
(5) *Radiopharmaceutical and source of origin*—enter in PDR.
(6) *Activity to be administered*—include any calculation schedule taking into account body weight and age (if such schedule is relevant).
(7) *Preparation of the radiopharmaceutical, including quality control procedures.*
(8) *Route*—i.e., oral, intravenous—and *time sequence of administration.*
(9) *Measurement of administered activity using an appropriate instrument*—e.g., activity meter. Enter in Laboratory Records.
(10) *Specification of instrument type*—e.g., gamma camera. Enter in PDR.
(11) *Measurement technique explanation*—i.e., "How it is done", including such details as positioning of the patient, instrument settings, collimator, use of computer.
(12) *Evaluation of output quality by instrument operator.*
(13) *Evaluation of results by the instrument operator*—e.g., calculations required in the determination of a clearance rate.
(14) *Additional special requirements*—some of which may be administrative (see section 6.3.4).
(15) *References* dealing with the basic methodology of the study.

6.1.4 *Diagnostic report*

The recommended requirements for the diagnostic report are listed in Table 20. The choice of which patient identification parameters should be used is left to individual centres, but they should be selected from those given in Table 18.

Table 20. Diagnostic report requirements

Data requirement
(1) Patient identification parameters.
(2) Date of study.
(3) Name of study.
(4) Radiopharmaceutical and administered activity.
(5) Study results—e.g., a graph or a series of images.
(6) Objective description of findings—e.g., morphological description of image(s).
(7) Diagnostic conclusions and recommendations.

It is recommended that the diagnostic conclusions should be more quantitative (whenever possible) rather than based on the present qualitative approach that employs vague adjectives such as "possible", "probable", "likely", which—except in the mind of the nuclear medicine physician making the conclusion—are difficult to quantify and communicate to a referring physician. A more numerate approach can be adopted in: (*a*) the specification of organ function; and (*b*) the use of a probability statement to describe the degree of confidence that the nuclear medicine physician chooses to allocate to his diagnostic conclusions (see reference *31*). The use of a probability statement for indicating the nuclear medicine physician's degree of certainty that an abnormality exists—e.g., from a liver image—is demonstrated in Table 21. In practice, the physician may choose whatever P_a value he wishes, and is not limited to values of 1.0, 0.75, 0.50, 0.25, and 0.

Table 21. Specification of diagnostic results using a probability statement

Probability of abnormality (P_a)	Implication
$P_a = 1.0$	A 100% certainty that an abnormality is detected.
$P_a = 0.75$	A 75% certainty that an abnormality is detectable.
$P_a = 0.50$	An equivocal result, since this implies that, in the opinion of the nuclear medicine physician, there is a 50% chance of abnormality and a 50% chance of normality. (If P_n is the probability of normality, then $P_a + P_n = 1$.)
$P_a = 0.25$	A 25% certainty that an abnormality is detectable.
$P_a = 0$	A 100% certainty that no abnormality is detectable.

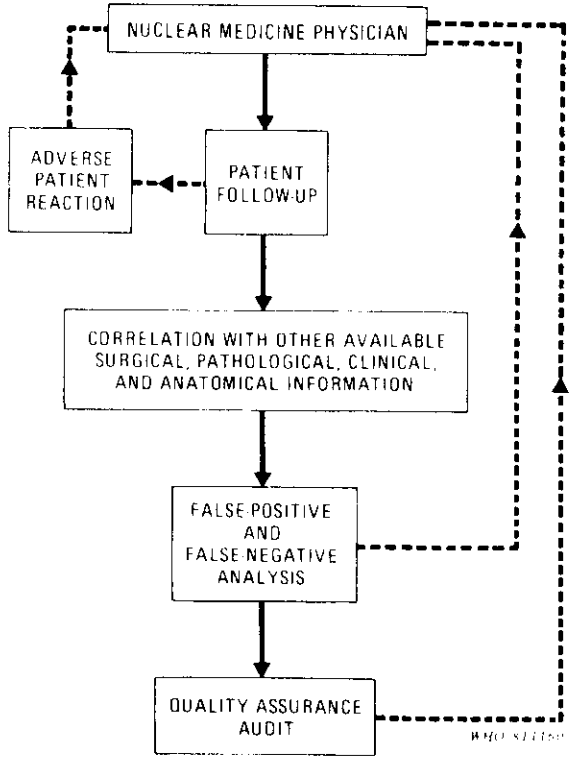
6.1.5 *Nuclear medicine physician quality assurance*

It is recommended that a procedure should be adopted for applying quality assurance to the diagnostic reports of the nuclear medicine physician, as well as to the radiopharmaceutical, instrumentation, and technical procedures.

An assessment of the incidence of false-positive and false-negative reports is necessary, although the implementation of such a task is not without difficulties—for example, it is only possible to obtain accurate follow-up information on a small proportion of patients. However, with forward planning involving well-designed computer-based registries sufficient patient numbers could be obtained in the future, particularly if centres enter into collaborative projects.

Fig. 3 indicates the pathways involved in implementing quality assurance of diagnostic reports issued by nuclear medicine physicians. The term "audit" in Fig. 3 implies that each centre should create interdisciplinary committees or groups responsible for conducting regular audits at reasonable intervals, in which individual diagnostic laboratory reports are reviewed and compared

Fig. 3. Quality assurance of the diagnostic reports issued by nuclear medicine physicians

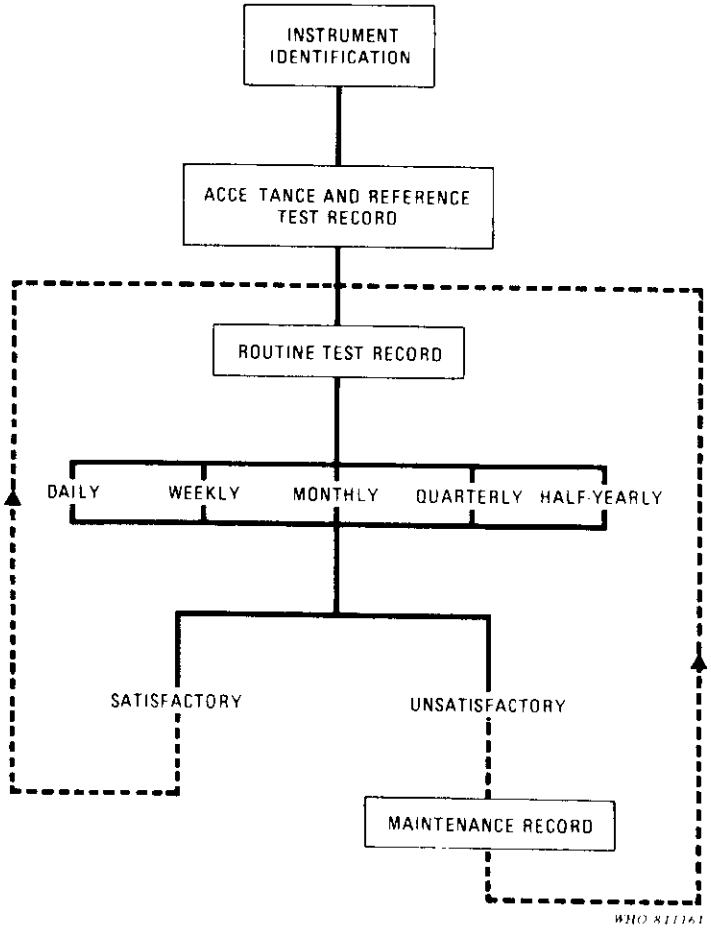


with findings at surgery and autopsy, and with the results of medical management. The conclusions reached at such meetings must then be submitted in writing to the nuclear medicine physicians who have prepared the reports.

6.2 Instrument records

Instrument records have been referred to briefly in section 4.2.5, and throughout this guide it has been emphasized that it is essential to provide accurate records for both the patient and the instrumentation. Details of parameters required for acceptance and reference testing and for routine testing are given in Chapter 4, and all relevant test results should be retained. Instrument records must be kept for each instrument, and this is usually achieved by means of a log-book and sometimes subsequent data storage in a computer. Fig. 4 specifies the types of instrument record that have to be retained, and the various courses of action which might be appropriate after

Fig. 4. Instrument record requirements



the acceptance of the instrument. It is most important that an adequate maintenance record should be kept.

The frequency of routine testing varies with the type of instrumentation; recommended frequencies, based on the information given in Chapter 4, are listed in Table 22.

