

THE DECONTAMINATION OF SURGICAL INSTRUMENTS AND OTHER MEDICAL DEVICES

**Report of a Scottish Executive Health Department
Working Group**

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CONTENTS

EXECUTIVE SUMMARY

1. INTRODUCTION AND BACKGROUND

- 1.1 Introduction
- 1.2 Background
- 1.3 Decontamination practice

2. REVIEW OF CURRENT DECONTAMINATION PRACTICES IN HEALTHCARE PREMISES

- 2.1 Aim and objectives
- 2.2 Methodology
- 2.3 Results
- 2.4 Conclusions

3. DISCUSSION AND RECOMMENDATIONS

- 3.1 Discussion
- 3.2 Recommendations

APPENDICES

- 1 Membership of Working Group
- 2 Glossary of terms used in the report
- 3 Decontamination Standards and Guidance used in the Review
- 4 Membership of Review of Decontamination Practice Teams
- 5 Bibliography

EXECUTIVE SUMMARY

Decontamination is the combination of processes, including cleaning, disinfection and/or sterilisation, used to render a re-useable medical device (e.g. surgical instrument) safe for further use. Today decontamination is an issue of public health importance because of concerns about preventing hospital acquired infections (HAI) and minimising the theoretical risk of iatrogenic transmission of transmissible spongiform encephalopathies (TSEs), especially variant Creutzfeldt Jakob Disease (vCJD).

There is little collated routine data on the efficacy of decontamination in the NHS. There has not been an in-depth study of this area for more than 40 years. The Scottish Executive Health Department (SEHD) therefore established a Decontamination Working Group to advise it with regard to the following:

1. Are current guidelines on the cleaning and sterilization of surgical instruments adequate?
2. How effectively is that guidance being implemented?
3. What practical difficulties are there in ensuring good practice?
4. What measures need to be taken to improve the effectiveness of decontamination in the NHS in Scotland?

The Working Group recommended that SEHD carry out a review. The Scottish Centre for Infection and Environmental Health were commissioned to carry this out with technical support from NHS Estates (England).

A team of specially trained assessors reviewed decontamination practice in 4 NHS Hospitals, 1 private hospital, 5 general medical and 5 general dental practices. They investigated:

- The management of the decontamination process;
- Central Decontamination Units (serving one or more hospitals);
- Local Decontamination Units (serving local clinical departments or general medical or dental practices).
- The safe use of medical devices

Indicators of good practice in each of the separate decontamination processes were derived from extant guidance. Key findings were identified as they related to these indicators.

Examples of excellent practice, with modern well maintained, validated, equipment in appropriate facilities with a controlled environment were found. Staff were on the whole hard working. This shows that high standards can be achieved. However most of the sites assessed were deficient in a number of key areas. In general decontamination processes have many shortcomings which could increase the likelihood of adverse health occurrences to both patients and staff.

Current guidelines are adequate in terms of their technical content although as more evidence becomes available on prions and vCJD, they are likely to require updating. However guidance is often written in language which makes it difficult for operators to understand its meaning and relevance to their work.

Current guidance is not being implemented effectively for two main reasons. The first is the lack of any organisation-wide, coherent management control of re-usable medical devices and their re-processing. The second is the lack of resource put into ensuring equipment meets performance criteria as indicated in British, European and other technical standards. This was a particular issue with washer disinfectors.

There are many practical difficulties in implementing the guidance. Decontamination often takes place in unsuitable environments which constrain the ability to separate “clean” from “dirty” processes. Many items of equipment are in need of replacement or upgrading. Documented evidence of training in decontamination practices is uncommon and a significant proportion of staff in local units receive no decontamination training. With the exception of flexible endoscopes, the matching of medical devices (such as surgical instrument trays) to the patients on whom they have been used is usually not possible.

The Working Group’s view is that the state of decontamination practice in the NHS in Scotland gives serious cause for concern. Urgent action is required to remedy a series of major deficiencies. It recommends the following

1. *Awareness:* SEHD urgently needs to increase NHS Trusts’ and other healthcare providers’ awareness of the importance of good decontamination practices.
2. *Guidance:* At the present time no new guidance is required. As a matter of urgency however, SEHD should review the style and presentation of guidance and how it is disseminated. Based on the findings of the review, actions should be taken to ensure that the right information on decontamination reaches the right person at the right time so that the recipient understands and can act on it.
3. *Standards:* Trusts, hospitals and primary care organisations require to audit their achievement of decontamination standards. SEHD should collaborate with other UK Health Departments in developing the methodology utilised in the review as a tool for this and should include monitoring the achievement of adequate standards in decontamination practice in its performance review and risk management processes.
4. *Compliance:* SEHD should collaborate with the other UK Health Departments in instituting any measures necessary to ensure that Trusts and other health care providers take action to improve poor levels of decontamination practice as soon as these are detected.
5. *Management:* Trust senior management should undertake an assessment of the infection and decontamination risks associated with their services, ensure that overall standards of decontamination practice are monitored and co-ordinate decision-making on decontamination, infection control, health and safety and the acquisition and disposal of surgical instruments. Infection control personnel should have a recognised role in advising on the purchase and planning of decontamination facilities and equipment.
6. *Staff performance:* Trusts should ensure that decontamination of re-usable medical devices is managed and undertaken only by suitably trained personnel. Trusts need to assess the recruitment, retention and training requirements of Central Decontamination Units and put in place measures which motivate staff to deliver an improved level of service.
7. *Training:* SEHD should develop a national framework for training in decontamination which determines the level of knowledge and skills required by NHS staff, indicates available accredited courses, integrates training in this area with continuous professional development and defines standards for monitoring Trusts and other organisations.

8. *Washer disinfectors*: Trusts should be requested to review whether their current equipment is meeting or is capable of meeting current standards, prepare plans for remedying any deficiencies and ensure that ongoing monitoring is undertaken by appropriately trained personnel. SEHD should collaborate with other UK Health Departments in investigating the efficacy of washer disinfectors in removing potentially infective tissue.
9. *Traceability*: Trusts should ensure that mechanisms are in place and operating at ward level.
10. *Surgical instruments*: SEHD should continue to collaborate with other UK Health Departments and professional organisations in defining standard sets of instruments for specific procedures. Trusts should review their stock of instruments to identify the level needed for decontamination units' turn-around times for reprocessing. Infection control personnel should be consulted on the procurement of instruments.
11. *Single use instruments*: SEHD should liaise with the other UK Health Departments and the Medical Devices Agency to ensure that the practice of re-using single use instruments ceases.
12. *Dentistry*: SEHD should develop a programme to improve decontamination and infection control practice in dentistry.
13. *Decontamination Units*: A review should be carried out to determine the most cost-effective configuration of decontamination units and operational practices (building on a previous SEHD report on their provision).
14. *Resources*: SEHD should urge Trusts and other healthcare providers to invest the level of resource needed to improve decontamination practice to an acceptable level. Immediate priorities for investment are:
 - To make guidance more understandable to users;
 - To develop a framework for training staff working in decontamination;
 - To increase stocks of surgical instruments to the levels necessary for good decontamination practice;
 - To upgrade washer disinfectors;
 - To install information systems which ensure traceability.

SEHD should review performance in these areas.

SECTION 1 - INTRODUCTION AND BACKGROUND

1.1 Introduction

There is a growing awareness of the impact of hospital acquired infection on resource utilisation in the NHS. Evidence is also increasing that this problem is affecting primary care services. The adequate decontamination of medical devices is one factor in their prevention.

With concern over the potential risk of person to person transmission of vCJD through the use of medical devices (iatrogenic transmission), the UK Health Departments have reiterated the importance of following published guidance on the decontamination of medical devices¹.

