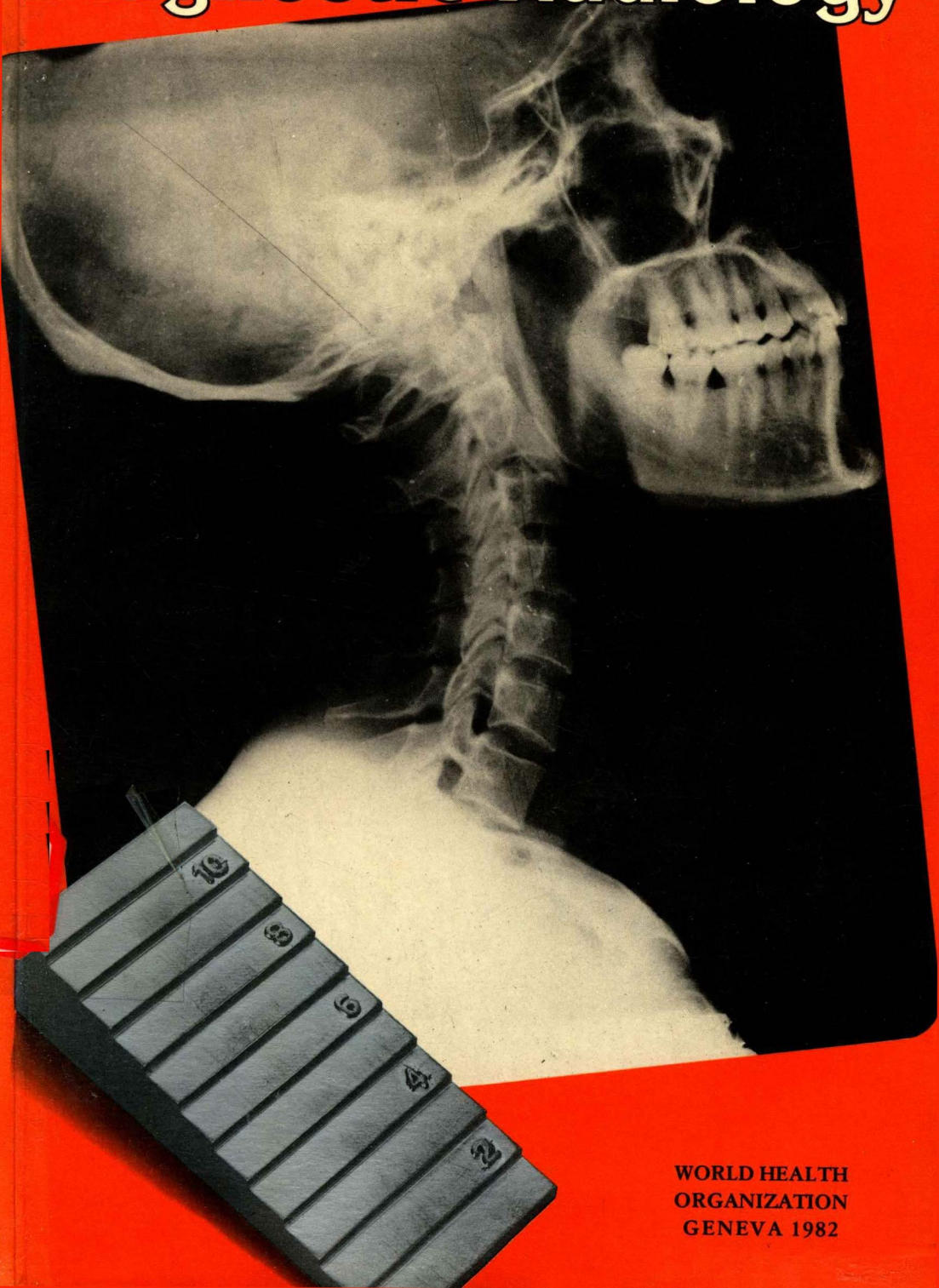
Quality Assurance in Diagnostic Radiology



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Quality Assurance in Diagnostic Radiology

A Guide Prepared Following a Workshop Held in Neuherberg, Federal Republic of Germany, 20–24 October 1980, and Organized Jointly by