Table 22. Routine testing frequency for various types of instrumentation

Type of instrumentation (and Table reference in this report)	Daily	Weekly	Monthly	Quarterly	Half-yearly
Activity meters (Table 4)	X	X		X	
Manual and automatic counting systems for gamma radiation measurements *in vitro* (Table 7)	X	X	X		X
Single- and multi-probe counting systems for gamma radiation measurements *in vivo* (Table 10)	X	X	X	X	X
Rectilinear scanners (Table 12)	X	X	X	X	X
Gamma cameras (Table 15)	X	X			X
Gamma camera whole body attachment (Table 16)	X	X			
Single photon emission computed tomographic systems using rotating cameras	Frequency not recommended, preliminary proposals only (see section 4.8).				
Data-processing systems (Table 17)		X		X	

6.3 Laboratory records

Laboratory records are of several types (see sections 6.3.1 -6.3.4) and relate not only to scientific information—such as the results of activity meter measurements and radiation survey measurements—but also to administrative information—such as the number of patients and details of radioactive wastes disposal—and to the retention of government-issued documentation—such as records of inspections, regulations, codes of practice relating to health and safety, licences, and authorization certificates.

6.3.1 *Government licences and authorization certificates*

It is apparent that there is no worldwide trend towards a uniform pattern of licensing, authorization, inspection, and accreditation. Indeed, in several countries, government involvement in nuclear medicine matters is minimal. It is therefore inopportune to summarize the widely divergent roles adopted by various governments, since these roles are still subject to change.

6.3.2 *Radiation protection*

Records should be retained of laboratory radiation surveys, patient absorbed dose estimates, the radioactive waste disposal limits allowed by regulations (if such regulations exist), personnel monitoring records of staff using radionuclides (thermoluminescence dosimeters, film badges, or personnel ionization monitors), and information relating to the regular calibration of radiation protection monitoring equipment.

It is also noted that the hospital or clinic should be aware that radiation protection should be regarded as important for patients as well as staff. As regards the former, this awareness should include knowledge of the radiation dose received by the patient during a particular radionuclide study. Only relatively few data have been published on this subject. A recent review by Roedler et al. (*37*) gives a summary of current knowledge.

6.3.3 *Interlaboratory comparison*

Interlaboratory comparison, also known as proficiency testing and external quality control, is a technique that permits a professional organization and/or a regulatory body to monitor the total performance of a laboratory facility in an objective manner. It is based on the use of unknown samples and phantoms, submitted for analysis or study to individual facilities and surveyed in a regularly scheduled manner. The data obtained from all surveyed facilities is then collated by the organizing bodies. Reports comparing the performance of individual facilities are then submitted to each laboratory.

The purpose of quality assurance procedures is to ensure that the end-product of a nuclear medicine procedure accurately reflects the status of the organ or physiological compartment studied, and that the results of such studies make a meaningful contribution to the patient diagnosis and management. The College of American Pathologists' (CAP) proficiency testing or interlaboratory comparison programme (*13, 14*), which has been in existence since 1973, has proved to be an essential component of such programmes, inasmuch as it provides an objective assessment of the total performance of laboratories. Because of this it has been formally endorsed by the Society of Nuclear Medicine and the American College of Radiology in the USA.

Programmes of quality control and quality assurance are in various stages of development throughout the world. In Europe, as the Heidelberg meeting revealed, there is no standard scheme for the implementation of quality assurance and quality control. Thus, there is no clear idea of the levels of quality of performance in European nuclear medicine laboratories at present. Consequently the meeting could not assess the efficacy of the practice of nuclear medicine in Europe or the quality of services provided by nuclear medicine facilities to their patients. To encourage the development of quality assurance programmes and to be able to evaluate the degree of success of this effort in the future a determination of the current state of the art in Europe is essential. To this end, a pilot study utilizing two College of American Pathologists (CAP) total-performance phantoms (*13, 14*) and the London liver total-performance phantom (*12, 29*) is needed.

In addition, a quality assurance total-performance study in Europe and North America should be carried out at the earliest possible date. The following conditions to be met with regard to organizational, manpower, and technical resources are as follows:

(1) The study should be internationally sponsored and overseen through a properly designated committee or group, comprising individuals who have voluntarily agreed to take responsibility for conducting such surveys in their own countries in a prompt and timely fashion.

(2) The phantoms used by each country in the study should comprise:

— 1 CAP brain phantom,
— 1 CAP liver phantom, and
— 1 London liver phantom.[1]

(3) Each collaborating country would ensure that the results were obtained from a minimum of ten nuclear medicine centres within its territory.

(4) The designated, internationally sponsored committee should prepare, within one year of the commencement of the study, a scientific report of the findings, which would be presented at a suitable meeting. Copies of the report would be sent to interested organizations, societies and associations — for example, WHO, the International Atomic Energy Agency, the American Association of Physicists in Medicine, the College of American Pathologists, the European Nuclear Medicine Society, the Hospital Physicists' Association, and the Society of Nuclear Medicine (New York).

6.3.4 *Management information statistics*

Unfortunately, statistics issued by large bodies, such as government departments, are often rather inaccurate—as in the case, for example, of certain cancer statistics (see reference *30*). Nevetheless, some reliable statistics must be made available for management decisions concerning, for instance, the purchase of capital equipment by hospitals. Such decisions are based in part on patient workload statistics and it is therefore of obvious advantage to a nuclear medicine facility to be able to supply authorities with accurate statistical information. It is recommended that, for their own benefit, nuclear medicine departments should make themselves aware of the particular management statistics that affect their own departmental environment, and then take appropriate measures to ensure that the correct records are obtained. These should then be incorporated into the total system for patient records, instrument records, laboratory records and management information records.

[1] The model of the liver for the London liver phantom would be based on that used in a recent United Kingdom Department of Health and Social Security (DHSS) survey (*12*) and use TEMEX tissue-equivalent rubber developed by Stacey et al. (*43*). The simulated tumour sizes and positions would be different from those used in the DHSS survey. Liver shells would be used with various tumour positions and size specifications, but since the liver shapes are identical, they would all fit the same TEMEX abdomen. The surface of the liver shells would be made opaque so that the participating centres would be unaware of the sizes and positions of the tumours. (TEMEX phantoms are manufactured by James Girdler & Co. Ltd., 458 Rotherhithe Street, London, SE 16.)

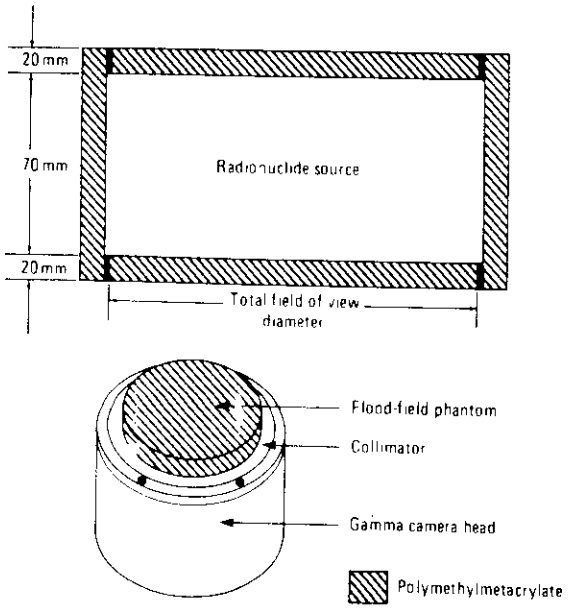
7. Phantoms

7.1 Flood-field phantoms

(1) *Hollow perspex flood-field phantom*. The recommended specification is given in Fig. 5, which has been adapted from a diagram published by Sano (*39*). For a more detailed description, see reference *22*. (see also Table 13 of the present guide.)

(2) ^{57}*Cobalt disc flood-field phantom*. See section 4.7.2.

Fig. 5. Flood-field phantom



Source: Adapted from Sano (*39*).