The Scottish Executive Health Department therefore established a Working Group, led by Dr. David Old, Reader in Microbiology at the University of Dundee Medical School to advise it with regard to these questions:

1. Are current guidelines on the cleaning and sterilisation of surgical instruments adequate?
2. How effectively is that guidance being implemented?
3. What practical difficulties are there in ensuring good practice?
4. What measures need to be taken to improve the effectiveness of cleaning and sterilisation in the NHS in Scotland?

The Working Group met on four occasions. Appendix 1 provides details of its membership.

There is little collated routine data on the efficacy of decontamination in the NHS. SEHD therefore commissioned NHS Estates and the Scottish Centre for Infection and Environmental Health (SCIEH) to carry out a review of current decontamination practices in healthcare premises in Scotland. Healthcare premises are defined as NHS Trust hospitals, general medical and dental practices and private hospitals. The aims and objectives, methodology, results and conclusions of the review are presented in section 2 of this report.

The findings of the Review were presented to the Working Group. Following careful consideration, the Working Group put forward a number of recommendations which are presented in Section 3 of this report.

1.2 Background

Decontamination is the combination of processes, including cleaning, disinfection and/or sterilisation, used to render a re-useable medical device safe for further use (see Appendix 2). Historically the development and introduction of decontamination techniques and practices have underpinned the expansion of healthcare especially in hospitals.

Today decontamination is an issue of public health importance because of:

a. Hospital acquired infection (HAI)

An estimated 9% of hospital in-patients have a hospital acquired infection at any one time³, the most common being urinary tract, surgical wound and lower respiratory tract infections. Common risk factors are the state of health of the patient (e.g. underlying chronic illness, concomitant infections, poor nutritional status), other therapies (especially immuno-suppression) and the type of procedure performed (especially catheterisation and “dirty” surgical operations)⁴.

It is estimated that between 15% and 30% of HAI can be prevented by better application of existing knowledge and realistic infection control practice⁵. The proportion of HAI which could be prevented by improved decontamination practice is difficult, if not impossible, to estimate. However it is well known that decontamination failures can result in a range of infections^{6,7}. It is likely that in many sporadic cases of HAI, the fact that ineffective decontamination has been a contributing factor, will often go unrecognised. Effective decontamination can therefore make an important contribution to lowering the prevalence of HAI.

b. The theoretical risk of iatrogenic transmission of vCJD

Available epidemiological evidence suggests that normal social or routine clinical contact with a patient suffering from any type of CJD (including vCJD) does not present a risk of transmission. There is no evidence of vCJD having been spread from person to person in healthcare situations. However the possibility that vCJD can be transmitted in this way arises from a number of reasons:

- Classical CJD has been transmitted from person to person by neurosurgery, corneal and dura mater transplantation and injection of human growth hormone. One study has found sporadic CJD to be significantly associated with surgical treatments⁸ although another did not confirm this.⁹
- Although there is no complete consensus as to the nature of the agent which causes BSE and vCJD, there is general agreement that a corrupted form of a protein, prion (PrP), is at least a component of such an agent. The disease specific form of PrP, designated PrP^{Sc}, has been found in the tonsils, spleens and lymph nodes of patients who have died from vCJD (and not in any of the same tissues from matched controls)¹⁰ and in the appendix of a vCJD case extracted 1 year before the onset of illness¹¹.
- PrP^{Sc} is resistant to the most common techniques for inactivating infectivity in tissue¹². The most effective heat kill for PrP^{Sc} requires exposure to steam heat at 134°C for 18 minutes in a porous load autoclave although up to an hour may be required and even this may not result in sterilisation. Concentrated sodium hypochlorite solutions appear to achieve complete inactivation¹³. The complete removal of infectivity appears therefore to be extremely difficult¹⁴ although current sterilisation techniques utilised in health care should reduce the level of infectivity present. Effective cleaning to remove protein from medical devices is therefore paramount.

The Spongiform Encephalopathy Advisory Committee (SEAC) which advises UK government departments on transmissible spongiform encephalopathies, considers that the effective decontamination of instruments is a key measure in reducing the risk of TSEs. Increasing attention is therefore being paid to ensuring medical devices are effectively decontaminated before re-use and when necessary and wherever possible, employing single-use instruments for a range of procedures.

A joint SEAC/ACDP (Advisory Committee on Dangerous Pathogens) group advises government and produces guidance on infection control measures related to vCJD and other TSEs in health care settings. Their most recent guidance was published in 1998¹⁵. It outlines a series of measures which are constantly reviewed in the light of new findings about these unusual diseases and the agents which cause them.

1.3 Decontamination Practice

The aim of decontamination is to make re-usable medical devices safe for use on a patient and for staff to handle without presenting an infection hazard.

The Working Group limited its considerations to the decontamination of re-usable medical devices particularly those that are invasive by intent, (e.g. surgical instruments) or are likely to be invasive inadvertently. Decontamination of sanitary appliances, general laundry processes, cleaning of crockery/cutlery etc. was not reviewed. Neither was the use of antibiotics as a decontamination measure considered.

The processes involved in decontamination are described using the model developed by NHS Estates, of the “life-cycle” of re-usable surgical instruments (see Figure 1.1). Relevant definitions are included in Appendix 2.

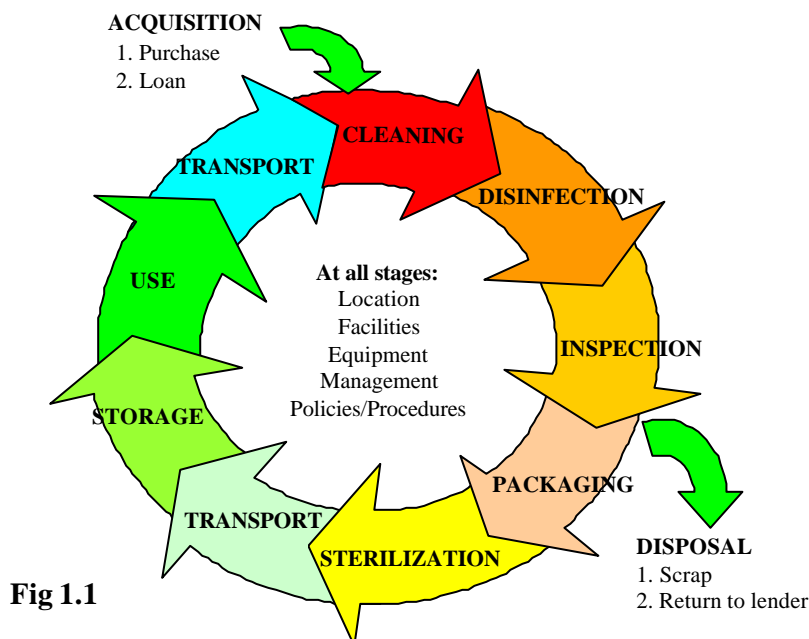


Fig 1.1

To undertake decontamination effectively requires all the processes illustrated in the life cycle to be implemented correctly, with appropriate controls and monitoring in place. The speed at which medical devices pass through the cycle can impact on the efficacy of decontamination. A key factor influencing this is the size of the stock of devices requiring processing. Achieving minimum

standards at each stage of the life cycle depends on location; facilities available; equipment used; how the process is managed, and the policies and procedures employed. The basic requirements for good decontamination practice are summarised in Table 1.

Table 1	
Basic requirements for good decontamination practice	
<ul style="list-style-type: none"> • An effective management control system is in place covering all aspects of the decontamination cycle; • Appropriate facilities are provided; • Appropriate equipment is utilised which is: <ul style="list-style-type: none"> – Fit for purpose; – Properly maintained and calibrated; – Properly monitored and validated. • Staff are properly trained and supervised; • Single use medical devices, are not reused; • Records of decontamination are kept. 	

