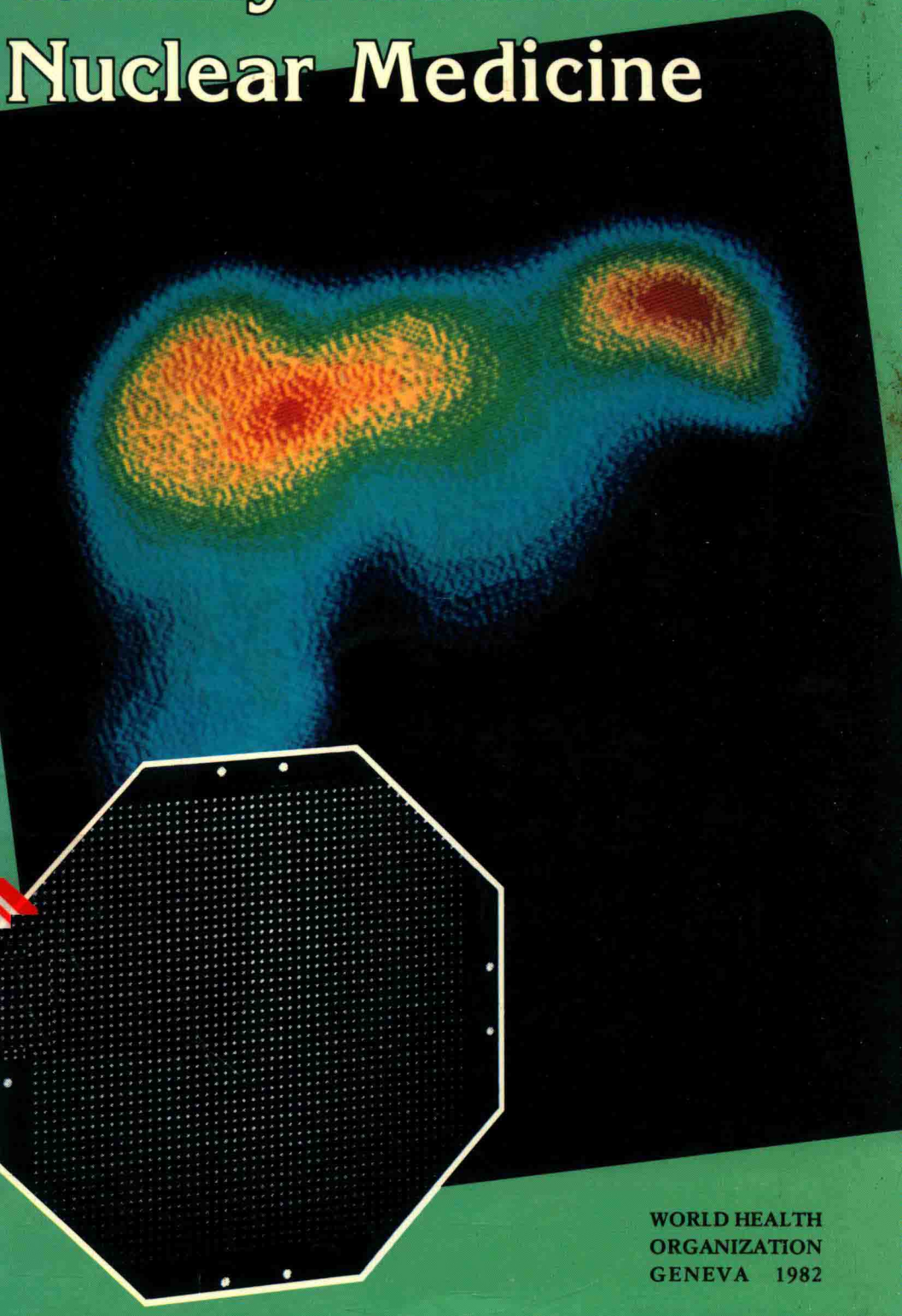
# Quality Assurance in Nuclear Medicine



WORLD HEALTH
ORGANIZATION
GENEVA 1982

# 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

# 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.<br>Acceptance testing.<br>Initial testing to enable reference values to be defined.<br>Design of record book/log-book. | Definition of standards.<br>Licensing/registration.<br>Quality assessment. |
| (2) Routine | Measurement of parameters.<br>Test procedures with selected radionuclide sources and phantoms.<br>Documentation of results in record book/log-book. | Acceptance procedures for "ready-for-use" pharmaceuticals.<br>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