

Gateway No 8199.

2007 Clarification and Policy Summary - Decontamination of Re-Usable Medical Devices in the Primary, Secondary and Tertiary Care Sectors (NHS and Independent providers).

Introduction

Improving and sustaining re-usable medical device decontamination services forms an important component of the Chief Medical Officer's strategy to combat Healthcare Associated Infection (HCAI) and is included in the reports 'Winning Ways'¹ and 'Getting Ahead Of The Curve'².

Healthcare organisations are required by the Health Act 2006 Code of Practice⁽³⁾ to provide a safe decontamination service that generates a clean and sterile product and is embedded as part of the Service culture in support of successful clinical outcomes and the associated wellbeing of patients and staff.

Major medical device decontamination improvement policies have, over the last eight years, focussed upon secondary or 'Acute Services' as this is where the perceived major risks of infection transmission particularly by surgical instruments exist. Much of this thinking was stimulated by continuing concerns over residual protein contamination, following decontamination, and the possibility that human prions could be spread in this way. Recent guidance from NICE draws renewed attention to the prion issues and has a particular focus on 'high risk tissues' including the brain and the structure of the back of the eye (posterior ophthalmics)⁴. The approach to the implementation of the NICE guidance together with other issues related to the Engineering and Science Advisory Committee into the decontamination of surgical instruments including Prion removal (ESAC-Pr) 2006 report⁵ are described in a Professional Letter from CMO (February 07)⁶.

However, the duty of care to all patients and staff crosses boundaries into all sectors of healthcare services and the risk of encountering pathogens, which may lead to Healthcare Associated Infection (HCAI), exists in Primary care as well as the Secondary and Tertiary care sectors. General Medical and Dental Services and other healthcare service providers will need to have in place modern services, and where relevant facilities that ensure decontamination is achieved in compliance with current DH Policy such that the quality and safety of the reprocessed or single use products is equal across all sectors.

This statement sets out the nature of that duty of care across all sectors of healthcare.

Background & overview

A sample survey (“snapshot”) of NHS surgical instrument decontamination activity in 1999 found many instances where the local implementation of decontamination services fell short of acceptable standards. The survey identified substantial improvements that could be achieved by more effective management of decontamination systems coupled with staff development and training.

In January 2001 the Minister for Health announced that the Government would invest £200 million to improve decontamination services in England under a programme administered and co-ordinated by the Department of Health Agency, NHS Estates. Two Health Service Circulars (HSCs)^{8,9} supported this change and improvement process.

Following on from the Snapshot Survey a more comprehensive review exercise was conducted which provided a basis for funding allocation and investment in the NHS. Recent surveys demonstrate a ‘step change’ including cultural improvements towards acceptance of decontamination work as a core service, without which the risk of iatrogenic spread of infection would be more pronounced. Current evidence suggests that the implementation of guidance has significantly improved and the service has moved markedly towards a professional basis with better standards of training and education¹⁰.

Context

In accordance with the philosophy engendered in the Policy ‘Shifting the balance of power’¹¹, as further described in the 07/8 NHS operating framework¹², responsibility for achieving acceptable standards of decontamination rests with Commissioners, individual Trusts and provider organisations.

Reprocessing units in healthcare establishments responsible for the decontamination of medical devices fall into two distinct categories when considering compliance with the EEC Medical Devices Directive (MDD)¹³ :

- Devices transferred between legal entities (example - reprocessing by one entity followed by use in another)(a).
- Devices remaining within one legal entity (example – reprocessing and use by the same entity or organisation)(b).

The MDD is adopted into UK law within the Consumer Protection Act¹⁴ as the Medical Devices Regulations (MDR) 2002^{15, 16}. For decontamination units, the Regulations lay down a set of essential requirements that must be met to ensure that reprocessed devices are safe and fit for purpose when they are placed on the market.

Key areas requiring compliance are stated within the Essential Requirements of the MDD/MDR. For decontamination units, these would include the control of processes and the working environment (e.g.: satisfactory equipment validation and maintenance programmes, segregation and control of differing zones of cleanliness). The MDR also require that a recognised quality management system be implemented across all areas of the unit. This can be demonstrated by compliance with the standard BS EN ISO 13485:2003¹⁷, *Medical Devices; Quality Management Systems*.

a. Devices transferred between legal entities – healthcare establishments reprocessing medical devices with the intention of offering them to another legal entity are subject to the full requirements of the MDR. If sterile devices are reprocessed and placed on the market, then the utilisation of a third party audit programme by a recognised Notified Body (NB) is required. An NB is a certification organisation or test house, which the Competent Authority, The Medicines and Healthcare products Regulatory Agency (MHRA) for the UK, designates to carry out one or more of the conformity assessment procedures described in the annexes of the MDR.