Wherever possible, decontamination processes should be automated. Systems should be in place which trace medical devices through the life cycle and can link them to the individual patients they have been used on.

In Scotland, the facilities in which the key decontamination processes of cleaning, disinfection and sterilisation take place fall into two broad, but not mutually exclusive categories:

- Sterile Services Departments (also known as Central Sterile Services Departments or Trust Sterile Services Units) where instruments from a number of clinical wards and departments are reprocessed on behalf of the Trust or hospital. Services are also provided to primary care. A review of sterile services provision undertaken in 1997 by a Scottish Office Health Department (Best Value) National Working Group identified at that time 29 departments in Scotland operating with assets in excess of £15m (including instrumentation) and processing over 31,000,000 instruments per annum. Five hundred whole time equivalent staff were employed with operating costs in excess of £16m per annum. For the purposes of this report these are referred to as '*Central Decontamination Units (CDUs)*'.
- Ward or operating theatre or clinic or general medical or dental practice based facilities where only instruments from within that clinical department are decontaminated before reuse. The number of these is unknown. The items of equipment employed are usually bench top sterilisers or washer disinfectors (see Appendix 4). Most staff carrying out decontamination processes will have other responsibilities. These facilities are referred to in this report as '*Local Decontamination Units (LDUs)*'.

Guidance and specific requirements relating to decontamination practice have been published over many years. The standards applied have become more stringent as a result of greater knowledge and experience. Technological advances such as microprocessor control systems have made better control economically feasible. Information about decontamination is currently available to healthcare organisations through:

- European and British Standards published by the British Standards Institution;
- Scottish Health Technical Memoranda (SHTM), Medical Device Bulletins, Health Department letters and other guidance documents published by the Scottish Executive Health Department and related government departments and agencies. The NHS in Scotland Healthcare Property and Environment Forum Executive produce the Scottish Health Technical Memoranda (SHTMs) and provide technical advice to the NHS in Scotland.

- Guidance produced by Government advisory bodies principally the Advisory Committee on Dangerous Pathogens (ACDP) and the Spongiform Encephalopathies Advisory Committee (SEAC);
- Guidance produced by professional bodies such as the Institute of Sterile Services Managers, British Dental Association, British Society for Gastroenterology, Central Sterilising Club etc;
- The current scientific evidence base.

A summary of principal standards and guidance is presented in Appendix 3. Guidance on the decontamination of medical devices has been collated in a CD-ROM and issued to all NHS Trusts and related organisations¹⁶.

No single agency has responsibility for ensuring compliance to standards and guidance related to the decontamination cycle. The following have a role:

- The Medical Devices Agency (MDA) is the government agency charged to ensure that medical devices meet appropriate standards of safety, quality and performance. It is the UK Competent Authority under the European Medical Devices Directives.
- Scottish Healthcare Supplies (a division of the Common Services Agency of the NHS in Scotland) offers a range of equipping and technical services to the NHS in Scotland including that of the Authorised Persons (Sterilisers) (AP(S)) as outlined in the SHTM 2010 (see Appendix 3). The role of the AP(S) is to:
 - provide general and impartial advice on all matters concerned with sterilisation;
 - advise on programmes of validation;
 - audit reports on validation, revalidation and yearly tests;
 - advise on programmes of periodic tests and periodic maintenance;
 - advise on operational procedures for routine production

- Health Boards

The SEHD's "Scottish Infection Manual"¹⁷ provides guidance on core standards for the control of infection in hospitals, healthcare premises and the community interface. Health Boards are responsible for ensuring that adequate standards of infection control are met by NHS organisations in their area especially by assessing the adequacy and effectiveness of infection control policies and procedures.

- NHS Trusts

Since 1 April 1999, the corporate governance of all NHS bodies in Scotland has encompassed both financial and quality issues. Trust Chief Executives are accountable for ensuring care delivered within each Trust meets relevant standards.

The SEHD Manual¹⁷ recommends that all Trusts have Infection Control Committees and Infection Control Teams, which are responsible for preparing infection control policies and monitoring compliance with standards (as specified by the Health Board). It is recommended that among those policies should be one for cleaning, disinfection and sterilisation.

The guidance contained in SHTM 2010 (see Appendix 3) indicates that senior management should designate a Microbiologist (Sterilizers) who is responsible for advising the user of sterilizers on the microbiological aspects of washing, disinfection and sterilization.

Healthcare providers have responsibilities under the Health and Safety at Work etc. Act 1974 and the Control of Substances Hazardous to Health (COSHH) Regulations to ensure the health and safety of their employees and others (including visitors and patients) and to control and manage the risk of infection.

SECTION 2

REVIEW OF CURRENT DECONTAMINATION PRACTICES IN HEALTHCARE PREMISES

2.1 Aim and Objectives

The aim of the Review was to provide an assessment of current practice in the cleaning and sterilisation of re-usable surgical instruments by:

- describing the nature of current decontamination practices across healthcare sectors in Scotland;
- evaluating how well these practices concord with current guidance;
- providing an evidence base for the development of further control measures to reduce the potential risk of iatrogenic spread of vCJD from surgical procedures.

2.2 Methodology

2.2.1 Study Population and sample

The following were chosen from across Scotland from each the main types of providers of healthcare services:

- 2 District General Hospitals (one serving a mixed urban/rural, one serving a predominantly rural population);
- 1 Dental Hospital;
- 1 Private Hospital;
- 1 Teaching Hospital;
- 5 General Medical Practices;
- 5 General Dental Practices.

There was no attempt to obtain randomisation or a 'blind trial'.

The study was therefore composed of 15 healthcare sites, of which all but the private hospital were part of NHS Trusts. CDUs and/or LDUs included in the survey provided decontamination services to a variety of clinical departments on the sites. Clinical departments are: hospital wards, outpatient clinics, A&E departments, operating theatres, general medical and general dental practices. The survey encompassed:

- hospitals and primary care sites in 9 NHS Trusts;
- 4 CDUs;
- 56 LDUs (including one in the private hospital);
- 152 clinical departments.

2.2.2 Survey Methods

The survey was led by a Project Co-ordinator from SCIEH with a Technical Co-ordinator charged with ensuring consistency in the assessment of equipment performance.

A Development of Reporting Forms

Standardised reporting forms were developed by an NHS Estates multidisciplinary working group using assessment criteria based on the requirements of relevant European and British standards and of other guidance on best practice (see Appendix 3). They were designed to ensure a consistent and comprehensive approach to data collection. The forms incorporated a number of internal quality checks to validate the accuracy of the data obtained.

B Data Collection

Teams of trained assessors, led by a lead assessor, visited each site by appointment and completed a set of reporting forms. All of the assessors took part in a three-day training programme. The site visits consisted of 3 to 4 days on site, for 3 to 4 assessors, for each NHS hospital; 1 day for 2 assessors for the private hospital and up to 1 day for 2 assessors in each primary care site.

Data was collected through observing practices, inspecting equipment, interviewing staff and reviewing documentation. Although the focus was on cleaning, disinfection and sterilisation practices, information was obtained on associated activities, which might affect the efficacy of reprocessing. These included the management and location of decontamination processes, healthcare activity at each site, facilities and equipment at each location, and the validation, testing and maintenance of equipment. It was therefore necessary to visit all parts of each site where instruments were either decontaminated or used.

The following key personnel were interviewed wherever possible: Chair of Infection Control Committee, Consultant Microbiologist, Microbiologist (sterilizers), infection control doctors and nurses, Sterile Services Manager, Estates Manager, and managers of clinical departments.

C Data quality

The Lead Assessor for each site visit checked the consistency of the collected data at the end of the visit. The Technical Co-ordinator undertook quality control of the process as it related to technical standards by reassessing equipment previously examined.

