

Decontamination of Medical Instruments – Information for LMCs and GPC members

Introduction

We are aware that there has been some confusion with regard to sterilisation and decontamination of medical devices from 1st April 2007.

The situation is still not entirely clear, but the Department of Health have informed us that there is to be no change in the legislative and regulatory framework that will apply to GP practices from 1st April 2007.

However, GP practices will need to (and should already) comply with current legislation and regulations for sterilisation and decontamination of medical devices. If they have not done so already, practices will need to take steps to ensure that they are in compliance. Ultimately, it is the responsibility of individual practices to ensure that they are compliant with current legislation.

There has been a change in legislation affecting PCTs, who are now obliged to ensure that organisations from which they commission healthcare services are in compliance with current legislation – hence the recent letters to practices informing them of “new regulations”.

Current legislation and regulation affecting decontamination is complex and scattered across a number of sources. Additionally, there is no one central guidance document covering this area. As a consequence, it may be challenging for GP practices to independently interpret the current requirements.

A number of key documents and sources that may assist practices have been detailed at the end of this document. In the first instance, however, practices who are uncertain of whether they comply with current legislation should contact their Strategic Health Authority, who will have drawn up their own decontamination policy and should be able to provide relevant locally focussed advice.

In view of the confusion currently surrounding decontamination, the GPC has requested that the Department of Health and Chief Medical Officer take steps to clarify the situation.

Practical impact

Those practices whose decontamination facilities meet current requirements can, of course, continue to use their own in-house facilities.

However, in many cases, it may not be practical or cost effective for GP practices to undertake sterilisation and decontamination in-house. In such cases, a number of alternative options are available. These include:

- Switch to single use instruments
- Send instruments for sterilisation at an off-site location that is compliant with current standards (for example, a local hospital CSSD site, a super-CSSD site, or even another GP practice).
- Use a combination of the above options

Each option has its advantages and disadvantages, and practices will need to carefully consider which approach will be the most suitable for their needs. Wessex

LMCs have produced a guidance document which explores these issues further, and may help with practices' decision making process:

<http://www.wessexlmcs.com/page112.html>

Many practices have purchased decontamination equipment, and will want to protect their investment. We are aware that a number of PCTs have offered to buy decontamination equipment from practices, and it may be helpful to explore this option. Other practices may want to consider whether it would be cost effective to make the further investment required to comply with current legislation, and perhaps then offer to decontaminate medical devices on a commercial basis for the use of other practices.

Practices may also wish to consider the impact that switching to off-site sterilisation or the use of disposables will have on the cost of services that they provide.

***GPC Secretariat
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Where to go for further information

NHS Decontamination Programme website:
<http://deconprogramme.dh.gov.uk/default.aspx>

NHS National Decontamination Training Programme:
http://www.decontamination.nhs.uk/lms/nhs_splash/nhs_splash.asp

Wessex LMCs guidance - Options for General Practices:
<http://www.wessexlmcs.com/page112.html>

Council of the European Communities Directive 93/42/EEC:
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML>

Health Service Circular 1999/178:
http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/HealthServiceCirculars/HealthServiceCircularsArticle/fs/en?CONTENT_ID=4004969&chk=FGE%2BEj

Health Service Circular 1999/179:
http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4004321

Health Service Circular 2000/032:
http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/HealthServiceCirculars/HealthServiceCircularsArticle/fs/en?CONTENT_ID=4002990&chk=sHEhLb

Health Technical Memorandum 2010:
http://195.92.246.148/knowledge_network/documents/HTM2010%20Sterilization%20Management%20policy%202003115124130578.pdf

Health Technical Memorandum 2030:
<http://www.grs.nhs.uk/instantkb13/Attachments/htm2030-GUID3732f3f645624282abc86223fb55e6ea.pdf>

National Decontamination Strategy (National Standards – Local Delivery):
http://www.dh.gov.uk/en/Policyandguidance/Organisationpolicy/Estatesandfacilitiesmanagement/EngineeringEnvironmentAndTechnology/DH_4118225