Decontamination units must also register with the MHRA and as such may be subject to compliance inspection by the MHRA itself¹⁰.

b. Devices remaining within one legal entity – if a healthcare establishment only provides reprocessed medical devices for use in the care of its' own patients within that same entity (i.e. there is no placing on the market) the requirements of the MDR do not apply.

Such decontamination departments do not need to register with the MHRA nor do they need to use a Notified Body, nevertheless they are subject to the duty of care imposed under Product liability legislation¹⁴.

However, as a matter of Policy such units should still meet the appropriate essential requirements of the MDR, producing goods "fit for purpose" and of suitable quality¹³. Compliance with the standard BS EN ISO 13485:2003, *Medical Devices; Quality Management Systems*¹⁷. Would be seen as demonstrating a commitment to producing goods of appropriate quality. This is consistent with previous advice in Executive Letter EL(98)5¹⁸, in that such units should operate to the same standards as industry and may provide a due diligence defence in the event of claims or litigation related to product liability.

In 2003, the Department of Health (NHS Estates) published its Strategy for Modernising the Provision of Decontamination Services¹⁹. This document set out 55 key recommendations for improving decontamination within the NHS. Over 20 of these recommendations focused upon technical aspects of the

decontamination process that organisations should ensure they adopt. The strategy is also essentially concerned with commercial involvement in decontamination services and creates the “supercentres,” which may be used as an option when seeking suitable suppliers.

Further Development, Audit and Inspection

Some decontamination providers including hospitals and PCTs still have a need for investment, to enable them to move out of unsuitable buildings, replace ageing equipment and to reduce inappropriate ‘local processing’ such as the use of non-compliant, non-validated bench top sterilizers. In addition, the demand for reprocessing is increasing because of rising surgical activity in primary, secondary and tertiary care settings.

The establishment and assessment under relevant Healthcare Standards is seen as key to ensuring effective and compliant decontamination services. As part of the empowerment agenda in ‘shifting the balance of power’, the responsibility for maintaining Standards is established with Commissioners, NHS Trusts and other Service providers.

The Regulatory responsibility for Healthcare Standards is vested with the Healthcare Commission (HCC)²⁰, with the decontamination of re-usable medical devices being included in their assessment programme from April 2007. The decontamination standard in Standards for Better Health (SfBH)²¹ for the NHS and alternatively for the Independent sector, National Minimum Standard. Both of these require decontamination to be responsibly carried out in facilities, which accord to guidance issued, by MHRA and the MDD 93/42/EEC.

Those decontamination departments registered with MHRA are already subject to the legal requirements of the MDR with conformity assessment and review by notified bodies as well as compliance inspection being part of the process. These registered departments will therefore not fall within the remit of the HCC for compliance with the MDR but will remain with their Notified Bodies and the MHRA as part of their legal requirement.

It is the intention that the HCC will use the appropriate MDR Essential Requirements as the basis for their scheme of inspection for those decontamination departments that are not required to register under the MDR. For the implementation of the NICE guidance HCC will use new requirements based on the outcomes from a stakeholder consultation process during spring of 2007.

Further to the Essential Requirements, there are a range of alternative methods of achieving a compliant service. Detailed below are a number of specific options to assist organisations when planning local responses to comply with Commissioners Decontamination Strategies and DH Policy. A key consideration in the selection of an appropriate strategy is Risk Management. Advice on strategy choice maybe available from SHA Estates groups. The national decontamination programme cited in option No 1 has been developed with risk transfer and affordability as key elements.

The options are:

1. Use a decontamination service which is registered with the MHRA who are compliant with the MDR and who use a Notified Body as their third party auditor.
2. Use a decontamination service, which is subject to the HCC audit programme.
3. Use of CE marked single use medical devices
4. Employ a strategy, which features a combination of the above.

Summary

Local needs and facilities will determine the ways in which the service is provided, but the decontamination service must comply with the DH Policy and MDR 'essential requirements'. A key consideration in the selection of an appropriate strategy is Risk Management.

The relative merits of the options should be evident through developing a business case highlighting the options, timescales, and costs benefit and reliability assessment. Any such plan should indicate the proposed compliance with 'standards for better healthcare' and provide a forward-looking aspect to progressively improve standards within approved timescales.

Those centres involved in procedures where high-risk tissues may be involved should be mindful of the requirements of the NICE guidance and seek compliance as the current ESAC-Pr Stakeholder consultation process develops and reports.

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