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

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

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1. Introduction

A MEETING on efficacy and efficiency in the diagnostic application of radiation and radionuclides, held in Neuherberg in December 1979 by the organizers of the 1980 Workshop, concluded that an important step in the development of efficacy/efficiency studies would be the design and adoption by all countries of a programme of quality control and assurance in the domain of radiodiagnostic and nuclear medicine, with the aim of improving the diagnostic quality of procedures and reducing wastage. The meeting felt that WHO and the International Atomic Energy Agency should play a catalytic role in the design and implementation of this quality control and assurance programme. It also considered that better diagnostic images, which could lead to more accurate diagnoses and better-informed decisions regarding treatment, would benefit not only the health of individual patients but also the health status of the population—albeit that this effect is very difficult to demonstrate.

As a result of the above conclusions, a limited number of countries have initiated *quality assurance programmes*[1] in diagnostic radiology and nuclear medicine at the national level. However, in a greater number of countries such programmes are still only a local initiative and depend on the particular interest of specialists (radiologists, medical physicists, medical radiology technicians, etc.). Data gathered from 15 European countries using a WHO questionnaire show that *quality assurance*[1] in diagnostic radiology has entered national regulations in only a few countries.[2] The time now appears to be ripe for an international effort towards a more systematic approach in this field. The aim of the 1980 Workshop[3] (in which the United States Bureau of Radiological Health contributed technical support) was to gather together specialists with different backgrounds—diagnostic radiologists and medical

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

[2] In developing countries—despite the great limitation of resources—very little has been done to introduce quality assurance activities.

[3] Another international meeting—on quality assurance in nuclear medicine—was held in November 1980. A guide on this subject has been published by WHO as a companion volume to the present publication.

physicists, representatives of international organizations connected with diagnostic radiology, and a representative of the United States Bureau of Radiological Health with several years' experience in organizing quality assurance programmes at a national level—in order to effect an exchange of views on the work being carried out in a number of countries and the current activities of various international bodies. The main purpose of this exchange of experience was to provide some solid recommendations to be applied at the international, national, and radiodiagnostic department levels.

The present guide endeavours to provide an outline of the type of quality assurance programme to be recommended for (1) routine implementation by those performing radiodiagnostic procedures (medical radiology technicians, medical physicists, and radiologists), (2) for application by the responsible national authorities, and (3) for use by international bodies such as the International Society of Radiology (ISR), the International Commission on Radiological Protection (ICRP), and the International Commission on Radiation Units and Measurements (ICRU).

It is worth mentioning in this context that in redrafting one of its publications (*25*) ICRP has already mentioned the important role of quality assurance and the problem represented by the retake rate. At its meeting in July 1980, ICRU decided to establish five new report committees, of which three will deal respectively with:

—quality assurance of diagnostic radiological equipment;
—quality assurance of external beam radiotherapy; and
—specifications and quality assurance of scintillation cameras.

This accrued interest in quality assurance in diagnostic radiology emphasizes the urgent need for realistic recommendations and explicit programmes in this area, and for their prompt implementation throughout the world.

When quality assurance programmes are envisaged, three objectives are usually considered:

—cost containment;
—reduction in radiation exposure; and
—improvement of medical imaging.

Although quality assurance is only one of the possible approaches for reaching the above objectives, its role is important and merits greater attention than that at present given in the majority of countries.

The former United States Department of Health, Education, and Welfare[1] estimated the cost of diagnostic imaging services at US $7800 million per year. If the Department's estimated retake rate of approximately 6% (*13*) is accepted as valid, it could be argued that US $470 million are wasted on images of nondiagnostic quality. Although some retakes cannot be avoided, if a quality assurance programme led to even a 50% reduction of the retake rate, a saving of US $ 235 million could be expected from such a programme, which might involve the investment of only a relatively small sum.

[1]Renamed the United States Department of Health and Human Services in 1980.

In addition to the reduction in film wastage resulting from quality assurance, there is the further advantage of reducing patient and radiological personnel exposure, which (although not easy to quantify) can be expressed in grays and/or sieverts.

It should be stressed that less than 30 % of the world's population is endowed with well-developed health care services, including good radiodiagnostic coverage. In this guide, consideration has therefore been given to some simple approaches that could be implemented in countries in which the present situation is unsatisfactory and in which the need for quality assurance—though it might not seem so immediately obvious—is, in fact, much greater and more basic than in other parts of the world.