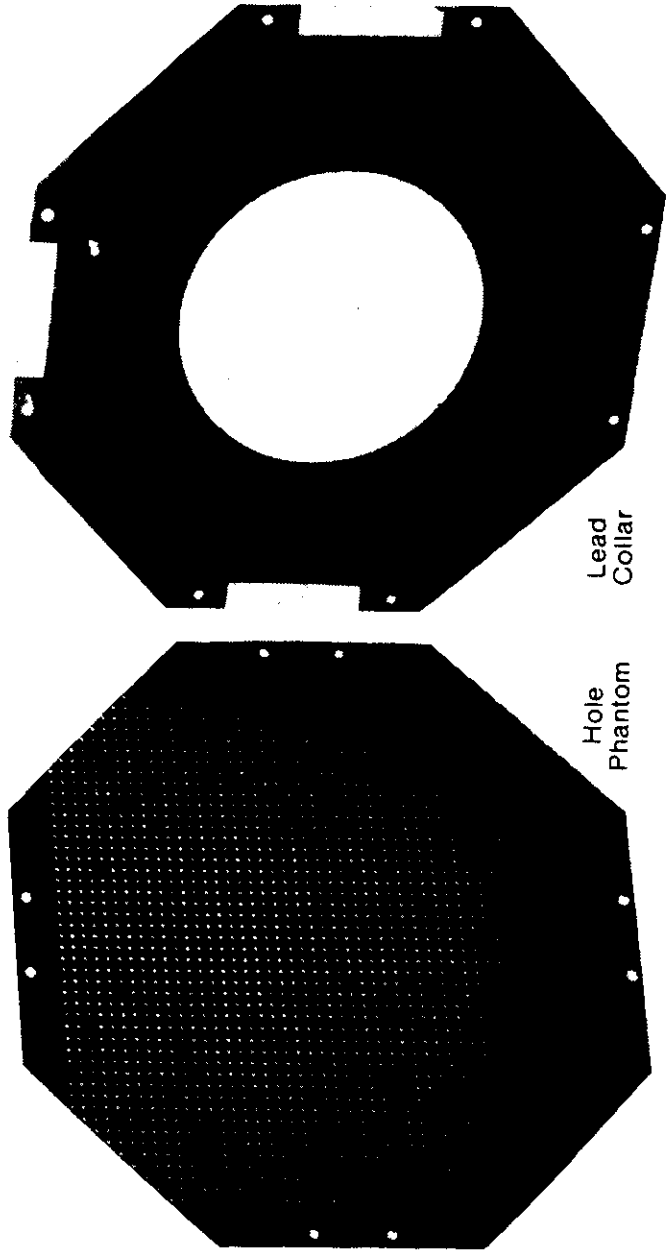


Fig. 6. The ortho test (SOH) phantom

Source: United States Bureau of Radiological Health.

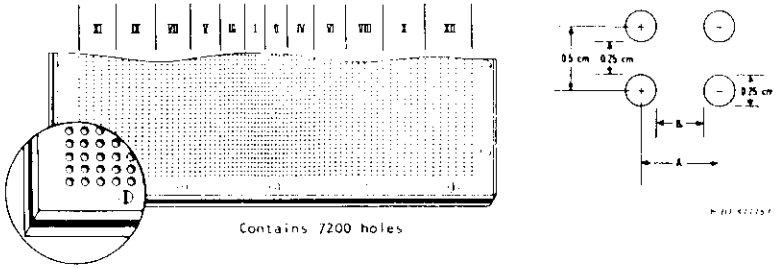
7.2 Orthogonal hole transmission pattern (OHTP) phantoms

See Tables 13 and 15. The ortho test (Smith orthogonal hole—SOH) phantom is recommended as the most appropriate phantom, but the OHTP (United States Bureau of Radiological Health—BRH) phantom can be used as an alternative.

(1) *Ortho test (SOH) phantom.* See Fig. 6 for details.

(2) *OHTP (BRH) phantom.* See Fig. 7 for details.

Fig. 7. The OHTP (BRH) phantom



Schematic section of test pattern. Hole separation (A_i) and minimal lead spacing between the holes (B_i) vary in the X direction in groups of six holes, as follows:

Group	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII
A_i (cm)	0.4	0.45	0.5	0.55	0.6	0.65	0.7	0.75	0.8	0.85	0.9	0.95
B_i (cm)	0.15	0.2	0.25	0.3	0.35	0.4	0.45	0.5	0.55	0.6	0.65	0.7

Source: United States Bureau of Radiological Health.

7.3 Count-rate performance phantom

See Table 13. The recommended specification is given in Fig. 8, which has been adapted from a diagram published by Sano (*39*). For a more detailed description, see reference *22*.

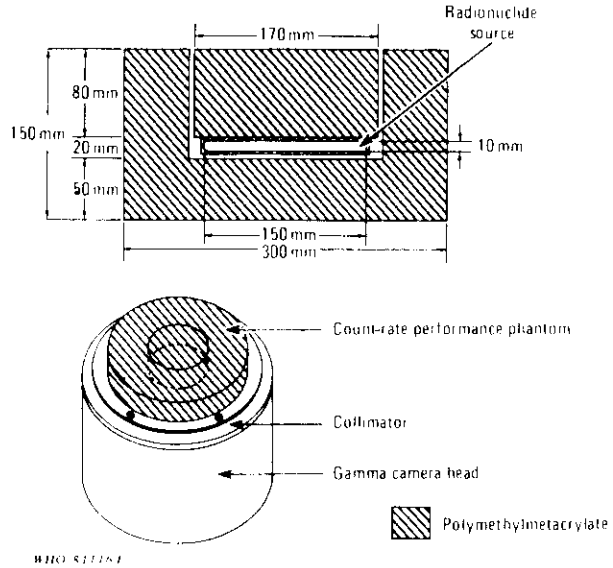
7.4 Resolution and linearity phantom

See Table 13. The recommended specifications are those given by the National Electrical Manufacturers' Association (NEMA). Fig. 9 has been adapted from a diagram published by Sano (*39*).

7.5 Step-wedge phantom

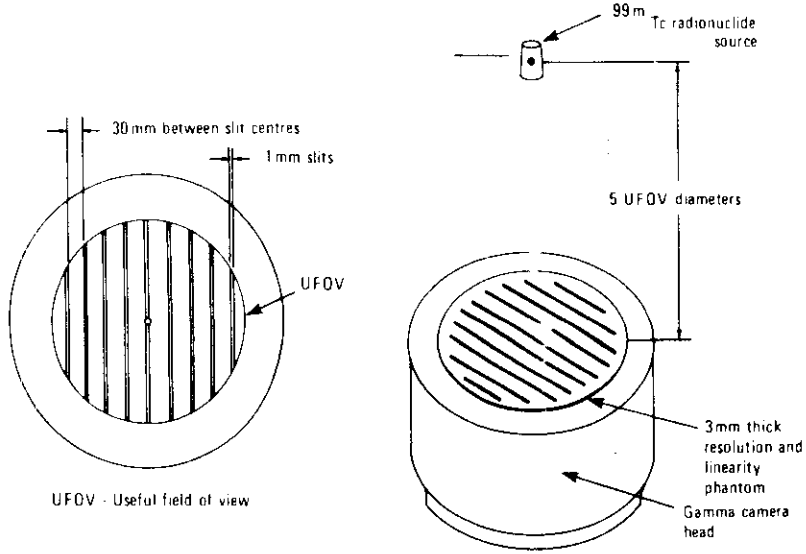
See Tables 11, 13–15 and section 4.7. Fig. 10 shows an emission type step-wedge phantom (*2*).

Fig. 8. Count-rate performance phantom



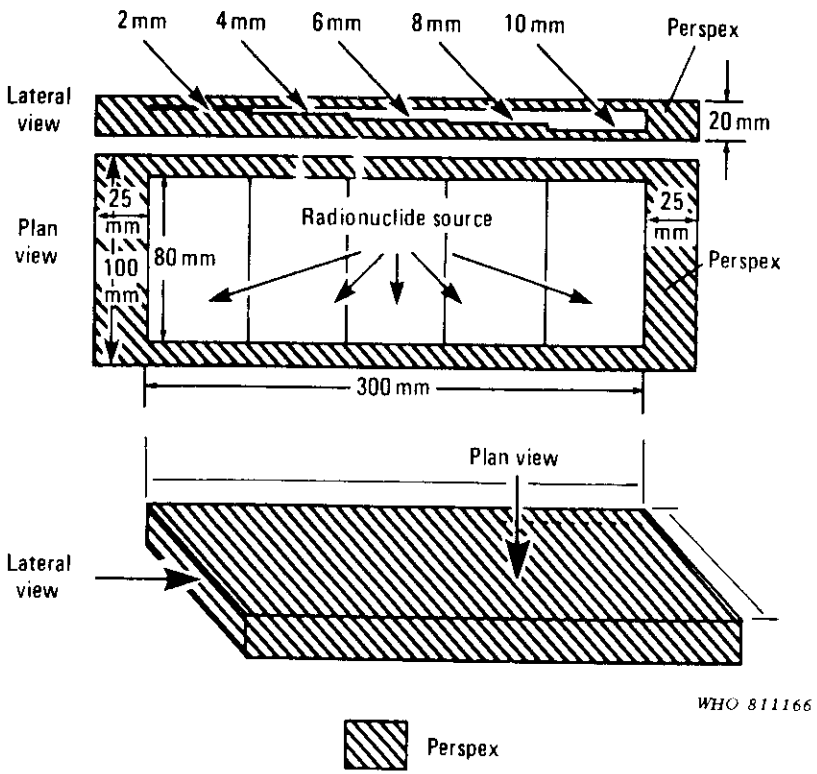
Source: Adapted from Sano (*39*).

