

NHSSCOTLAND: STERILE SERVICES PROVISION REVIEW GROUP: 1st REPORT – THE GLENNIE FRAMEWORK

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EXECUTIVE SUMMARY

Introduction

This is the first of a series of reports by a Group led by John Glennie, Chief Executive Borders General Hospital NHS Trust (the 'Glennie Group') that is undertaking a review of sterile service provision across NHSScotland.

The Group was established in response to recommendations in a report by a Group chaired by Dr David Old (then Reader in Medical Microbiology at the University of Dundee) that reviewed NHSScotland's compliance with published guidance on the decontamination of medical devices.

The driver behind both reviews is a public health priority to reduce the potential risk of person to person transmission of vCJD via re-usable surgical instruments.

The conclusion of the 'Old Report' was that whilst there were examples of good practice, many decontamination processes fell below current standards. In some cases, practice was unacceptably poor. As a result there is a continuing risk of adverse health occurrences to both patients and staff.

The 'Glennie Group' was established in December 2000. Membership details are at Appendix A.1 and the Group's initial remit was as follows:

- To identify the nature and scope of current sterile service provision in NHSScotland.
- To develop a framework for change with specific regard to achieving the required technical and operational standards in the most cost effective way possible.
- To identify the means of achieving change.

Review Coverage

The review included a self assessment survey by Scottish NHS Trusts and Island Health Boards of their decontamination practices and procedures. The following report refers to this survey as the Main Review. The data gathered from the review, covering management and operational aspects of service provision, underpin the Group's analyses and initial conclusions.

Additionally, an independent assessment was made of the decontamination processes in the 10 units in Scotland that carry out neurosurgical or ophthalmological procedures involving the back of the eye. This followed concerns expressed by the UK Government's Spongiform Encephalopathy Advisory Committee (SEAC) about the higher risk (theoretical) of person to person transmission of vCJD through surgical instruments used in such procedures. This is referred to as the 'Fast Track' Review.

Key Findings

The main headlines to come from both the main and fast track reviews were:

- There are 28 central sterile services departments (CSSDs) operating in Scotland. The total includes one private provider, Trust Sterile Supplies Ltd. (TSSL), based at Bellshill, Lanarkshire. A map of the 28 locations is at Appendix B.1.
- Only 4 of the 28 CSSDs (3 NHS and TSSL) are currently accredited to the required EN46002 quality standard in accordance with medical devices directive 93/42/EEC. Accreditation is awarded by a notified body appointed for this purpose by the Medical Devices Agency (MDA). Appendix D.2 refers.
- A further 3 NHS trusts have committed investment to achieve EN46002 accreditation.

- ❑ Only 1 of the 10 neurosurgery and ophthalmic surgery sites met set technical requirements (Appendix E).
- ❑ Excluding TSSL and Island Health Boards, revenue costs are approximately £15 million.
- ❑ Overall some 37 million instruments are estimated to be processed annually in CSSDs by approximately 450 NHS employed whole time equivalents (WTEs).
- ❑ Local decontamination units (LDUs)¹ process a further (estimated) 32.3 million instruments annually.
- ❑ An additional (estimated) 164 million instruments are processed locally by independent general dental practitioners annually.
- ❑ The majority of CSSDs currently operate significantly below optimum capacity levels.
- ❑ Facilities are generally operated on a single day shift system 5 to 5.5 days per week with partially manned back and night shifts systems.
- ❑ Staffing/productivity ratios differ between CSSDs with consequent variations in processing costs. The cost per item ranges between £1.11 and £0.16 against an average of £0.46.

This Report

This Report, the Glennie Framework, addresses the first two remit objectives listed above. It focuses mainly on the acute sector, the area with the highest level of risk relative to vCJD, covering activity for all centralised sterile service departments (CSSDs), all locally processed acute sector activity, dental hospital activity, and minor procedures by general medical practitioners. It does not cover, in any great detail, locally processed primary care trust (PCT) activity nor dental activity in community healthcare facilities and by private or independent dental practitioners. Further data is being collected for these areas of activity and will be reported upon at a later stage.