D Data Processing & Analysis

Data was entered into a relational database and analysed using EXCEL and SPSS v10. Sites and decontamination units were allocated a code to ensure confidentiality.

Data were analysed and discussed by the Project Co-ordinator, the Technical Co-ordinator and staff from NHS Estates. The key findings from this process were presented to the Review Team members and discussed as to their accordance with their observations made during the survey.

E Data Presentation and feedback

Indicators of good practice in each of the separate processes in the decontamination cycle were derived from extant guidance and reported as they related to:

- The management of the decontamination process (unless otherwise indicated, findings are from the 15 sites);

- Central decontamination units (findings are from the 4 CDUs);
- Local decontamination units (unless otherwise indicated, findings are from the 56 LDUs);
- The safe use of medical devices (findings are from sites, LDUs and clinical departments).

At the end of each visit, the Lead Assessor prepared a summary report and fed back key points to management representatives. The NHS hospitals in the survey subsequently received a full written report and a further visit to consider the report and resultant action.

2.3 Results

2.3.1 Management of the Decontamination Process

a. Roles and Responsibilities

Key Indicators of good practice
1. One senior manager responsible to an Executive Director in the healthcare organisation maintains an overview of decontamination processes.
2. Managers of CDUs and clinical departments with LDUs have defined roles and responsibilities related to decontamination.
3. Each Trust has an Infection Control Committee.

The review found no evidence of a senior manager having specific responsibility for the range of decontamination processes (as defined in Figure 1.1), which took place in the healthcare organisation visited. There were a variety of organisational arrangements for managers of CDUs. The review found that managers of clinical departments with LDUs were often unclear as to their responsibilities with regard to the decontamination processes.

All hospitals reviewed had an Infection Control Committee (ICC). There were no committee structures found for infection control in primary care. In all but one hospital, ICCs had representation from Estates Departments. In all hospital sites, the roles and responsibilities of the various staff involved in infection control were documented. Only 1 of 10 Primary Care sites had the roles and responsibilities of personnel defined and documented.

b. Risk Assessment

Key indicator of good practice
1. Risk assessments undertaken to identify hazards related to decontamination.

Only one site had identified the risks attendant on poor decontamination practice. The risk assessment however was restricted to consideration of the process chemicals used and the risk of blood borne infection from needle stick injury.

c. Policies and Procedures

Key indicators of good practice
1. Infection Control policy contains decontamination section and guidance on TSEs
2. There is a documented policy on the procurement of medical devices and decontamination equipment.

All of the hospital sites had a documented policy for infection control. Three of the 5 hospital sites' infection control policy contained a reference to decontamination. However this related either to the disinfection of the clinical environment or to the use of specified chemical disinfectants in washer disinfectors. In only 2 hospital sites was there a policy concerning the use of CDU versus LDU services.

Two of 5 general dental and 3 of 5 general medical practices had a policy for infection control. In only one of the 10 primary care sites did infection control policy refer to decontamination but not as it related to medical devices. One primary care site had a policy concerning the choice of CDU or LDU.

In no sites did the infection control policy cover specifically the whole process of decontamination of flexible endoscopes. Clinical departments with endoscope washers had produced their own local policies. In some cases these were in direct conflict with the site control of infection policy on the suitability of particular disinfectants.

Only five sites (four hospitals, one primary care) had procedures in place through their infection control policy, to implement the guidance given in the ACDP/SEAC publication on Transmissible Spongiform Encephalopathy Agents¹⁵ or the recent Management Executive Letter on decontamination¹⁶.

Only one site (a hospital) had a policy on the purchase of medical devices, which included formal consideration of their decontamination. Four sites (3 hospital and one primary care) had evidence of a policy on the choice of re-usable or single-use medical devices where both were available for a given procedure. Eight sites had a policy prohibiting the re-use of medical devices designated as single use.

Fifty-two of the 152 clinical departments included in the survey responded to a request for information about a local policy for the acquisition of medical devices. Twenty-seven (26 hospital, 1 primary care) had a documented specification for a medical device drawn up prior to its purchase. Nine had undertaken reviews to establish the decontamination requirements of the devices involved.

d. Standards and monitoring

Key indicators of good practice
1. An Authorised Person (Sterilizers) provides independent auditing and advice on sterilization and on washing/disinfection.
2. Microbiologist (Sterilizers) provides guidance on various aspects of decontamination.
3. Infection Control Nurse undertakes periodic audits of LDUs.
4. Clinical and non-clinical staff are aware of key guidance relevant to their duties.

Of the 5 hospital sites reviewed, 3 had appointed an AP(S). Only one of the AP(S) appointed was asked to discharge the full range of duties specified for this role. None of the five hospitals had appointed a Microbiologist (Sterilizers). Only 1 primary care site had appointed an AP(S). None had appointed a Microbiologist (Sterilizers).

All NHS hospitals had an Infection Control Nurse. All 5 general practices and 1 of the 5 dental practices could seek advice from local hospital Control of Infection Nurses. Only 2 out of 5 hospitals reviewed had a system for periodic audit of LDUs.

Staff on all sites were offered the opportunity to comment on the available guidance. The following summarises the main points raised:

- most guidance documents are difficult to obtain and understand;
- information on a single decontamination topic is often dispersed through a number of documents;
- occasional publications (such as Device Bulletins (published by the MDA) and Management Executive Letters) do not always reach the appropriate person;
- there is a limited availability of the CD-ROM on Decontamination Guidance¹⁶ in CDUs and LDUs;
- there is a lack of awareness of the guidance on TSE agents¹⁵ in hospital sites outside of neurology, ophthalmology and morbid anatomy departments;
- there is a low level of knowledge of the meaning of the graphical symbols specified in the guidance for use on Medical Devices.

e. Training

Key indicator of good practice
1. Documented evidence exists of training relevant staff in appropriate decontamination procedures.

All CDUs reported that staff were trained in decontamination procedures. Documented evidence of the training received was found in only one CDU. Evidence was obtained of training in the other CDUs but this was not recorded. Thirty-five out of the 56 LDUs reported that they undertook training but documented evidence of the training received was only available in 11. Twenty-one LDUs (16 hospital and 5 primary care) reported that all staff involved in decontamination had received no training in this aspect of their work.

Several Control of Infection doctors expressed concern that documents published by the Health Department stated that 'the advice of the microbiologist should be sought' on topics for which they considered their training had been inadequate e.g. the quality of water for endoscope washer disinfectors.

2.3.2 Central Decontamination Units

The 4 NHS hospital sites included in the study each received decontamination services from a CDU. Two of these CDUs were part of the hospital complex and two at some distance from it. All the CDUs provided services to clinical departments in other hospitals and primary care sites in addition to those included in the survey.

The private hospital used an LDU. One primary care site had all its devices cleaned, disinfected and sterilised by a CDU, part of a hospital complex, which was not included in the survey.

Of the 136 clinical departments based in NHS hospitals included in the survey, 94 received all their decontamination services exclusively from CDUs. Of the remaining 42 NHS hospital clinical departments, 36 used both LDU and CDU for decontamination. One hospital received all decontamination services (except endoscope decontamination) for all its clinical departments exclusively from a single CDU.