Fig. 9. Resolution and linearity phantom



Source: Adapted from Sano (*39*).

Fig. 10. Emission step-wedge phantom



Source: Adapted from Bergmann & Havlik (*2*).

7.6 Total-performance phantoms

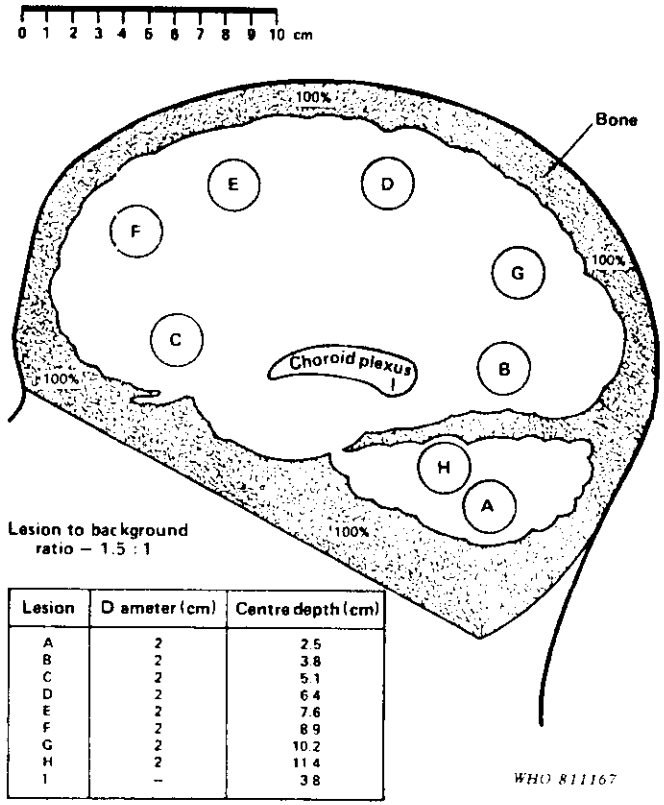
See sections 4.8 and 6.3.3, and Tables 13–15. The definition of a *total-performance test* is given in Annex 1 of this guide.

7.6.1 *College of American Pathologists' (CAP) phantoms*[1]

See section 6.3.3 for CAP liver and CAP brain phantoms. Literature references *5*, *13–15* are relevant to these phantoms. Fig. 11 shows a CAP brain phantom from Hine et al. (*15*). (Other CAP brain phantoms are also available.)

[1] For inquiries concerning CAP phantoms, contact Dr N. Herrera, Director of Laboratories, Danbury Hospital, Danbury, CT, USA.

Fig. 11. CAP brain phantom containing eight 2-cm diameter areas of increased activity at indicated depths



Lesion	Diameter (cm)	Centre depth (cm)
A	2	2.5
B	2	3.8
C	2	5.1
D	2	6.4
E	2	7.6
F	2	8.9
G	2	10.2
H	2	11.4
I	–	3.8

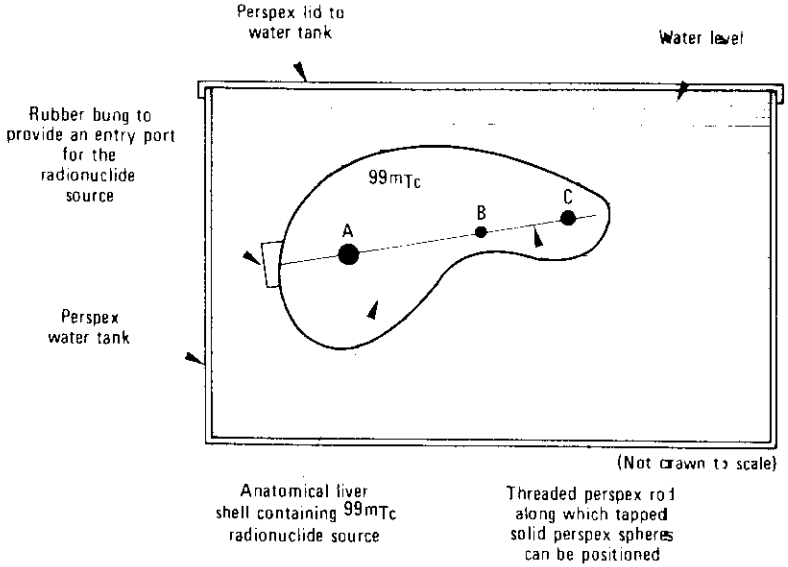
Source: Hine et al. (*15*).

7.6.2 *The London liver phantom*[2]

See section 6.3.3 and Fig. 12. This phantom was used in a national survey in the United Kingdom (*12*) and is currently being used by the DHSS (UK) for a further survey of more recently manufactured gamma cameras. Specifications of the liver shell required for simulating various positions and sizes of tumours are given in reference *29*. A water-bath was used to simulate the rest of the body. TEMEX (*43*) tissue-equivalent rubber abdomens may be used instead of a water-bath.

[2] For inquiries concerning London liver phantoms, contact Dr R. F. Mould, Principal Physicist, Westminster Hospital and Medical School, London, England.

Fig. 12. Schematic diagrams of the London liver phantoms, types "A" and "B"



(i) Scintigrams using type "A"

London liver type "A". The tissue surrounding the liver is simulated using a tank of water. Solid perspex spheres A, B, C, represent liver tumours, and can be positioned at chosen positions along the threaded perspex rod. Tumour sizes can be varied by using different diameter spheres. Background activity can be simulated by placing a small amount of radionuclide activity in the water. The liver shell is supported by a perspex stand (not shown in the diagram) within the water tank.

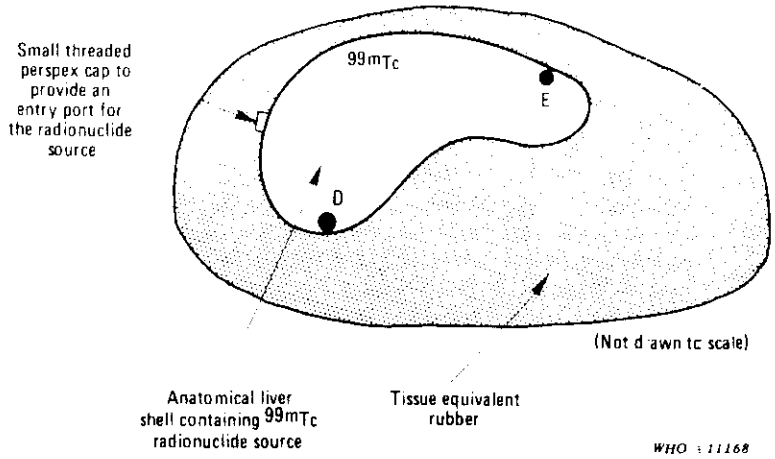


Fig. 12 (*continued*)

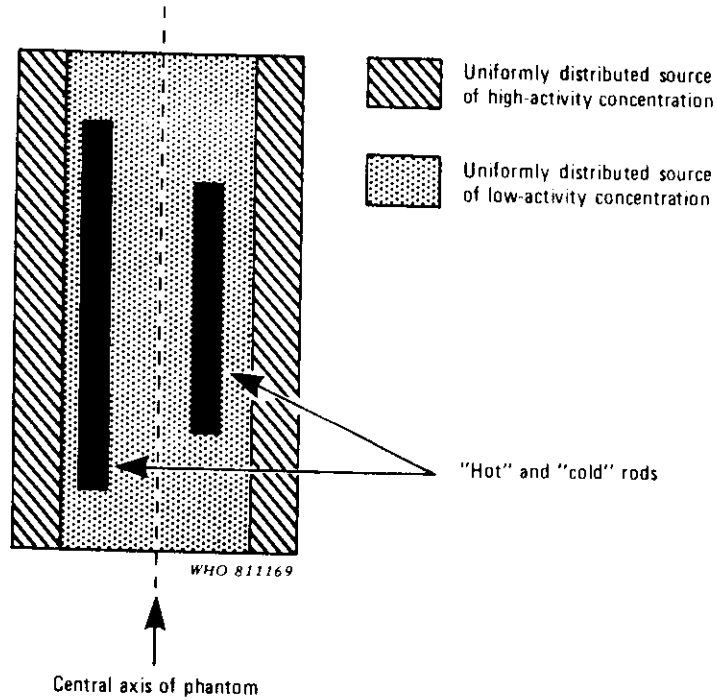
(ii) Type "B".