2. Aims of quality assurance in diagnostic radiology

THE provision of high-quality health care is the goal of all medical services. In the case of *diagnostic radiological facilities*,[1] patient selection, the conduct of the examination, and the interpretation of the results can all have an impact on the achievement of this goal. With respect to the conduct of the examination, it has been increasingly recognized that quality assurance programmes directed at equipment and operator performance can be of great value in improving the diagnostic information content, reducing radiation exposure, reducing medical costs, and improving departmental management. Quality assurance programmes thus contribute to the provision of high-quality health care.

2.1 Identification of needs

Experience has drawn attention to the needs and potential benefits to be derived from the implementation of effective quality assurance programmes. Several studies have indicated that many diagnostic radiological facilities produce poor-quality images and give unnecessary radiation exposure. An early indication of the existence of these problems was revealed by a medical surveillance programme conducted in the USA by the National Institute for Occupational Safety and Health in association with the Department of Labor's Pneumoconiosis Compensation Program. Trout et al. (*49*) found that, despite the prescreening of facilities and readers, 44 % of the facilities participating in the first round of examinations had from 10 % to 40 % of their submitted radiographs rejected as being of inadequate quality for the diagnosis of pneumoconiosis. These inadequate images represented unproductive radiation exposure as well as unsatisfactory medical care. Some of the reasons for the inadequacy were related to poor equipment performance.

An evaluation of preauthorization dental radiographs submitted to Pennsylvania Blue Shield (a statewide medical insurance plan) in the USA

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

found that approximately 20% were unsatisfactory for reasons probably related to poor equipment performance (*5*).

A study of a number of general radiography facilities by the Du Pont Company (Delaware, USA) revealed that, on average, 13% of the radiographs processed were rejected as being of inadequate quality (*16*). An average of 9% of the radiographs taken had to be repeated. An analysis of the reasons for these rejections led to the conclusion that poor equipment performance was an important problem.

These three studies indicated that poor equipment performance made a significant contribution to the high prevalence of poor image quality. This finding is supported by the results of other studies, which have shown that electrical or mechanical problems may affect the performance of a large percentage of X-ray units (*7*, *43*, *44*).

The effect of poor-quality images is twofold. Obviously the radiologist would prefer to study an optimum-quality image even though he or she might be able to draw some useful conclusions from a poor image. If the image is not of adequate quality, practitioners may not have all the possible diagnostic information that could have been made available to them, and this may lead to an incorrect diagnosis. In addition, if the quality of the radiograph is so poor that it cannot be used, then the patient will have been unproductively exposed to radiation, causing an increase in the cost of diagnosis.

Unnecessary radiation exposure may also occur in the production of adequate-quality radiographs. Data from the Nationwide Evaluation of X-ray Trends (NEXT) programme, administered by the United States Bureau of Radiological Health, revealed that the "standard patient" (as defined in reference *37*) can receive widely different exposures depending on the facility (or even on the machine within a facility) performing the examination (*9*). Even when a consideration of the NEXT data is limited, for example, to exposures by machines with a nominal peak tube potential of 80 kVp and half-value layers (HVL) of 2.5 mm of aluminium, the output at 30 cm varied from less than 12.9×10^{-7} C/kg to 258×10^{-7} C/kg when a current of one milliampere was applied for one second (*9*). Similar variations have been found in studies carried out in other countries (*2*, *20*). The United States Bureau of Radiological Health has also studied the impact of the choice of image receptor on the exposure variation. Statistical analysis of the posterior/anterior (P/A) chest projection data has been carried out using the factors of kVp, HVL, relative speed of the image receptor, grid, type of processing, and $C.kg^{-1}$. It was found that these factors can account for only 50% of the exposure variation (*41*). In the Bureau of Radiological Health's view, machine malfunction causing the actual kVp and $C.kg^{-1}$ to deviate from the machine settings selected by the practitioner is a major cause of this variation. Such machine malfunction can be greatly reduced by effective quality assurance programmes.