The four CDUs in the survey contained the following major items of equipment (see Appendix 2):

- 18 porous load Sterilizers;
- 2 ethylene oxide Sterilizers;
- 18 washer disinfectors (includes 5 free-standing ultrasonic washers but no endoscope washer disinfectors).

a. Facilities

Key indicator of good practice
1. Environmental controls are present to reduce microbial or particulate contamination especially ventilation and separation of contaminated items from clean and sterilised items

The facilities provided for 3 out of 4 CDUs did not meet the basic requirements for segregation of clean and ‘dirty’ processes. The mechanical ventilation systems in the wash/decontamination areas were found to be ineffective in 2 CDUs. This results in windows and external doors being left open.

b. Cleaning and disinfection

Key indicators of good practice
1. use of washer disinfectant, if not available, a dedicated sink where washing by hand takes place under water
2. personal protective equipment including eye protection used by staff involved in cleaning
3. washer disinfectant regularly validated to ensure capable of meeting the temperature, time and pressure requirements
4. each cycle monitored to ensure the temperature and time requirements are met
5. regular maintenance to ensure washer disinfectant safe and working efficiently
6. devices undergoing sterilization should receive prior disinfection

Manual washing

All CDUs had a dedicated sink for manual washing with separate handwashing facilities. Cleaning is carried out entirely under water in 2 of the 4 CDUs. Gloves and a waterproof overall were worn in all CDUs, eye protection in three and masks in two. All staff were trained in manual washing procedures.

Washer Disinfectors

Excluding ultrasonic washers, 9 of the remaining 13 washer disinfectors were 10 years old or more and of a type that it is unlikely could be economically upgraded to current standards. No washer disinfectant had been validated and no periodic or routine testing was carried out (see Appendix 4). Excluding ultrasonic washers, only 9 of the 13 were fitted with independent temperature monitoring. Only three of the 13 documented process variables for each cycle.

c. Packaging

Key indicator of good practice
1. separation of contaminated items from clean and/or from sterilised items

In 2 of the 4 CDUs the assembly of packages of disinfected instruments for sterilization did not take place in a dedicated area, segregated from cleaning and/or sterilization areas.

d. Sterilization

Key indicators of good practice
1. equipment is regularly validated to ensure capable of meeting the steam quality, load, temperature, time and pressure requirements
2. each cycle is monitored to ensure the parameters relevant to the factors outlined above are met
3. regular maintenance occurs to ensure equipment safe and working efficiently

Three of the 4 CDUs did not comply with steam quality requirements

Of 18 porous load sterilizers surveyed, 6 were more than 15 years old. All sterilizers underwent daily and weekly testing and all but 2 underwent an annual revalidation. For no sterilizer was there a formal review of the nature of the loads processed. The one CDU operating ethylene oxide sterilizers was found to be reprocessing inappropriate loads, e.g. surgical gloves.

e. Traceability

Key indicators of good practice
1. labelling to identify devices or sets of devices
2. information system to match label or code to healthcare procedure and patient

Two CDUs had a system (stick-on labels with cycle number and date printed) in place allowing the traceability of sterilised devices back to the sterilizer used.

Systems, which could ensure the traceability of theatre trays to patients, were in place in 3 of the 4 CDUs. However only one clinical department on a hospital site was found where every appropriate patient note contained a traceability label. No systems were in place, which allowed the traceability of instruments which were included as supplements to a standard set.

f. Storage

Key indicator of good practice
1. separation of contaminated items from clean and from sterilised items

Although sterile stores with good stock rotation and standards of hygiene were seen, storage facilities were inadequate in 2 of the 4 CDUs. In these, sterile items were found on the floor and where they could be exposed to splash contamination.

g. Transport

Key indicator of good practice
1. separation of contaminated items from clean and from sterilised items

Ninety-nine of the 152 clinical departments provided information about transport of devices to their CDU. Trolleys and/or vehicles were used for transport. In only 49% of the clinical departments did the trolleys or vehicle used have a physical separation between contaminated and sterile instruments.

2.3.3 Local Decontamination Units

Fifty-six LDUs were identified in the 15 sites: 13 on 9 Primary Care sites, 1 in the Private Hospital and 42 in hospital wards and departments. One hospital and 1 general practice prohibited any local decontamination, sending all items to a CDU. Many LDUs were located in clinical departments, which also received a CDU service even though 74% of CDU users surveyed in this review found the service reliable.

Table 2 provides details of the major items of equipment in the LDUs.

Table 2			
Type of Equipment in LDUs by type of site			
TYPE	Hospital (Clinical departments=43)	General Medical Practice (Clinical departments =4)	General Dental Practice (Clinical departments=9)
Porous load sterilizers	1	0	0
Benchtop sterilizers	35	6	10
Washer-disinfectors	26*	0	7**

* Includes 10 free-standing ultrasonic washers and 7 endoscope washer-disinfectors

** All ultrasonic washers

The key indicators of good practice for LDUs were the same as for CDUs.

a. Facilities

Thirty-one LDUs (55%) did not have a dedicated area for decontamination. Seventeen units (30%) were located in areas stated to be also used for patient treatment. Nine LDUs (18%) were in areas used for dirty procedures such as cleaning and waste disposal. In only 11 LDUs (20%) was there segregation between activities on soiled devices and those on clean, disinfected devices.

b. Cleaning and disinfection

Cleaning of instruments took place in LDUs and also in clinical departments using CDUs. Manual washing of instruments was identified in 66 of the 152 clinical departments (57 hospital and 9 primary care). Forty-one (66% of those carrying out manual washing) used a suitable general purpose detergent or enzymic cleaner; 19 (28%) were using unsuitable detergents, of which 3 (5%) were hand-washing solutions. Detergent concentration was controlled in 12 (18%) and water temperature in 5 (8%).

With regard to the 56 LDUs, in only 24 (42%) (18 hospital and 6 primary care) was the sink used dedicated for manual washing only. In no LDU were manually washed instruments subsequently disinfected before sterilisation. Although procedures in LDUs involved scrubbing instruments which generate aerosols, a minority of staff were wearing eye protection (40 %) and/or a mask (29%).

Observations in LDUs on hospital sites of the manual washing of flexible endoscopes prior to processing in washer disinfectors revealed this to be intricate and labour intensive. Staff commented upon the difficulty of undertaking this procedure because of time pressures.

Washer Disinfectors (including endoscope washers)

There was no evidence that any washer-disinfector met recommended performance criteria. This was due to an absence of testing.

The 7 ultrasonic washers in LDUs in general dental sites did not meet maintenance and operational standards. No information about their age was available on site.

c. Sterilization

Fifty-one benchtop bowl and instruments sterilizers (see Appendix 2) were identified although only 36 were in routine use. Their location is shown in Table 3.

Location	Number
Ward	1
Operating Theatre	7
OP Clinic / A&E	19
General Practice	6
Dental Surgery	10
Estates Departments	6
Other	2
Total	51*

Nineteen bench-top sterilizers (37%) were less than 10 years old. Nine (18%) were more than twenty years old.

Twelve sterilizers (24%) had been subjected to installation and commissioning tests to HTM 2010 (see Appendix 3). Documented validation and testing was found in only one site (primary care). Weekly tests were being carried out on 29 (57%) of bench-top sterilizers, quarterly thermometric test and instrument calibration were being carried out on 19 (37%) and yearly test on 32 (62%) (see Appendix 4).

Seventeen of the 29 sterilizers (55%) in use on hospital sites were being filled with sterile water for irrigation or injection as recommended but only 1 of 16 (6%) in primary care. The reservoir of 8 sterilizers in primary care was being filled with tap water. Inappropriate loads (e.g. wrapped or narrow lumen instruments) were processed in 13 (25%) of the bench-top sterilisers (8 in primary care, 5 in hospital).

d. Traceability

Flexible endoscopes were traceable to patients in all LDUs where cleaning and disinfection took place. Their accessories however e.g. biopsy forceps, were not. Apart from these devices, no records were present in LDUs, which would allow traceability of instruments.

e. Storage

Storage of sterile goods was found to be a considerable problem in many local decontamination units. Sterile items were stored in the decontamination area in 15 (27%) LDUs.

2.3.4 Safe use of medical devices

Key indicators of good practice
1. Medical devices designated as single-use by the Medical Devices Agency should not be re-used.
2. Stocks of surgical instruments should be sufficient to facilitate their effective decontamination

Tonometer heads used in ophthalmology, designated as a single use item, were being reprocessed on 4 hospital sites.