London liver type "B". In this liver phantom type the simulated tumours, D, E, are fixed in position and their size cannot be varied. The tissue equivalent rubber abdomen is constructed in two halves so that when filled with technetium, the liver shell can be inserted within the abdomen. The shells can be covered with an opaque paint so that interlaboratory comparisons can be made without a knowledge of the position and size of the various tumours, and a *blind* study undertaken. Several liver shells containing different tumour specifications can be used with the same standard tissue equivalent rubber abdomen.

7.7 Phantom for use with single photon emission computed tomographic systems using rotating cameras

See section 4.8 and Fig. 13.

Fig. 13. Schematic diagram of a phantom for use with single photon emission computed tomographic systems using rotating cameras



* *
*

Further reading

The phantoms described in sections 7.1–7.7 are the ones specifically recommended in this guide. Many other phantoms exist (*5*, *18*), but, to avoid confusion, these are only briefly mentioned in the present guide (see below). However, it is recognized that some of the phantoms concerned can provide reasonable alternatives to those recommended, if none of the latter are available. However, care must be taken when departing from the recommendations of this guide.

Miscellaneous phantoms:

(*a*) Hine-Duley bar phantom, PLES bar phantom, 90° bar quadrant phantom, Anger "Pie" phantom, Sorensen phantom, Genna diverging wedge phantom, Rollo phantom, Hine cylindrical step phantom, IAEA (liver slice) phantom, Williams (liver slice) phantom, and Picker thyroid phantom—see reference *5* for details.

(*b*) Anger "Pie" phantom, Bar phantoms, Flood-source phantoms, BSI source for measurement of count-rate capability, BSI source for measurement of plane sensitivity, Modified Williams liver slice phantom—see reference *18* for details.

8. Conclusions

NUCLEAR medicine is a specialty offering many advantages in solving a wide range of diagnostic health problems. Indeed, there is hardly a branch of medicine in which this discipline cannot make a significant contribution to the health care of the individual and the community. However, nuclear medicine can only play an important role in the health care system of a country if the services it provides have been properly planned, established, and implemented.

It is recognized that in order to achieve effective utilization of nuclear medicine instrumentation and to maintain a high standard of diagnostic reliability and accuracy, a quality assurance programme must be in force. As part of this programme, regular quality control tests should be applied to the instrumentation, to radiopharmaceuticals, and (ideally) to the entire diagnostic process as described in the previous chapters of this guide.

Finally, the following principles are considered to be of special importance in promoting the concept of quality assurance:

(1) Nuclear medicine laboratories, institutions, and individual specialists—such as physicians, medical physicists, radiopharmacists and radiochemists—should be encouraged to initiate and implement quality control procedures within their working environment as part of an integrated quality assurance programme.

(2) The methods used to implement quality assurance should follow, as closely as possible, internationally agreed principles. This will ensure the establishment of a good basis for quality assurance and quality control on a national and international level.

(3) The procedures for routine quality control for nuclear medicine instrumentation, radiopharmaceuticals, records, and the evaluation of results described in this guide should be implemented.

(4) Internationally coordinated interlaboratory comparisons and quality control programmes, with the aim of improving the standard of nuclear medicine diagnostic procedures, should be planned and initiated under the auspices of international bodies.

(5) Governments, nongovernmental professional organizations, and national professional associations and societies should be encouraged to initiate and support the establishment of quality assurance and quality control programmes in their countries; and in particular to incorporate this work into national training programmes in nuclear medicine.

(6) Quality assurance and quality control programmes should be supported and implemented through:

(*a*) the collection and distribution of information;

(*b*) the preparation and publishing of training material, including guidelines and manuals; and

(*c*) the organization of training seminars and workshop meetings at regional and interregional levels.

REFERENCES

This list of references is not intended to be a comprehensive review of the literature, but is a compilation of publications considered to be of general interest.

1. American Association of Physicists in Medicine. *Draft report: Scintillation camera acceptance testing and performance evaluation.* Chicago, 1979.
2. Bergmann, H. & Havlik, E. Evaluation of wedge shaped phantoms for assessment of scanner display as a part of quality control of scanner performance. In: *Proceedings of an International Symposium on Medical Radionuclide Imaging, Heidelberg, September 1980.* Vienna, International Atomic Energy Agency, 1981 (IAEA–SM–247/208).
3. British Institute of Radiology. *Guidelines for the preparation of radiopharmaceuticals in hospitals.* London, 1975 (Special Report No. 11).
4. Bureau of Radiological Health. *Workshop manual for quality control of scintillation cameras in nuclear medicine.* Washington, DC, United States Department of Health, Education, and Welfare, 1976 (DHEW Publication, FDA–76–8039).
5. Bureau of Radiological Health. *Quality control for scintillation counters.* Washington, DC, United States Department of Health, Education, and Welfare, 1976 (DHEW Publication, FDA–76–8046).
6. Bureau of Radiological Health. *Radionuclide handling and radiopharmaceutical quality control.* Washington, DC, United States Department of Health, Education, and Welfare (in press).
7. Cohen, Y. & Besnard, M. Analytical methods of radiopharmaceutical quality control. In: *Radiopharmaceuticals.* New York, Society of Nuclear Medicine, 1975.
8. European Joint Committee on Radiopharmaceuticals. Reporting of adverse reactions and drug defects. *Compact news in nuclear medicine*, **11**: 82 (1980).
9. *European Pharmacopoeia*, Volume III, 1975 (Supplement 1977). Moulins-lès-Metz, Maisonneuve, 1977.
10. Ford, L. et al. Society of Nuclear Medicine drug problem reporting system. *Journal of nuclear medicine*, **19**: 116 (1976).
11. Frier, M. & Hesslewood, S. R., ed. *Quality assurance of radiopharmaceuticals: a guide to hospital practice. Journal of nuclear medicine communication*, special issue (1980).
12. Goddard, B. A. et al. *A survey of some radionuclide imaging equipment with an anthropomorphic liver phantom.* London, H. M. Stationery Office, 1978 (DHSS Technical Branch, STB/3/78).
13. Hermann, G. A. et al. Rationale, techniques, and results of a quality control programme of imaging procedures. In: *Proceedings of an International Symposium on Medical Radionuclide Imaging, Los Angeles, October, 1976.* Volume I. Vienna, International Atomic Energy Agency, 1977 (IAEA–SM–210/122).
14. Hermann, G. A. et al. The College of American Pathologists Phantom Series: an assessment of current nuclear imaging capabilities. *American journal of clinical pathology*, **74**: 591 (1980).
15. Hine, G. et al. *Measurements of the performance parameters of gamma cameras, Part 1.* Washington, DC, United States Department of Health, Education, and Welfare, 1978 (DHEW Publication, FDA–78–8049).
16. Hine, G. et al. *Measurements of the performance parameters of gamma cameras, Part 2.* Washington, DC, United States Department of Health, Education, and Welfare, 1979 (DHEW Publication, FDA–79–8049).