A survey of the numbers and causes of spoilt X-ray films, which was carried out under the aegis of the Radiation Protection Committee of the British Institute of Radiology (*6*), revealed that exposure faults in 47% of the cases were the major reason for retakes—particularly in films taken with portable

radiographic equipment. Malpositioning was shown to be the second major cause of retakes (25%).

In 1980 a study was conducted (*52*) at a district hospital near Nairobi, Kenya, to evaluate the image quality of 50 X-ray films of the skull taken in both P/A and lateral positions: 20% of the P/A views and 34% of the lateral views were considered poor. Fogging and other reasons causing poor detail recognition were responsible for 50% of the poor-quality P/A views, while 42% of the poor-quality lateral views were attributable to malpositioning.

According to an Australian study (*33*), positioning errors were the major cause of film wastage—ranging from 8.8% to 13.0% for different film sizes. Also, there was a higher frequency of positioning errors in trauma patients. Exposure faults came second and equipment malperformance came third. There is no doubt that radiographic errors as well as poor equipment performance can contribute significantly to the need for retakes.

Thus several studies have identified problems of poor image quality and unnecessary radiation exposure in diagnostic radiological facilities. A more complete description of such findings has been published by the United States Bureau of Radiological Health (*10*). Quality assurance programmes directed at the equipment and its use are expected to have a major impact on reducing these problems.

2.2 Solution to the problem

A quality assurance programme may be defined as an organized effort by the staff operating a facility to ensure that the diagnostic images produced by the facility are of sufficiently high quality so that they consistently provide adequate diagnostic information at the lowest possible cost and with the least possible exposure of the patient to radiation. In its most comprehensive form, the quality assurance programme monitors each phase of operation of the diagnostic radiological facility, beginning with the request for an examination and ending with the interpretation of the examination and the communication of this interpretation to the referring physician. Included within this programme are actions to ensure that the radiology equipment used for the examination will yield the information desired about the patient. The actions considered in this guide include appropriate selection of equipment, as well as monitoring and maintenance of its performance.

Quality assurance programmes, designed to ensure that the radiology equipment can yield the desired information, include both *quality control*[1] techniques and *quality administration procedures*.[1] Quality control techniques are used to test the components of the radiological system to verify that the equipment is operating satisfactorily. Quality administration procedures encompass management actions designed to verify that the quality control monitoring techniques are performed regularly and properly, that the results

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

of these techniques are evaluated promptly and accurately, and that the necessary corrective measures are taken in response to these results. Quality administration procedures include the assignment of responsibility for quality assurance actions, the establishment of standards of quality for equipment in the facility, the provision of adequate training, and the selection of the appropriate equipment for each examination.

The question of the appropriateness of the equipment should be considered at the time it is ordered and installed. This involves a determination of the clinical imaging requirements for the equipment and the translation of these requirements into technical specifications, followed by the selection of equipment which satisfies the technical specifications, and finally the *acceptance inspection (acceptance test)*[1] of the equipment after installation to confirm that it actually performs at the level described in the technical specifications agreed upon by the manufacturer and the purchaser (*10*, *17*, *36*).

This approach to the equipment selection phase of a quality assurance programme for radiology equipment is outlined in Table 1. During the acceptance testing phase, performance data are compiled which serve as a comparative standard for similar data collected subsequently during routine quality control monitoring of the equipment as it is used diagnostically.

Table 1. Quality assurance in diagnostic radiology

Identification of imaging requirements Development of equipment specifications Selection of equipment	*Equipment selection phase*
Installation and acceptance testing of equipment Release of equipment for clinical use	*Acceptance phase*
Monitoring of equipment performance	*Quality control phase*

The quality control phase must be supported by quality administration procedures, which include the assignment of responsibility for monitoring and corrective actions and for the evaluation and review of the effectiveness of the overall quality assurance programme.

The fundamental responsibility for a quality assurance programme for any radiological facility must be placed upon the individual in charge of the facility. If the programme is to be successfully implemented, however, the responsibility for the routine quality control equipment monitoring phase must be delegated to the radiographers, who use the equipment on a day-to-day basis.

In facilities where they are available, physicists, radiology engineers, or specially trained quality control technicians should play a major role in the quality assurance programme. These specialized personnel may be assigned responsibility for the day-to-day administration of the programme and may

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