

Evaluation and routine testing in medical imaging departments —

Part 1: General

Committees responsible for this British Standard

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- British Institute of Radiology
- College of Radiographers
- Department of Health
- Institute of Physical Sciences in Medicine (IPSM)
- Royal College of Radiologists
- Society of X-ray Technology

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National foreword

This Part of BS 7725 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with IEC Publication 1223-1:1993 *Evaluation and routine testing in medical imaging departments* — Part 1: *General aspects*, prepared by the Technical Committee 62 Electrical equipment in medical practice and published by the International Electrotechnical Commission (IEC).

Cross-references

International Standard	Corresponding British Standard
IEC 601-1:1988	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i> (Identical)
IEC 788:1984	BS 6641:1985 <i>Glossary of medical radiology terms</i> (Identical)
IEC 1223-2-1:1993	BS 7725 <i>Evaluation and routine testing in medical imaging departments</i> Section 2.1:1994 <i>Method for film processors</i> (Identical)

NOTE ISO 8402:1986 referenced in clause 2 is not quoted in this technical report. This error has been reported to the relevant body for action.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 12, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Introduction

In recent years, QUALITY ASSURANCE PROGRAMMES have been initiated in several countries — mostly on a local basis, sometimes on a national level — with the purpose of either maintaining or improving the quality of daily operations in diagnostic X-ray departments.

As far as these operations depend on the use of equipment, and as part of an international effort towards a more uniform approach in this field, the IEC issues Particular Publications (International Standards or technical reports) which describe the methods and provide the guidelines for establishing QUALITY ASSURANCE PROGRAMMES for individual items of equipment or systems of equipment in a diagnostic X-ray department.

An effective QUALITY ASSURANCE PROGRAMME will help to achieve and maintain:

- radiological information of adequate quality for medical diagnostic purposes;
- minimum radiation dose to the PATIENT and medical staff, compatible with adequate quality of the radiological information;
- maximum cost containment by minimizing wastage of time and resources (for example reduction of rejected RADIOGRAMS).

Benefits arise also through the enhancement of the professional and public reputation of the department.

The Particular IEC Publications (International Standards or technical reports) describing guidelines for establishing effective QUALITY ASSURANCE PROGRAMMES are concerned with test methods for monitoring the imaging performance of equipment.

To encourage the adoption of these test methods in a large number of diagnostic X-ray departments, emphasis is placed upon test methods suitable to be carried out by OPERATORS involved in the daily use of the equipment.

Effective activities for QUALITY ASSURANCE depend on quality administrative elements as well as on QUALITY CONTROL techniques.

Quality administrative elements ensure that

- testing is done by qualified personnel to an effective schedule;
- test results are analyzed to determine whether problems exist; and
- appropriate corrective action is undertaken where necessary.

QUALITY CONTROL techniques comprise physical testing and monitoring of the functional performance of the equipment in order to determine whether or not corrective action is needed to adjust the equipment to maintain the desired quality of the radiological information.

The USER is responsible for preventive and corrective maintenance of the equipment in the diagnostic X-ray department.

A QUALITY ASSURANCE PROGRAMME involves a continuous evaluation of the adequacy and effectiveness of QUALITY CONTROL. Both the QUALITY ASSURANCE PROGRAMME and QUALITY CONTROL should be reviewed and adjusted as appropriate to maintain continued effectiveness.

1 Scope and object

1.1 Scope

This technical report applies to equipment and subassemblies forming those constituent components of diagnostic X-RAY INSTALLATIONS that generate, influence the propagation of, and detect the X-RADIATION, and process, present and store the radiological information.

1.2 Object

This technical report presents the concept of QUALITY ASSURANCE in diagnostic X-ray departments, and introduces a series of test methods to be carried out under the responsibility of the USER.

The test methods introduced in this technical report are solely concerned with monitoring the constancy of functional performance of equipment and ASSOCIATED EQUIPMENT by means of test instrumentation and TEST DEVICES that are simple to use.

The test methods are not intended to deal with aspects of safety, such as mechanical and electrical safety, except where the intended function of the equipment or devices is to provide safety.

The individual test methods for QUALITY CONTROL are described in, and published as, separate Particular IEC Publications.

The individual tests carried out in a diagnostic X-ray department shall be linked to those aspects of a QUALITY ASSURANCE PROGRAMME, which are described in this technical report.

This technical report is not intended to cover matters of clinical judgement in the management of the patient.

2 References to other publications

The following IEC/ISO publications are quoted in this technical report:

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

Amendment No. 1, 1991

IEC 788:1984, *Medical radiology — Terminology*.

IEC 1223-2-1:1993, *Evaluation and routine testing in medical imaging departments — Part 2-1: Constancy tests — Film processors*.

ISO 8402:1986, *Quality — Vocabulary*.

3 Terminology

3.1 Use of terms

In this technical report, terms printed in small capital letters are used as defined:

- in IEC 788;
- in IEC 1223-2-1;
- and in 3.2 of this part 1.

(See Annex A, Terminology — Index of terms)

3.2 Definitions

3.2.1

QUALITY ASSURANCE

planned and systematic actions necessary to provide adequate confidence by ensuring that a product or service will satisfy given requirements for quality

3.2.2

QUALITY ASSURANCE PROGRAMME

detailed instruction for carrying out actions of QUALITY ASSURANCE for individual items of equipment, systems of equipment or facilities, including quality administrative elements and QUALITY CONTROL techniques

3.2.3

QUALITY CONTROL

operational techniques and activities that are used to fulfil requirements for quality

3.2.4

ACCEPTANCE TEST

test carried out after new equipment has been installed, or major modifications have been made to, existing equipment, in order to verify compliance with contractual specifications (see Table 1)

3.2.5

STATUS TEST

test carried out to establish the functional status of equipment at a given time (see Table 1)

3.2.6

CONSTANCY TEST

each of a series of tests, carried out:

- to ensure that the functional performance of equipment meets ESTABLISHED CRITERIA; or
- to enable the early recognition of changes in the properties of components of the equipment (see Table 1).

3.2.7

BASELINE VALUE

reference value of functional parameter:

- either the value obtained for this parameter in the initial CONSTANCY TEST immediately following a STATUS TEST; or
- where described in a corresponding Particular Standard, the mean value of values obtained in a series of initial CONSTANCY TESTS, immediately following a STATUS TEST.

3.2.8

ESTABLISHED CRITERIA

in a QUALITY ASSURANCE PROGRAMME, acceptable variations in results of a CONSTANCY TEST which signal satisfactory functional performance of the equipment tested

4 QUALITY ASSURANCE: QUALITY CONTROL and quality administration

4.1 General aspects

There is increased concern and awareness among users, manufacturers and competent authorities of the need for optimal use of resources and for ensuring that radiological information of adequate quality is produced in a diagnostic x-ray department, taking the radiation dose to the patient into account.

This technical report emphasizes QUALITY CONTROL techniques and activities that monitor the constancy of the functional performance of the equipment.

These techniques and activities should be carried out after the USER is satisfied that the functional performance of the diagnostic X-RAY INSTALLATION is acceptable (for example, that it complies with the contractual specification). Prior to starting a series of CONSTANCY TESTS, the functional status of a diagnostic X-RAY INSTALLATION has to be established and documented.

The results of the initial CONSTANCY TEST, or of the first series of initial CONSTANCY TESTS, constitute the BASELINE VALUES against which the results of all subsequent CONSTANCY TESTS are compared.