17. HOSPITAL PHYSICISTS' ASSOCIATION. *The hospital preparation of radiopharmaceuticals*. London, 1976 (Scientific Report Series, No. 16).
18. HOSPITAL PHYSICISTS' ASSOCIATION, The theory, specification and testing of Anger type gamma cameras. London, 1978 (Topic Group Report, No. 27).
19. IIO, M. Survey of adverse reactions to radiopharmaceuticals. *Japanese journal of nuclear medicine*, **16**: 511 (1979).
20. INTERNATIONAL ATOMIC ENERGY AGENCY. *Proceedings of International Symposium on Medical Radionuclide Imaging, Heidelberg, September, 1980*. Vienna, 1981 (IAEA-SM-247/208).
21. INTERNATIONAL ATOMIC ENERGY AGENCY. *Quality control schedules for nuclear medicine instrumenta ion*. (Recommendations of an advisory group on the quality control of *in-vivo* rad onuclide procedures. Convened by the International Atomic Energy Agency, Vienna, August, 1979). Vienna, 1980.
22. INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Characteristics and test conditions of radionuclide imaging devices*. Geneva, 1980. Draft report (IEC document 62C Central Office.
23. JORDAN, K. *Medizinische Physik 78. Kriterien zur Qualitätsbeurteilung der Gamma-Kamera*. Heidelberg, Huthig Verlag, 1978, pp. 393–407.
24. JORDAN, K. Normung von Messbedingungen zur Beurteilung der Leistung von Gamma-Kameras. *Der Nuklearmediziner*, **1**: 49 (1980).
25. KEELING, D. In: Gorrod, J. W., ed. *Side effects associated with the use of radiopharmaceuticals in drug toxicity*. London, Taylor & Francis, 1979, p. 285
26. KRISTENSEN, K. *Preparation and control of radiopharmaceuticals in hospitals*. Vienna, International Atomic Energy Agency, 1979 (Technical Report Series, No. 194).
27. KRISTENSEN, K. Quality control of radiopharmaceuticals. In: *Proceedings of an International Symposium on Medical Radionuclide Imaging, Heidelberg, September, 1980*, Vienna, International Atomic Energy Agency, 1981 (IAEA-SM 247/208).
28. KROHN, K. A. & JANSHOLT, A. Radiochemical quality control of short-lived radiopharmaceuticals. *International journal of applied radiation and isotopes*, **28**: 213 (1977).
29. MOULD, R. F. A liver phantom for evaluating camera and scanner performance in clinical practice. *British journal of radiology*, **44**: 810 (1971).
30. MOULD, R. F. Cancer statistics. *British medical journal*, **1**: 86 (1976).
31. MOULD, R. F. Nuclear imaging and probability levels. *Jounrnal of nuclear medicine*, **20**: 364 (1979).
32. NATIONAL ELECTRICAL MANUFACTURERS' ASSOCIATION. *Performance measurements of scintillation cameras*. Washington, DC, 1980 (NEMA Standards Publication, No. NU 1).
33. PARAS, P. Quality assurance in nuclear medicine. In: *Proceedings of an International Symposium on Medical Radionuclide Imaging, Los Angeles, October*, 1976. Volume I. Vienna, International Atomic Energy Agency, 1977 (IAEA-SM-210/301).
34. PARAS, P. Performance and quality control of nuclear medicine instrumentation. In: *Proceedings of an International Symposium on Medical Radionuclide Imaging, Heidelberg, September, 1980*. Vienna, International Atomic Energy Agency, 198 (IAEA-SM-247/208).
35. PAUWLES, E. K. J. & FEITSMA, R. Radiochemical quality control of technetium-99m labelled radiopharmaceuticals: some daily practice guidelines. *European journal of nuclear medicine*, **2**: 97 (1977).

36. RHODES, B. A. *Quality control in nuclear medicine: radiopharmaceuticals, instrumentation and* in-vitro *assays*. St Louis, Mosby, 1977.
37. ROEDLER, H. D. ET AL. *Internal radiation dose in diagnostic nuclear medicine*. Berlin, Hoffmann, 1978, p. 38.
38. ROLLO, D. *Nuclear medicine physics, instrumentation and agents*. St Louis, Mosby, 1977.
39. SANO, R. M. Performance standards: Characteristics and test conditions for scintillation cameras. In: *Proceedings of an International Symposium on Medical Radionuclide Imaging, Heidelberg, September, 1980*. Vienna, International Atomic Energy Agency, 1981 (IAEA-SM-247/208).
40. SERVIAN, J. L. Report of an International Atomic Energy Agency meeting on quality control of radiopharmaceuticals (C-14 sterility testing: limulus pyrogen testing). *International journal of applied radiation and isotopes*, **28**: 653 (1977).
41. SHANL, J. ET AL. Adverse reactions to radiopharmaceuticals. *Seminars in nuclear medicine*, **6**: 305 (1976).
42. SINN, H. ET AL. An efficient method for routine production of o-iodohippuric acid labelled with iodine-131, iodine-125 or iodine-123. *International journal of applied radiation and isotopes*, **28**: 809 (1977).
43. STACEY, A. J. ET AL. A new phantom material employing depolymerised natural rubber. *British journal of radiology*, **34**: 510 (1961).
44. *WHO Chronicle*, **31**: Supplement (1977). Good practice in the manufacture and quality control of drugs (resolution WHA28.65).
45. WHO Technical Report Series, No. 567, 1975 (*Specifications for pharmaceutical preparations*: Twenty-fifth report of the WHO Expert Committee).

ACKNOWLEDGEMENTS

Gratitude is expressed to the Government of the Federal Republic of Germany for its generous financial and administrative support.

Thanks are also due to the institutions co-sponsoring the meeting, and to the following individuals, for their valuable organizational contributions: Professor H. Kriegel, Professor W. J. Lorenz, Dr H. Ostertag, Professor H. D. Roedler, Professor K. Scheer, Dr W. Seelentag, and Professor F.-E. Stieve.

The work of Dr R. F. Mould, who undertook the difficult task of editing the guide, which was based on individual presentations, contributions of working groups, and plenary discussions, is deeply appreciated.

Annex 1

Definitions of terms

The definitions of terms given below apply to the terms as used in this guide, and are not necessarily valid for other purposes.

Acceptance inspection (acceptance test)

Inspection to determine whether an item delivered or offered for delivery is acceptable (ISO 3534-1977). Such inspection may include tests carried out following the installation of equipment to determine whether it has been manufactured and installed in accordance with the agreed technical specifications; the results of these tests provide reference values against which the future performance of the equipment may be assessed when routine testing is undertaken.

After-repair test

A procedure carried out following the repair of defective equipment in order to determine whether the repairs have been properly effected and whether the instrument is functioning according to specifications.

Overall uncertainty

Overall uncertainty, often simply called the accuracy, is an estimate of the possible divergence of the quoted result from the true value. It must allow for the uncertainty attributable to statistical variations and for the total limits of uncertainty due to assessable systematic error (ICRU Report No. 12).

Quality assurance

All those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service (ISO 6215-1980). Satisfactory performance in service implies the optimum quality of the entire diagnostic process—i.e., the consistent production of adequate diagnostic information with minimum exposure of both patients and personnel.

Quality assurance programme

The overall management and procedures covering the quality assurance actions for the execution of a specific contract or project (ISO 6215-1980). It is

an organized activity designed to provide quality assurance in nuclear medicine, and includes both quality control techniques and quality administration procedures. The nature and extent of this activity will vary with the size and type of the facility, the types of examination conducted, and other factors.

Quality control

The set of operations (programming, coordinating, carrying out) intended to maintain or to improve quality [. . .] (ISO 3534-1977). As applied to a diagnostic procedure, it covers monitoring, evaluation, and maintenance at optimum levels of all characteristics of performance that can be defined, measured, and controlled.

Reference test

A test of an instrument whose results provide a measure against which future performance of the instrument may be comprehensively assessed.

Routine test

A procedure, to be carried out at regular intervals, whereby a few attributes of an instrument or of a radiopharmaceutical are checked to ensure that the performance of the instrument has not altered or that the radiopharmaceuticals can be expected to meet given specifications.

Total-performance phantom

A device that permits the evaluation of an imaging procedure, including the performance of the equipment and of the nuclear medicine personnel.

Total-performance test

An uncomplicated test for verifying the overall performance of a nuclear medicine procedure without separately testing each individual factor involved in the procedure.

References

INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS. *Certification of standardized radioactive sources*, Washington, DC, 1968 (ICRU Report No. 12).

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Statistics— vocabulary and symbols*, Geneva, 1977 (International Standard ISO 3534-1977).

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Nuclear power plants—quality assurance*, Geneva, 1980 (International Standard ISO 6215-1980).