The Report is not a blue print for future service provision. Instead it provides a Framework within which NHS trusts and the Island Health Boards can plan to upgrade and/or reconfigure their decontamination processes to comply with the Technical Requirements (listed at Appendix D.1) that the Group considered will minimise risks for the potential transmission of vCJD. It provides trusts and health boards with data and a range of options on which to develop and cost local solutions to suit local circumstances. In so doing it seeks to encourage collaboration and joint working between trusts.

Framework Criteria

The Group considered the two key issues relative to the future provision of decontamination activity were:

- ❑ Compliance with the set Technical Requirements for managing the risk of vCJD transfer.
- ❑ Identification of nature and scope of future CSSD provision with specific regard to:
 - Location
 - Activity
 - Value for Money (VFM)
 - Technical Requirements

¹ For the purpose of this Report LDUs are taken to mean 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 use. The items of equipment employed are usually bench top sterilisers or washer disinfectors.

The Group was aware that a considerable number of legislative and best practice standards exist for decontamination of re-usable medical devices. However, the Group's primary concern was to address the potential risk of transmitting vCJD through such devices.

Accordingly, the Group devised a Technical Requirements matrix (Appendix D.1) to categorise clinical procedures into risk ratings of High, Medium and Low, and allocates the legislative/advisory standards against them at 'Interim' and 'Full' levels and across the function headings of Equipment, Facilities, Staff and Management. The risk matrix relates specifically to CJD and does not mirror other risk classifications drawn from the Microbiological Advisory Committee Manual.

The Group considered that all CSSDs must comply with the Full Technical Requirement by no later than March 2004. But in between, CSSDs dealing with high risk instruments must reach the Interim Requirement by December 2001 and all other CSSDs, dealing with medium and low risk procedures, by end March 2002. The situation for primary care trusts and dental practitioners will be addressed and reported later.

Framework Options

Options for change in service configuration were considered on the following activity scenarios, each level being related to the previous on a sequential basis:

Level 1: All current CSSD related activity including the three dental hospitals.

Level 2: All activity associated with Level 1 above plus transferring to CSSDs all localised acute hospital related activity and activity associated with minor procedures undertaken by general medical practitioners.

Level 3: All the activity associated with Levels 1 and 2 above plus transferring to CSSDs all localised primary healthcare related activity managed by Primary Care Trusts (community dentistry and chiropody predominantly) and all activity associated with independent and private dental practitioners.

The key principle for all options is to make best use of the existing infrastructure by upgrading CSSDs where this is considered feasible. Where that is not the case, the options highlight possible new-build requirements.

Based on the information provided by trusts, through the main and fast track reviews, it was established that only 10 of the 24 mainland NHS sites could feasibly be upgraded to the set Technical Requirements. Additionally, it was considered that given the current state of 6 of the CSSDs in Glasgow (i.e. excluding linen services and the dental hospital), future sterile service provision in Glasgow could only be accommodated through either a new build solution, leasing or outsourcing.

At this stage, no consideration was given to whether Public/Private Partnerships (PPP) leasing or outsourcing were the preferred routes for reconfiguration. That issue will be addressed by trusts when developing their business cases at the post-Framework stage, where major investment is required.

Therefore, for the purposes of developing options, the Group considered that the future maximum number of NHS mainland CSSD sites should be 12, i.e. 10 upgrades and 2 new builds. On this basis the estimated cost for reconfiguration to 12 sites, including investment for Fast Track upgrading, was calculated as:

Net capital costs	£17,031,000
Non recurring Revenue Costs	£8,235,100
Recurring Revenue Costs	£2,152,500

Costings were also made for a service configuration based on 11, 10 and 9 sites. The variations to the above estimates were not significant and fell in the following ranges for 11 sites down to 9 sites:

Net capital costs	£16,831,000 - £16,381,000
Non recurring Revenue Costs	£6,443,900 - £6,737,300
Recurring Revenue Costs	£2,162,500 - £2,217,500

Irrespective of the number of CSSDs maintained, to allow the local acute activity to be processed centrally (per Level 2 options) the following costs will be incurred. These are additional to the costs detailed above and relate specifically to upgrading the facilities at Ninewells Hospital (Tayside).