Of the 56 LDUs included in the survey, 6 (11%) (4 hospital and 2 primary care) reported that they were reprocessing single use devices on cost grounds.

Staff commented that the surgical instrument inventory was too small to allow the "turn around" time required by a CDU in all except one CDU.

2.4 Conclusions

Examples of excellent practice, with modern well maintained, validated, equipment in appropriate facilities with a controlled environment were found in the review. Staff were on the whole hard working. This shows that good practice standards can be achieved. However most of the sites assessed were deficient in a number of key areas. In general decontamination processes have many shortcomings which could increase the likelihood of adverse health occurrences to both patients and staff. The following text summarises these shortcomings:

The management of the decontamination processes

Senior management control of the decontamination processes is limited. There appears to be no coherent policy on surgical instrument procurement. An approach, which links decontamination with the procurement of medical devices, health and safety and infection control, is lacking. There is little evidence that managers were aware of the risk posed to staff and patients from inadequate decontamination. As a result quality systems for reusable medical devices in acute and primary care are rarely used.

Guidance at national and local level is not 'user friendly'. Awareness of what constitutes good practice is often low. There is little documented training at all levels. Hard working staff are often conscientiously applying inappropriate decontamination procedures.

Central Decontamination Units

Many decontamination processes are being carried out in unsuitable environments, which constrain the ability to separate "clean" from "dirty" processes. There is no evidence that any washer disinfector complies with current performance standards due to a lack of testing. Many items of decontamination equipment are of an age, which indicates that they are likely to require replacement.

Matching trays of surgical instruments reprocessed in CDUs to the patient on whom they have been used is possible but with a few exceptions, this is not being undertaken.

Local Decontamination Units

A majority of LDUs are located in inappropriate facilities with no physical separation between clean and dirty processes. Almost all units demonstrated evidence of poor practice in one or more of the decontamination process. This was common to both hospital and primary care sites. Many units were carrying out sterilization in clinical departments, which were also receiving the services of a CDU with no identifiable need for the LDU being evident.

As with CDUs, there was a lack of testing of washer disinfectors. A high proportion of sterilizers are not routinely used and of those which are, many are inadequately maintained with regard to on-going testing and calibration.

With the exception of flexible endoscopes, matching medical devices decontaminated in LDUs to the patient on whom they have been used is not possible.

The safe use of medical devices

A significant minority of units were reprocessing single use instruments. Current stocks of surgical instruments held by healthcare providers may be inadequate to permit the desired turnaround times for the decontamination cycle.

SECTION 3 –DISCUSSION AND RECOMMENDATIONS

3.1 Discussion

The remit of the Working Group was to answer the following questions:

- a. Are current guidelines on the cleaning and sterilisation of surgical instruments adequate?**

These appear to be adequate in terms of their technical content although as more evidence becomes available on prions and vCJD transmission, they are likely to require amendment. However outside the engineering function and Central Decontamination Units, there was a widespread ignorance of guidance on decontamination. Often guidance was written in language which made it difficult for operators to understand its meaning and its relevance to their work.

- b. How effectively is that guidance being implemented?**

Overall guidance is not being implemented effectively for two main reasons. The first is the lack of any organisation-wide, coherent management control of re-usable medical devices and their re-processing. The second is the lack of resource put into ensuring equipment met performance criteria as indicated in British, European and other technical standards. This was a particular issue with washer disinfectors.

- c. What practical difficulties are there in ensuring good practice in this area?**

These are many. Facilities often do not meet recommended standards. Many items of equipment are in need of replacement or upgrading. Documented evidence of training in decontamination practices is rare. Staff turnover in central decontamination units is high and this constrains the effectiveness of training initiatives. With the exception of flexible endoscopes (but including endoscopic accessories such as biopsy forceps) re-usable medical devices (such as surgical instrument trays) are often not uniquely identified and cannot be traced through re-processing and use on patients.

- d. What measures need to be taken to improve the effectiveness of cleaning and sterilisation in the NHS in Scotland?**

Overall the Working Group's view is that the state of decontamination practice in the NHS in Scotland gives serious cause for concern and requires a series of actions to remedy a number of major deficiencies. The necessary actions are presented in the recommendations (see 3.2).

The benefits from taking these measures would be:

a. Improving the cost-effectiveness of services decontaminating or using medical devices

Not considering decontamination when purchasing medical devices (especially those which are difficult to clean), is likely to have important on-going economic consequences. Decisions based on the immediate purchase price do not consider the total cost over the life of an instrument.

As with purchasing instruments, failing to take action on LDUs and CDUs will have an economic cost. Many clinical departments in hospitals receive decontamination services both from a CDU and LDU. Given the number of the latter with major deficiencies and the resources needed to remedy these, a high proportion of LDUs are unlikely to be cost effective in the medium to long term. A significant proportion of the equipment in CDUs is old and facilities need improved. The cost of upgrading means that rationalisation of the number of CDUs in Scotland is likely to be the most economic option.

For most devices there are likely to be few savings by reprocessing items intended for single use. In addition, single use items are not designed to undergo the rigours of decontamination and may be damaged by the process. This could be an obstacle to achieving a suitable outcome from the procedure involved.

b. Meeting the requirements of the Health and Safety at Work Act

Inadequate segregation of clean and dirty items can lead to recontamination of sterile equipment. Poor training can mean that staff may fail to decontaminate instruments properly. Failure to comply with maintenance regimes does not necessarily mean that items of equipment are not working. However they may be and this is likely to lead to a greater chance of breakdown. All these factors indicate that healthcare providers may not be fulfilling their health and safety obligations in this area.

c. Reducing the risk of infections in hospitals and other healthcare facilities

The evidence of poor practice in cleaning and disinfection is of concern. Good standards in manual washing can be achieved but the process is difficult to reproduce and thus open to error. If medical devices are poorly washed, protein materials such as blood or tissue may remain.

d. Managing incidents related to HAI or TSEs.

The lack of a traceability system for medical devices can obscure links between patients with similar hospital acquired infections where a decontamination failure may be the cause. It can impede the management of incidents where it is necessary to trace the use of surgical instruments.

3.2 Recommendations

1. *Awareness*: SEHD urgently needs to increase NHS Trusts' and other healthcare providers' awareness of the importance of good decontamination practices.
2. *Guidance*: At the present time no new guidance is required. As a matter of urgency however, SEHD should review the style of and methods used in disseminating guidance on decontamination and other related areas. Based on the findings of the review, actions should be taken to ensure that the right information on decontamination reaches the right person at the right time so that the recipient understands and can act on it.