Annex 2

Participants in the Heidelberg Workshop

Dr E. H. Belcher, International Atomic Energy Agency, Vienna, Austria
Dr H. Bergmann, Department of Nuclear Medicine, University Medical Clinic II, Vienna, Austria
Professor U. Büll, Department of Nuclear Medicine, Grossharden Clinic, University of Munich, Federal Republic of Germany
Mrs E. Busemann Sokole, Department of Nuclear Medicine, University of Amsterdam, Netherlands
Professor B. Delaloye, Autonomous Division of Nuclear Medicine, Central University Hospital of Vaud, Lausanne, Switzerland (*representing the European Nuclear Medicine Society*)
Mr E. Elmer, Department of Radiation Protection, Federal Institute for Health Care, Berne, Switzerland
Dr K. Ennow, National Institute of Radiation Hygiene, Copenhagen, Denmark
Professor H. Frischauf, University Medical Clinic I, Vienna, Austria
Dr G. Georgescu, Head of the Nuclear Medicine Laboratory, Institute of Physical Medicine, Bucharest, Romania
Dr N. E. Herrera, Director of Laboratories, Danbury Hospital, Danbury, CT, USA
Dr M. Iio, Department of Nuclear Medicine and Radiological Sciences, Tokyo Metropolitan Geriatric Hospital, Tokyo, Japan
Dr W. K. Jasinski, Department of Nuclear Medicine, Centre for Medical Education, Warsaw, Poland
Dr A. Jolivet, Health and Safety Directorate, Commission of the European Communities, Plateau du Kirchberg, Luxembourg
Professor K. Jordan, Department of Nuclear Medicine, Hanover Medical School, Hanover, Federal Republic of Germany (*representing the International Electrotechnical Commission*)
Professor G. Van Kaick, German Cancer Research Centre, Heidelberg, Federal Republic of Germany (*representing the International Society of Radiology*)
Professor Y. N. Kasatkin, Vice-Rector, Central Institute for the Education of Postgraduate Physicians, Moscow, USSR
Professor H. Kriegel, Society for Radiation and Environmental Research, Neuherberg, Federal Republic of Germany
Dr K. Kristensen, Director of Isotope Pharmacy, National Board of Health, Copenhagen, Denmark (WHO Collaborating Centre for Nuclear Medicine (Radiopharmaceuticals))
Professor W. J. Lorenz, German Cancer Research Centre, Heidelberg, Federal Republic of Germany
Dr S. Mattsson, Head of the Department of Radiation Physics, Malmö General Hospital, Malmö, Sweden
Professor J. L. Moretti, Biophysics Laboratory, University of Paris, Créteil, France
Dr R. F. Mould, Principal Physicist, Westminster Hospital and Medical School, London, England (*Rapporteur*)
Dr S. M'Timet, Salah Azaiz, Bab Saadoun, Tunis, Tunisia
Professor E. Oberhausen, Department of Nuclear Medicine, University Clinic, Hamburg-Saar, Federal German Republic of Germany
Dr A. Oppelt, Research Unit for Nuclear Medicine, Prague, Czechoslovakia
Dr H. Ostertag, German Cancer Research Centre, Heidelberg, Federal Republic of Germany
Dr P. Paras, Assistant Director for Nuclear Medicine, Bureau of Radiological Health, United States Food and Drug Administration, Rockville, MD, USA

Professor H. D. Roedler, Institute of Radiation Hygiene, Federal Health Office, Neuherberg Federal Republic of Germany (*Co-Secretary*)
Professor J. C. Roucayrol, Cochin Group Hospital, Paris, France (*representing the World Federation of Nuclear Medicine and Biology —Co-Chairman*)
Professor K. Scheer, German Cancer Research Centre, Heidelberg, Federal Republic of Germany
Ms E. Schillemans, Driel, Netherlands (*representing the International Society of Radiographers and Radiological Technicians*)
Dr W. Seelentag, Ministry of the Interior, Bonn, Federal Republic of Germany
Dr A. Skretting, The Norwegian Radium Hospital, Oslo, Norway
Dr L. H. M. Van Stekelenburg, Oosterbeek, Netherlands (*representing the International Radiation Protection Association*)
Professor F.-E. Stieve, Institute of Radiation Hygiene, Federal Health Office, Neuherberg, Federal Republic of Germany (*Co-Chairman*)
Dr V. Volodin, Radiation Medicine, WHO, Geneva, Switzerland (*Co-Secretary*)

WHO publications may be obtained, direct or through booksellers, from

ALGERIA	Société Nationale d'Edition et de Diffusion, 3 bd Zirout Youcef, ALGIERS
ARGENTINA	Carlos Hirsch SRL, Florida 165, Galerías Güemes, Escritorio 453/465, BUENOS AIRES
AUSTRALIA	*Mail Order Sales*: Australian Government Publishing Service, P.O. Box 84, CANBERRA A.C.T. 2600, *or over the counter from*: Australian Government Publishing Service Bookshops *at*: 70 Alinga Street, CANBERRA CITY, A.C.T. 2600; 294 Adelaide Street, BRISBANE, Queensland 4000; 347 Swanston Street, MELBOURNE, VIC. 3000; 309 Pitt Street, SYDNEY, N.S.W. 2000; Mt Newman House, 200 St. George's Terrace, PERTH, W.A. 6000; Industry House, 12 Pirie Street, ADELAIDE, SA 5000; 156–162 Macquarie Street, HOBART, TAS. 7000 — Hunter Publications, 58a Gipps Street, COLLINGWOOD, VIC. 3066 — R. Hill & Son Ltd, 608 St. Kilda Road, MELBOURNE, VIC. 3004; Lawson House, 10–12 Clark Street, CROW'S NEST, NSW 2065
AUSTRIA	Gerold & Co., Graben 31, 1011 VIENNA 1
BANGLADESH	The WHO Programme Coordinator, G.P.O. Box 250, DACCA 5 — The Association of Voluntary Agencies, P.O. Box 9145, DACCA 5
BELGIUM	Office international de Librairie, 30 avenue Marnix, 1050 BRUSSELS — *Subscriptions to World Health only*: Jean de Lannoy, 202 avenue du Roi, 1060 BRUSSELS
BRAZIL	Biblioteca Regional de Medicina OMS/OPS, Unidade de Venda de Publicações, Caixa Postal 20.381, Vila Clementino, 04023 SÃO PAULO, S.P.
BURMA	see India, WHO Regional Office
CANADA	*Single and bulk copies of individual publications (not subscriptions)*: Canadian Public Health Association, 1335 Carling Avenue, Suite 210, OTTAWA, Ont. K1Z 8N8. *Subscriptions*: *Subscription orders, accompanied by cheque made out to the* Royal Bank of Canada, Ottawa, Account World Health Organization, *should be sent to the* World Health Organization, P.O. Box 1800, Postal Station B, OTTAWA, Ont. K1P 5R5. *Correspondence concerning subscriptions should be addressed to the* World Health Organization, Distribution and Sales, 1211 GENEVA 27, Switzerland
CHINA	China National Publications Import Corporation, P.O. Box 88, BEIJING (PEKING)
COLOMBIA	Distrilibros Ltd., Pio Alfonso García, Carrera 4a, Nos 36–119, CARTAGENA
CYPRUS	Publishers' Distributors Cyprus, 30 Democratias Ave Ayios Dhometious, P.O. Box 4165, NICOSIA
CZECHO-SLOVAKIA	Artia, Ve Smeckach 30, 111 27 PRAGUE 1
DENMARK	Munksgaard Export and Subscription Service, Nørre Søgade 35, 1370 COPENHAGEN K
ECUADOR	Libreria Científica S.A., P.O. Box 362, Luque 223, GUAYAQUIL
EGYPT	Osiris Office for Books and Reviews, 50 Kasr El Nil Street, CAIRO
EL SALVADOR	Libreria Estudiantil, Edificio Comercial B No 3, Avenida Libertad, SAN SALVADOR
FIJI	The WHO Programme Coordinator, P.O. Box 113, SUVA
FINLAND	Akateeminen Kirjakauppa, Keskuskatu 2, 00101 HELSINKI 10
FRANCE	Librairie Arnette, 2 rue Casimir-Delavigne, 75006 PARIS
GERMAN DEMOCRATIC REPUBLIC	Buchhaus Leipzig, Postfach 140, 701 LEIPZIG
GERMANY, FEDERAL REPUBLIC OF	Govi-Verlag GmbH, Ginnheimerstrasse 20, Postfach 5360, 6236 ESCHBORN — W. E. Saarbach, Postfach 101 610, Follerstrasse 2, 5000 COLOGNE 1 — Alex. Horn, Spiegelgasse 9, Postfach 3340, 6200 WIESBADEN
GHANA	Fides Enterprises, P.O. Box 1628, ACCRA
GREECE	G.C. Eleftheroudakis S.A., Librairie internationale, rue Nikis 4, ATHENS (T. 126)
HAITI	Max Bouchereau, Librairie "A la Caravelle", Boite postale 111-B, PORT-AU-PRINCE
HONG KONG	Hong Kong Government Information Services, Beaconsfield House, 6th Floor, Queen's Road, Central, VICTORIA
HUNGARY	Kultura, P.O.B. 149, BUDAPEST 62 — Akadémiai Könyvesbolt, Váci utca 22, BUDAPEST V
ICELAND	Snaebjörn Jonsson & Co., P.O. Box 1131, Hafnarstraeti 9, REYKJAVIK
INDIA	WHO Regional Office for South-East Asia, World Health House, Indraprastha Estate, Ring Road, NEW DELHI 110002 — Oxford Book & Stationery Co., Scindia House, NEW DELHI 110001; 17 Park Street, CALCUTTA 700016 (*Sub-agent*)
INDONESIA	M/s Kalman Book Service Ltd., Kwitang Raya No. 11, P.O. Box 3105/Jkt, JAKARTA
IRAN	Iranian Amalgamated Distribution Agency, 151 Khiaban Soraya, TEHRAN
IRAQ	Ministry of Information, National House for Publishing, Distributing and Advertising, BAGHDAD
IRELAND	The Stationery Office, DUBLIN 4
ISRAEL	Heiliger & Co., 3 Nathan Strauss Street, JERUSALEM
ITALY	Edizioni Minerva Medica, Corso Bramante 83–85, 10126 TURIN; Via Lamarmora 3, 20100 MILAN
JAPAN	Maruzen Co. Ltd., P.O. Box 5050, TOKYO International, 100–31
KOREA REPUBLIC OF	The WHO Programme Coordinator, Central P.O. Box 540, SEOUL
KUWAIT	The Kuwait Bookshops Co. Ltd., Thunayan Al-Ghanem Bldg, P.O. Box 2942, KUWAIT
LAO PEOPLE'S DEMOCRATIC REPUBLIC	The WHO Programme Coordinator, P.O. Box 343, VIENTIANE
LEBANON	The Levant Distributors Co. S.A.R.L., Box 1181, Makdassi Street, Hanna Bldg, BEIRUT

