

Medical Device Services

Because you need to be sure

Management is the key

There are a variety of legislative and guidance documents relating to:

- the requirement to manage medical devices
- the requirement to undertake formal, regular and recorded training of staff in how to safely use medical devices
- DoH/MHRA safety alerts and notices.

Why do staff need to do this?

Health and Safety at Work act 1974:

“It is incumbent upon both owners and occupiers of premises to ensure that there is a management regime for the proper... Operational management of plant, equipment and systems”.

Provision and Use of Work Equipment Regulations 1992:

The aim of these regulations is to ensure safe work equipment and safety in its use. It includes “any machine, appliance, apparatus or tool”, and clearly covers medical gas pipeline installations and equipment.

COSHH Regulations:

“The specific responsibilities for employers include assessment, protection and control, monitoring, health surveillance and information and training”.

MHRA (Medicines and Healthcare products Regulatory Agency) Device Bulletin DB 2006(05) Nov 2006 - Managing Medical Devices

This document provides detailed guidance on the management, training, and maintenance and repair of medical devices.

“It is intended to help .. set up systems that minimise risks associated with the use of medical devices.”

“Training is a key element in medical device safety. A training policy should be developed by the medical devices management group.”

“Professional users need to understand how it works normally, to be able to use it effectively and safely.”

“The frequency of servicing should be based on the manufacturer’s recommendations otherwise the provider will carry increased liability in any subsequent litigation.”



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So that is what is needed for the equipment, but what about the care and safety of the patient?

Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 – Regulation 16:

- 16.1 The registered person must make suitable arrangements to protect service users and others who may be at risk from the use of unsafe equipment by ensuring that equipment provided for the purposes of carrying on of a regulated activity is –
- (a) properly maintained and suitable for its purpose; and
 - (b) used correctly

CQC – Care Quality Commission – the “independent regulator of health and social care”

Publish ‘Essential Standards of Quality and Safety’

Outcome 11 specifically deals with – Safety, availability and suitability of medical devices and refers to Regulation 16 (above)

11A People are safe because, where equipment is provided or used as part of the regulated activity and the equipment is:

Installed, used and maintained correctly with reference to the specifications, manufacturer’s instructions, legislation and appropriate guidance from expert bodies.

Properly maintained, tested, serviced and renewed under a recorded programme.

11C People are safe because, where equipment is provided as part of the regulated activity, there are clear procedures followed in practice, monitored and reviewed. Wherever necessary these include:

How the equipment is maintained and used.

11F People who use services receive care, treatment and support that:

Ensures the medical devices used to meet their needs are:

Only used by the person, or by staff, once they know how to use and operate them correctly

Monitored while being used and action taken if they do not appear to be working correctly

Routinely maintained in line with the manufacturer’s instructions and by people who are competent to do so

Any nurse, dentist or doctor that plugs a flowmeter into an outlet or uses a medical gas cylinder is using the MGPS (Medical Gas Pipeline System)

Heath Technical Memorandum - HTM02-01 Part B Section 7

- 7.3 “It is essential therefore that personnel at all levels have a sound general knowledge of the principles and functions of MGPS (medical gas pipeline systems)”.

What can BOC Healthcare do to help?

BOC Healthcare can provide an annual test and inspection service to help you manage your medical devices. This service is just one of the Managed Equipment Services we offer.

Our partnership approach to our service not only achieves the requirement of your Chief Executive but also creates the foundations for you and your staff to ensure your own safety and the continuity of a safe system of life support for your patients.

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