3. *Standards:* Trusts, hospitals and primary care organisations require to audit their achievement of decontamination standards. SEHD should collaborate with other UK Health Departments in developing the methodology utilised in the review as a tool for this and should include monitoring the achievement of adequate standards in decontamination practice in its performance review and risk management processes.
4. *Compliance:* SEHD should collaborate with the other UK Health Departments in instituting any measures necessary to ensure that Trusts and other health care providers take action to improve poor levels of decontamination practice as soon as these are detected.
5. *Management:* Trust senior management should undertake an assessment of the infection and decontamination risks associated with their services, ensure that overall standards of decontamination practice are monitored and co-ordinate decision-making on decontamination, infection control, health and safety and the acquisition and disposal of surgical instruments. Infection control personnel should have a recognised role in advising on the purchase and planning of decontamination facilities and equipment.
6. *Staff performance:* Trusts should ensure that decontamination of re-usable medical devices is managed and undertaken only by suitably trained personnel. Trusts need to assess the recruitment, retention and training requirements of Central Decontamination Units and put in place measures which motivate staff to deliver an improved level of service.
7. *Training:* SEHD should develop a national framework for training in decontamination which determines the level of knowledge and skills required by NHS staff, indicates available accredited courses, integrates training in this area with continuous professional development and defines standards for monitoring Trusts and other organisations.
8. *Washer disinfectors:* Trusts should be requested to review whether their current equipment is meeting or is capable of meeting current standards, prepare plans for remedying any deficiencies and ensure that ongoing monitoring is undertaken by appropriately trained personnel. SEHD should collaborate with other UK Health Departments in investigating the efficacy of washer disinfectors in removing potentially infective tissue.
9. *Traceability:* Trusts should ensure that mechanisms are in place and operating at ward level.
10. *Surgical instruments:* SEHD should continue to collaborate with other UK Health Departments and professional organisations in defining standard sets of instruments for specific procedures. Trusts should review their stock of instruments to identify the level necessary for decontamination to be carried out effectively. Infection control personnel should be consulted on the procurement of instruments.
11. *Single use instruments:* SEHD should liaise with the other UK Health Departments and the Medical Devices Agency in ensuring that the re-use of single use instruments ceases.
12. *Dentistry:* SEHD should develop a programme to improve decontamination and infection control practice in dentistry.
13. *Decontamination Units:* A review should be carried out to determine the most cost-effective configuration of decontamination units and operational practices (building on a previous SEHD report on their provision).
14. *Resources:* SEHD should urge Trusts and other healthcare providers to invest an appropriate level of resource and improve practice in this area to an acceptable level. Immediate priorities for non-recurring revenue investment are:

- improving the accessibility to users of NHS guidance;
- developing a training framework;
- increasing stocks of surgical instruments in Trusts which can identify the level necessary to facilitate good decontamination practice;
- upgrading washer disinfectors;
- installing systems to ensure traceability.
- SEHD should review performance in this area.

APPENDIX 1
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APPENDIX 2

GLOSSARY OF TERMS

Decontamination is the combination of processes, including cleaning, disinfection and/or sterilization, used to render a re-useable item safe for further use. The decontamination process is intended to:

- make the item safe for staff to handle without presenting an infection hazard;
- make the item safe for use on a patient, (after any additional processing) - including, when relevant, ensuring freedom from contamination that could lead to erroneous diagnosis.

Cleaning is the process that physically removes soiling including large numbers of micro-organisms and the organic material on which they thrive.

Disinfection is the reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use.

Sterilization is the process used to render a product sterile. EN 556 specifies that to be labelled 'sterile' a medical device should have been subjected to a validated sterilization process so that there is less than a 1×10^{-6} probability of a surviving micro-organism.

Medical device is defined in the Medical Device Directive as “an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which –

- a) is intended by the manufacturer to be used for human beings for the purpose of:
 - i. diagnosis, prevention, monitoring, treatment or alleviation of disease
 - ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
 - iii. investigation, replacement or modification of anatomy or of a physiological process, or
 - iv. control of conception; and
- b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means.

The term Medical Device also includes accessories necessary for the correct functioning of the medical device. Washer-disinfectors and sterilizers for use in healthcare facilities are classified as medical devices.

Benchtop (steam) sterilisers are intended for the sterilisation of unwrapped instruments and utensils for use in the immediate patient environment. They require no permanent connections or installation, and are capable of being moved manually from one site to another without the need for lifting tackle

Porous-load sterilizer is a clinical sterilizer designed to process, by exposure to high temperature steam under pressure, porous items such as towels, gowns and dressings, and also medical devices that are wrapped in porous materials such as paper or fabrics.

Ethylene Oxide steriliser is a clinical steriliser designed to sterilise loads by exposure to ethylene oxide gas or EO gas mixtures

Washer Disinfectors is a machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. Dedicated washer disinfectors are available which are intended specifically for processing endoscopes. These may incorporate a chemical disinfection or sterilization stage, or may require that after processing in the washer disinfectors, the endoscope is terminally sterilised using a suitable low temperature sterilisation process.

Ultrasonic machines use ultrasound energy to effect the mechanical removal of soiling from the surface of the product.

APPENDIX 3

DECONTAMINATION STANDARDS AND GUIDANCE

British Standards

Independently accredited compliance with BS EN ISO 9002, and BS EN 46002 is only essential for decontamination units which are required to be registered as manufacturers under the Medical Device Regulations. However, these standards together with the associated guidance standard BS EN 724, provide a framework for all the aspects of management control that need to be considered in the provision of an appropriate decontamination service. It is in that context that these standards were used as the basis of the survey.

Harmonised European standards, eg EN 554, afford a presumption of compliance to the relevant essential requirements given in Annex 1 of the Medical Device Directive. All healthcare facilities should be complying with these standards and hospitals were advised of this in Medical Device Bulletin 18a and also in an executive letter from the NHS Executive to all Chief Executives in January 1998¹.

British Standards such as BS 5295 (cleanrooms), BS 2745 (Washer – disinfectors) and BS 3970 (sterilizers) are being replaced by International and/or European standards but in the meantime represent the extant position in the UK.

BS EN ISO 9002: 1994 Quality systems. Model for quality assurance in production, installation and servicing

Quality system requirements for use where a supplier's capability to supply conforming product to an established design needs to be demonstrated.

The standard's requirements are based on the concept of an organisation providing:

- formal planning of what needs to be done;
- definition of the responsibility and authority of all staff involved;
- control of documents, data and records;
- use of documented procedures to control activities;
- determination and provision of appropriate resources, including trained staff.

The standard also calls attention to specific consideration at the various stages in the product life-cycle.

The requirements are complementary, not alternative, to technical requirements for the product and are generic and thus independent of any specific industry. In order to tailor the requirements of the standard to the medical device industry, BS EN ISO 9002 is supplemented by the requirements of BS EN 46002.

BS EN 46002: 1997 Specification for Application of EN ISO 9002 to the manufacture of medical devices.

EN ISO 9002 is intended to be a general standard defining quality system requirements. EN 46002 provides particular requirements for suppliers of medical devices that are more specific than the general requirements specified in EN ISO 9002

In conjunction with EN ISO 9002, this European Standard defines requirements for quality systems relating to the production, installation and servicing of medical devices. It embraces the principles of good manufacturing practice (GMP) widely used in the manufacture of medical devices. It can only be used in the manufacture of medical devices. It can only be used in combination with EN ISO 9002 and is not a 'stand alone' standard.

¹ EL(98)5 "MEDICAL DEVICES DIRECTIVE – CE MARKING" issued 23 January 1998

The key areas in which EN 46002 specifies requirements particular for medical devices may be summarised as:

- a master device file;
- retention of specifications/records for at least the product lifetime;
- retention of purchasing documents for the purpose of traceability;
- procedures to distinguish refurbishment from virgin production;
- procedures for traceability;
- personnel; health, cleanliness and clothing;
- environment; defined, controlled and monitored;
- cleanliness of product;
- maintenance;
- installation;
- special processes;
- validated sterilization process (see EN 554);
- identity of inspector for active implantable and implantable devices;
- documented procedures for customer complaint, corrective action, regulatory reporting advisory notices and recalls;
- procedures for storage of devices with limited shelf life;
- particular requirements for packaging;
- labelling of implantable and active implantable devices;
- retention of quality records for 2 years from despatch/not less than product life;
- batch records for traceability;
- training/supervision of personnel working in controlled environment.

BS EN 724: 1995 Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002

This European Standard provides guidance to organisations providing a non-active medical device who wish to ensure that they will comply with EN 29001/EN 29002 and the particular requirements given in EN 46001/EN 46002. It is also intended to provide guidance for certifying and regulatory bodies. The guidance in this standard for the fulfilment of requirements should always be in relation to the products being manufactured and interpreted accordingly.