A/1/81

WHO publications may be obtained, direct or through booksellers, from:

LUXEMBOURG	Librairie du Centre, 49 bd Royal, LUXEMBOURG
MALAWI	Malawi Book Service, P.O. Box 30044, Chichiti, BLANTYRE 3
MALAYSIA	The WHO Programme Coordinator, Room 1004, Fitzpatrick Building, Jalan Raja Chulan, KUALA LUMPUR 05-02 — Jubilee (Book) Store Ltd, 97 Jalan Tuanku Abdul Rahman, P.O. Box 629, KUALA LUMPUR 01-08 — Parry's Book Center, K. L. Hilton Hotel, Jln. Treacher, P.O. Box 960, KUALA LUMPUR
MEXICO	La Prensa Médica Mexicana, Ediciones Científicas, Paseo de las Facultades 26, Apt. Postal 20-413, MEXICO CITY 20, D.F.
MONGOLIA	*see* India, WHO Regional Office
MOROCCO	Editions La Porte, 281 avenue Mohammed V, RABAT
MOZAMBIQUE	INLD, Caixa Postal 4030, MAPUTO
NEPAL	*see* India, WHO Regional Office
NETHERLANDS	Medical Books Europe BV, Noorderwal 38, 7241 BL LOCHEM
NEW ZEALAND	Government Printing Office, Publications Section, Mulgrave Street, Private Bag, WELLINGTON 1; Walter Street, WELLINGTON; World Trade Building, Cubacade, Cuba Street, WELLINGTON. *Government Bookshops at* Hannaford Burton Building, Rutland Street, Private Bag, AUCKLAND; 159 Hereford Street, Private Bag, CHRISTCHURCH; Alexandra Street, P.O. Box 857, HAMILTON; T & G Building, Princes Street, P.O. Box 1104, DUNEDIN — R. Hill & Son Ltd, Ideal House, Cnr Gillies Avenue & Eden Street, Newmarket AUCKLAND 1
NIGERIA	University Bookshop Nigeria Ltd, University of Ibadan, IBADAN
NORWAY	J. G. Tanum A/S, P.O. Box 1177 Sentrum, OSLO 1
PAKISTAN	Mirza Book Agency, 65 Shahrah-E-Quaid-E-Azam, P.O. Box 729, LAHORE 3
PAPUA NEW GUINEA	The WHO Programme Coordinator, P.O. Box 5896, BOROKO
PHILIPPINES	World Health Organization, Regional Office for the Western Pacific, P.O. Box 2932, MANILA — The Modern Book Company Inc., P.O. Box 632, 922 Rizal Avenue, MANILA 2800
POLAND	Składnica Księgarska, ul Mazowiecka 9, 00052 WARSAW *(except periodicals)* — RKWZ Ruch, ul Wronia 23, 00840 WARSAW *(periodicals only)*
PORTUGAL	Livraria Rodrigues, 186 Rua do Ouro, LISBON 2
SIERRA LEONE	Njala University College Bookshop (University of Sierra Leone), Private Mail Bag, FREETOWN
SINGAPORE	The WHO Programme Coordinator, 144 Moulmein Road, G.P.O. Box 3457, SINGAPORE . — Select Books (Pte) Ltd, 215 Tanglin Shopping Centre, 2/F, 19 Tanglin Road, SINGAPORE 10
SOUTH AFRICA	Van Schaik's Bookstore (Pty) Ltd, P.O. Box 724, 268 Church Street, PRETORIA 0001
SPAIN	Comercial Atheneum S.A., Consejo de Ciento 130-136, BARCELONA 15; General Moscardo 29, MADRID 20 — Libreria Diaz de Santos, Lagasca 95 y Maldonado 6, MADRID 6, Balmes 417 y 419, BARCELONA 22
SRI LANKA	*see* India, WHO Regional Office
SWEDEN	Aktiebolaget C.E. Fritzes Kungl. Hovbokhandel, Regeringsgatan 12, 10327 STOCKHOLM
SWITZERLAND	Medizinischer Verlag Hans Huber, Langgass Strasse 76, 3012 BERNE 9
SYRIAN ARAB REPUBLIC	M. Farras Kekhia, P.O. Box No. 5221, ALEPPO
THAILAND	*see* India, WHO Regional Office
TUNISIA	Societe Tunisienne de Diffusion, 5 avenue de Carthage, TUNIS
TURKEY	Haset Kitapevi, 469 Istiklal Caddesi, Beyoglu, ISTANBUL
UNITED KINGDOM	H.M. Stationery Office, 49 High Holborn, LONDON WC1V 6HB; 13a Castle Street, EDINBURGH EH2 3AR; 41 The Hayes, CARDIFF CF1 1JW; 80 Chichester Street, BELFAST BT1 4JY; Brazennose Street, MANCHESTER M60 8AS; 258 Broad Street, BIRMINGHAM B1 2HE; Southey House, Wine Street, BRISTOL BS1 2BQ. *All mail orders should be sent to* P.O. Box 569, LONDON SE1 9NH
UNITED STATES OF AMERICA	*Single and bulk copies of individual publications (not subscriptions)*: WHO Publications Centre USA, 49 Sheridan Avenue, ALBANY, N.Y. 12210. *Subscriptions. Subscription orders, accompanied by check made out to the* Chemical Bank, New York, Account World Health Organization, *should be sent to the* World Health Organization, P.O. Box 5284, Church Street Station, NEW YORK, N.Y. 10249; *Correspondence concerning subscriptions should be addressed to the* World Health Organization, Distribution and Sales, 1211 GENEVA 27, Switzerland. *Publications are also available from the* United Nations Bookshop, NEW YORK, N.Y. 10017 *(retail only)*
USSR	*For readers in the USSR requiring Russian editions*: Komsomolskij prospekt 18, Medicinskaja Kniga, MOSCOW — *For readers outside the USSR requiring Russian editions*: Kuzneckij most 8, Meždunarodnaja Kniga, MOSCOW G-200
VENEZUELA	Editorial Interamericana de Venezuela C.A., Apartado 50 785, CARACAS 105 — Libreria del Este, Apartado 60.337, CARACAS 106 — Libreria Medica Paris, Apartado 60.681, CARACAS 106
YUGOSLAVIA	Jugoslovenska Knjiga, Terazije 27/II, 11000 BELGRADE
ZAIRE	Librairie universitaire, avenue de la Paix N° 167, B.P. 1682, KINSHASA 1

Special terms for developing countries are obtainable on application to the WHO Programme Coordinators or WHO Regional Offices listed above or to the World Health Organization, Distribution and Sales Service, 1211 Geneva 27, Switzerland. Orders from countries where sales agents have not yet been appointed may also be sent to the Geneva address, but must be paid for in pounds sterling, US dollars, or Swiss francs.

Price: Sw. fr. 11.— **Prices are subject to change without notice.**