

**GUIDANCE ON THE ELECTRICAL  
AND  
MECHANICAL SAFETY TESTING  
OF  
MAMMOGRAPHIC X-RAY EQUIPMENT**

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## 1. INTRODUCTION

### 1.1 Requirements for safety testing

The *Health and Safety at Work Act 1974* states that it shall be the duty of every employer to ensure as far as is reasonably practicable, the health, safety and welfare at work of all their employees.<sup>1</sup> This implies that equipment should be checked for all aspects of safe operation including electrical and mechanical safety. The *Recommended Standards for the Routine Testing of Diagnostic X-ray Imaging Equipment* published by the Institute of Physics and Engineering in Medicine (IPEM) suggests that electrical and mechanical safety tests are required in addition to radiation safety tests and that these are performed as part of the acceptance procedure.<sup>2</sup>

Recent information suggests that many X-ray systems may go into clinical use without these tests being carried out. Therefore, the NHS Breast Screening Programme (NHSBSP) National Coordinating Group for Equipment strongly recommends that the guidance given in this document is acted upon.

### 1.2 Previous arrangements

The supplier or installer of the equipment generally carries out a range of electrical and mechanical safety tests and documents the results. However, this does not provide independent verification of safety or compliance. In the past, each NHS region was assigned a Department of Health inspecting officer who attended all new installations and part of whose duties was to carry out these tests. At a later date, these duties were devolved to the individual regions that, in general, appointed one or more specialist regional X-ray engineers. Subsequent changes in the regional structure have resulted in the responsibilities being devolved to individual trusts or hospitals and the disappearance of nearly all of the regional X-ray engineering posts.

### 1.3 Current arrangements

Currently, a small number of trusts/hospitals employ an 'in house' X-ray engineer who should be able to carry out the relevant tests. Also, some Medical Physics or Medical Engineering Departments offer electrical and mechanical safety testing in addition to radiation safety testing. A small number of private organisations can offer these services. In every case, it should be confirmed that the organisation carrying out the tests has sufficient expertise and appropriate test equipment.

## 2. ELECTRICAL AND MECHANICAL SAFETY TESTING IN THE NHSBSP

### 2.1 Equipment to be tested

Within the NHSBSP, electrical and mechanical safety tests need to be performed on mammography X-ray units and accessories, for example stereotactic devices and biopsy systems; on processing equipment including automatic film processors, chemical mixers and film handling devices; and on specimen radiography systems. This document is designed to provide general advice on ensuring that the tests are carried out and on the range of tests that can be practically performed.

### 2.2 Responsibility for arranging testing

Within the NHSBSP, it is the responsibility of the purchaser or owner of the equipment, or a nominated representative, to arrange for the safety testing to be carried out. The representative may typically be the superintendent or lead radiographer or the medical physicist providing routine quality assurance services.

The National Co-ordinating Group for Equipment advises that the tests are performed by a third party to provide an independent check of any measurements made by the supplier or installer of the equipment. Advice on suitable organisations that can provide the required services may be obtained locally or from the authors of this guidance. The tests should be performed prior to the system going into clinical use, and prior to, or concurrently with, the commissioning and radiation safety tests. A report should be provided to the purchaser or owner of the equipment, who should make arrangements for any action or actions required.

### 2.3 Documentation and CE Marking

Safety testing is primarily carried out to ensure compliance with the relevant requirements of *Medical Electrical Equipment. General Requirements for Safety (British Standard BS 5724-1: 1989, IEC 60601-1:1998)*.<sup>3</sup>

Reference may also be made to other documents such as:

- *Technical Requirements for the Supply and Installation of Radiological Apparatus (TRS 89)* (this document may be subject to revision in the near future)<sup>4</sup>
- *Requirements for Electrical Installations (IEE Wiring Regulations, 16th edition) (British Standard BS 7671: 2001)*<sup>5</sup>
- *Medical Electrical Equipment. Particular Requirements for Safety. Specification for Mammographic X-ray Equipment and Mammographic Stereotactic Devices (British Standard BS 5742-2.45, IEC 60601-2-45 1998)*<sup>6</sup>

- *Commissioning and Routine Testing of Mammographic X-ray Systems (IPSM Report No 59, second edition)*<sup>7</sup>.

All medical equipment offered for sale in the European Union should carry a CE mark to demonstrate compliance with the Medical Device Directive (MDD). The supplier or manufacturer should be able to provide details of the standards to which the unit has been tested (which should normally include *BS 5724-1/IEC 60601-1*).<sup>3</sup>

The electrical and mechanical safety testing of X-ray and ancillary equipment is a specialised field and few comprehensive texts providing relevant information are available. However, general advice can be found in several documents such as:

- *The Harrogate Seminar (STD/89/03)*
- *Acceptance Inspection of Radiological Apparatus (STB6A/85/15)*
- *Technical Guidance for Pre-installation Work for Diagnostic Imaging and Radiotherapy Equipment (TGP 1.0/93)*.

Reference can also be made to the series of NHSBSP Guidance Notes published by the Medical Devices Agency, in particular *Further Revisions to Guidance Notes for Health Authorities and NHS Trusts on Mammographic X-ray Equipment for Breast Screening* (MDA 01011). The authors of this guidance or the Medicines and Healthcare Products Regulatory Agency (MHRA) of the Department of Health may also be contacted.

### **2.3 Pre-installation and enabling work**

The pre-installation or enabling work that is required for new or re-installed mammography equipment will be provided by a contractor nominated either by the trust/hospital or by the equipment supplier and may be part of a 'turnkey' contract for the complete project. Projects that are not being managed by the equipment supplier or are not 'turnkey' will require to be designed, monitored and managed by a person with adequate experience of all the requirements for the task. This includes design layout for the area, equipment specification, and electrical, mechanical and radiation safety requirements to comply with all relevant regulations and guidance documents.