This standard needs to be read in conjunction with the EN 29000 series of standards with which compliance is sought. This standard is not intended as a replacement for EN 29004, which has its own very distinct relationship with the EN 29000 series of standards.

The combination of EN 29001/EN 46001 and EN 29002/EN 46002 embraces the principles of Good Manufacturing Practices (GMP) which have been in operation in the manufacture of non-active medical devices for a number of years.

This document seeks to assist in the transition from GMP to quality systems by presenting familiar concepts under the relevant paragraphs of EN 29001/EN 46001 and EN 29002/EN 46002.

BS EN 554: 1994 Sterilization of medical devices – Validation and routine control of sterilization by moist heat.

The object of this European Standard is standardisation in the field of validation and routine monitoring of moist heat sterilization processes and procedures that are carried out by those who sterilize medical devices. The validation of sterilization procedures presupposes that the sterilizer complies with appropriate specifications.

This standard contains requirements for the validation and routine monitoring of sterilization by moist heat and guidance on its application.

BS 2745: 1993 Washer-disinfectors for medical purposes.

This standard specifies washer-disinfectors in which the load remains within the machine until the cycle is completed. All such machines within the scope of this standard are required to include a heat disinfection stage

during the cleansing cycle. This heat disinfection stage raises all parts of the maximum permitted load to a specified temperature and maintains that temperature for a specified period of time. Thermal disinfection is achieved by use of hot water or steam in direct contact with all potentially contaminated surfaces after the complete removal of soil.

If the specified temperature is not reached or is not held for the required time, this has to be clearly indicated and it has to be ensured that it will not be possible to remove the contents without appreciating that such a failure has occurred, even when the operator is unfamiliar with the machine. The specified disinfection temperature and holding time should have a lethality sufficient to reduce the number of viable micro-organisms in a load but which may not necessarily inactivate some viruses and bacterial spores.

In addition, the machine's washing sequence should remove all visible evidence of any soiling likely to have occurred during the normal use of each item of a load or any soil deposited on the chamber walls during the process, provided that the total load does not exceed the specified maximum. This specification should ensure that a machine is safe to operate and conforms to any relevant existing standards, taking account of all legal requirements given in the Acts and documents detailed in this foreword. This standard avoids unnecessary restrictions on size, shape and materials to be used.

BS 2745 has been prepared on the basis that every individual washer-disinfector will be subjected to functional performance tests. Unless otherwise stated in this standard, conformity to the performance requirements is checked by visual inspection or direct measurement.

The test methods and requirements of this British Standard are equally applicable for assessing the functional performance of the washer-disinfector throughout its life.

BS 5295:1989 Environmental cleanliness in enclosed spaces

In the preparation of this revision of this British Standard, account was taken of:

- a) The United States of America Federal Standard 209D 'Clean rooms and work station requirements, controlled environment', and proposals for its revision;
- b) The Institute of Environmental Sciences Tentative Recommended Practice IES-RP-CC006-84-T November 1984 'Testing clean rooms'.

BS 5295 sets out, in detail, the requirements to which clean rooms and clean air devices are to conform in order to provide assurance of achieving the requisite level of cleanliness expressed as a particulate concentration in air. Methods of test and of monitoring to demonstrate these levels are given, together with details of procedures and methods of working which will enable the levels to be maintained.

Guidance documents

1. Health Technical Memoranda (HTM)

HTMs are produced to provide healthcare facilities with a framework of best practice in the choice, purchasing, installation, validation, monitoring and routine operation of equipment. They are compatible with existing British and European standards and as far as practicable anticipate standards which are currently being developed in Europe.

HTM 2010 Sterilization

Health Technical Memoranda (HTM) 2010 Sterilization gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of the types of sterilizers commonly found in the National Health Service. HTM 2010 is published in five volumes:

- 1 – *Management policy* – is a summary of the information required by non-technical personnel responsible for the management of sterilization services. It discusses the various types of sterilizer, for

both clinical and laboratory use, and also contains guidance on legal and policy matters, and on the appointment and responsibilities of personnel.

2 – *Design considerations* – contains information relevant to the specification and installation of new sterilizing equipment. It discusses the requirements for each type of sterilizer and outlines the specifications to be included in any contract. Practical considerations for the installation of sterilizers are discussed, including siting, heat emission, ventilation, noise and vibration, and mains services with an emphasis on steam quality.

3 – *Validation and verification* – covers all aspects of validation and periodic testing of sterilizers. It includes detailed schedules and procedures for tests and checks to be carried out for commissioning and performance qualification and for subsequent periodic testing.

4 – *Operational management* with Part 6 – *Testing and validation protocols* – covers all aspects of the routine operation and maintenance of sterilizers, stressing the need for a planned maintenance programme along with the type of records to be kept. Advice on the safe and efficient operation of sterilizers is given, as well as procedures for reporting defects and accidents; and Part 6 – provides step-by-step guidance on testing and validation of processes.

5 – *Good practice guide* – provides supplementary advice on a number of matters concerned with the effective usage of sterilizers.

HTM 2030 Washer-disinfectors

HTM 2030 provides guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of the types of washer-disinfectors (WDs) commonly found in the National Health Service. The guidance is currently produced in three volumes:

1. *Operational management* – is a summary of the information required by personnel responsible for the management of facilities in which washer-disinfectors are used. It discusses the various types of WDs, for both clinical and laboratory use, and also contains guidance on legal and policy matters, and on the appointment and responsibilities of personnel. It covers all aspects of the routine operation and maintenance stressing the need for a planned maintenance programme along with the type of records to be kept. Advice on the safe and efficient operation of WDs is given, as well as procedures for reporting defects and accidents.
2. *Design considerations* - contains information relevant to the specification and installation of new WD equipment. It discusses the requirements for each type of WD and outlines the specifications to be included in any contract. Practical considerations for the installation of WDs are discussed, including siting, heat emission, ventilation, noise and vibration, and mains services with an emphasis on water quality.
3. *Validation and verification* - covers all aspects of validation and periodic testing of WDs. It includes detailed schedules and procedures for tests and checks to be carried out for commissioning and performance qualification and for subsequent periodic testing.

HTM 2031 Clean steam for sterilization

HTM 2031 is published in a single volume covering the nature of contamination in steam supplies, regulatory requirements for steam quality, the new “clean steam” specification, engineering measures for the generation of clean steam, validation and periodic testing of clean steam supplies, and guidance on the analysis of steam samples. It is designed to supplement the guidance on steam quality in HTM 2010 Sterilization.

2. Building notes

HBN 13 Sterile services department

Health Building Note 13 provides guidance for the planning and design of a sterile services department, with particular requirements for cleaning, disinfecting and sterilizing, storage and materials handling and good

manufacturing practice. Supplement 1: Ethylene oxide sterilization section – provides guidance for the planning and design of a dedicated ethylene oxide sterilization section integrated within a sterile services department.

3. Guidance produced by the Institute of Sterile Services Management

Quality Standards and Recommended Practices for Sterile Service Departments

This document succeeds the “Guide to Good Manufacturing Practice” (GMP) issued by the Institute in 1989. It aims to provide a framework for SSD Management to audit compliance against quality standards and recommended practices. It also updates the data provided in the GMP guide, and in particular, provides references to the relevant European or British Standards.

4. Guidance produced UK Government Scientific Advisory Committees

The Advisory Committee on Dangerous Pathogens: Spongiform Encephalopathy Advisory Committee (SEAC) “Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection”.

This guidance gives advice on work with transmissible spongiform encephalopathy agents (TSEs) in experimental and clinical settings.

Separate information (listed in the bibliography to this guidance) is available to cover incidental exposure such as in farms, abattoirs or other work with animals.

APPENDIX 4
MEMBERSHIP OF REVIEW OF DECONTAMINATION PRACTICE TEAM

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APPENDIX 5 BIBLIOGRAPHY

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