The equipment supplier or installer should ensure that the required services are provided and that they are in the correct location and comply with current regulations. All requirements should be detailed in the equipment specifications and installation documents and supported with detailed layout drawings for each installation. The electrical supply will either be single or three phase and should be of adequate rating with correct earthing and protection and be provided with a mains isolator easily accessible to the user and a designated earth reference terminal (ERT).

### **3. RANGE OF ELECTRICAL AND MECHANICAL SAFETY TESTS**

#### **3.1 Range of tests**

This section is a guide to the tests that can be practically performed as part of the inspection procedure and is not intended to be a definitive list of all tests. The range of tests will depend on the experience of the testers and the test equipment available but, in general, should demonstrate compliance with the requirements of TRS 89. It can be useful to arrange for a service engineer to be present during the tests, particularly if it is required to remove access covers. The report should clearly identify the scope of the inspection and the range of tests performed.

#### **3.2 Electrical safety**

The electrical supply should be examined with respect to the rating, protection (fuses) and provision of an accessible isolator and designated earth reference terminal. The integrity of the earthing to all accessible metal parts of the equipment should be checked. The wiring (both inside and outside the equipment) should be neat and tidy, modifications, additions or extra wiring should be investigated (the internal wiring should only be examined if a service engineer is present). Cables should be protected where they pass through metal panels and covers and should not be strained or stretched. Access and protective covers should only be removable with the aid of tools to prevent possible accidental access to live parts.

#### **3.3 Mechanical safety**

Equipment should be installed following prescribed instructions and should be stable. Powered movement should, in general, be operated via 'dead man' type controls and emergency stop devices should be provided. X-ray tube assemblies should have over pressure protection or equivalent.

#### **3.4 Safety tests specific to mammography X-ray machines**

Many of these tests will already form part of the existing commissioning checks. An interlock should be provided to prevent powered vertical movement or powered rotation of the U-arm assembly with compression applied. The compression device must not be able to apply a compression force exceeding 300 Newtons and the maximum power driven compression force should be limited to 200 Newtons. Provision for emergency release of compression, in the event of system failure, must be provided.

### **3.5 Marking and accompanying documentation**

Equipment should carry labels with details of the manufacturer, country of origin, date of manufacture, model and serial numbers. The focal plane and details of the beam filtration should be marked. All controls should be clearly labelled as to their function. All equipment should be provided with clear operator instructions, service documents should also be provided and left on site with the equipment.

## **4. ENQUIRIES**

### **4.1 Technical Enquiries**

Technical enquiries in connection with this document should be addressed to:

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### **4.2 General advice**

General advice regarding electrical and mechanical safety testing may be addressed to the authors of this guidance. Alternatively, the Imaging and Acute Care section of the Device Technology and Safety group at the Department of Health Medicines and Healthcare Products Regulatory Agency (MHRA) may also be contacted.

### **4.3 National office of the NHS Cancer Screening programmes**

Further copies of this publication can be obtained from:

NHS Cancer Screening Programmes  
The Manor House  
260 Ecclesall Road  
Sheffield, S11 9PS

Telephone: 0114 271 1060  
Fax: 0114 271 1089  
E-mail: [NHS.screening@sheffield-ha.nhs.uk](mailto:NHS.screening@sheffield-ha.nhs.uk)

Information about the full range of NHSBSP Publications can be found on the NHS Cancer Screening Programmes website ( [ww.cancerscreening.nhs.uk](http://www.cancerscreening.nhs.uk))

### **4.4 Medical Devices Agency (MDA)**

Copies of MDA publications can be obtained from:

NHS Responseline  
Telephone: 08701 555 455  
Fax: 01623 724 524  
E-mail: [doh@prolog.uk.com](mailto:doh@prolog.uk.com)

Further information can be found on the Medical Devices Agency website ([www.medical-devices.gov.uk](http://www.medical-devices.gov.uk)).

## REFERENCES

1. *The Health and Safety at Work Act 1974*. Her Majesty's Stationary Office, 1974.
2. *Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Equipment*. Institute of Physics and Engineering in Medicine, 1997 (IPEM Report No 77).
3. *Medical Electrical Equipment: General Requirements for Safety*. British Standards Institution, 1989 (BS 5724-1: 1989, IEC 60601-1:1988).
4. *Technical Requirements for the Supply and Installation of Equipment for Diagnostic Imaging and Radiotherapy*. Department of Health, 1989 (TRS 89).
5. *Requirements for Electrical Installations (full revision of the 16th Edition of the IEE Wiring Regulations)*. British Standards Institution, 2001 (BS 7671: 2001).
6. *Medical Electrical Equipment, Particular Requirements for Safety - Specification for Mammographic X-ray Equipment and Mammographic Stereotactic Devices*. British Standards Institution, 2001 (BS 5724-2.45: 2001, IEC 60601-2-45: 2001).
7. *Commissioning and Routine Testing of Mammographic X-ray Systems*. Institute of Physical Sciences in Medicine, 1994 (IPSM Report No 59, 2nd edition).
8. *The Harrogate Seminar*, Department of Health, 1989 (STD/89/03).
9. *Acceptance Inspection of Radiological Apparatus*. Department of Health, 1985 (STB6A/85/15).
10. *Technical Guidance for Pre-installation Work for Diagnostic Imaging and Radiotherapy Equipment*, 1994 (TGP 1.0/93) (available from the authors of this guidance).
11. *Further Revisions to Guidance Notes for Health Authorities and NHS Trusts on Mammographic X-ray Equipment Requirements for Breast Screening*. Department of Health, 2001 (MDA01011).