Capital costs	£3,000,000
Non recurring Revenue Costs	£337,847
Recurring Revenue Costs	£2,028,110

Options: Key Points Summary

Level 1 Options

- ❑ A maximum of 10 CSSDs are capable of being upgraded to meet the set technical requirements.
- ❑ Glasgow requires a maximum of two facilities (new build/ leased/ contract out).
- ❑ To ensure acceptable operational capacity is achieved there should be a maximum of 12 CSSDs and a minimum of 9.
- ❑ Capital requirements range from £17.031 million for 12 sites to £16.381million for 9 sites.
- ❑ Approximately £8.5 million is required for additional instrumentation and non-capital equipment.
- ❑ Recurring revenue costs of approximately £2 million per annum will be incurred.

Level 2 Options

- ❑ All locally processed acute sector activity can be accommodated within the Level 1 options.
- ❑ Inclusion would incur additional capital costs of £3 million, non-recurring revenue of £0.338 million, and recurring revenue of £2.028 million.

Level 3 Options

- ❑ Only 3.5 percent of locally processed primary health care sector activity and activity associated with independent and private dental practitioners can be accommodated within Level 1 and 2 options.

Preferred Option

The Group decided not to make a firm recommendation on any option. This reflects the complexity and incompleteness of the data and the extent to which reliance must, at this stage, be placed on assumptions and estimates. It also reflects the strong view of the Group that for the required reconfiguration to be implemented effectively and timeously, it must have NHS trust ownership and support.

However, the Group considered it should identify a preferred option on which discussions for local solutions could be based. The Group's considerations are at section 4.4 of the Report and the conclusion, particularly in light of capacity and contingency considerations, the 12 site option is the preferred model.

Recommendations

- With immediate effect, all posterior ophthalmic and neurosurgical re-usable instrumentation processed locally must be processed in line with the 'Protocol for Local Decontamination of Surgical Instruments' (Appendix D.3).
- By end December 2001, all posterior ophthalmic and neurosurgical re-usable instrumentation should transfer to CSSDs that meet the Interim Technical Requirements per Appendices D.1.
- By end March 2002, all other CSSDs must comply with Interim Technical Requirements.
- By no later than March 2004, and within individually set timescales, all reconfigured CSSDs/sites must comply with the Full Technical Requirements.
- By end October 2001, all acute trusts to prepare a local action plan to detail how they will progress to both the Interim and Full Technical Requirements.
- Action plans with capital/non-recurring investment proposals for reaching the Full Technical Requirement to be supported by an Interim Agreement submission.
- Any central resources made available by SEHD should be:
 - for capital and non-recurring revenue purposes only;
 - limited to works that secure the Full Technical Requirement;
 - for schemes that align to the Framework or offer viable alternatives.
- Agreed investment proposals to be processed in accordance with SEHD's Capital Investment procedures and within stipulated timescales.
- Further work is undertaken for the remaining activity associated with primary care trusts and independent dental practitioners.

Action and Next Steps

The NHS trusts involved in the Fast Track reviews have already presented action plans for bringing their facilities up to the Interim Technical Requirement by the due date of December 2001. Given the potentially high risk nature of services in this area, the Scottish Executive Health Department has agreed to fund duly approved upgrading costs.

All NHS trusts will be advised by SEHD to prepare action plans for making their service provision compliant to the Interim and Full Technical Requirements. The submission deadline for acute NHS trusts is end October 2001. The deadline for primary care trusts will be set later, following further data collection and analysis by the Glennie Group.

The Glennie Group's second report, due in the latter part of 2001, will summarise the acute trusts' action plans and make costed recommendations for reconfiguring decontamination services and the pace of implementation.

1. INTRODUCTION AND BACKGROUND

1.1 Introduction

1.1.1 This report, the Glennie Framework, is the first of a series of reports by a Group led by John Glennie, Chief Executive Borders General Hospital NHS Trust that reviews the current and possible future configuration and provision of NHS sterile services across Scotland. The need for the review stems from clinical opinion that there is a potential risk of person to person transmission of vCJD via re-usable surgical instruments that have not been properly decontaminated.

1.1.2 For this report, 'sterile services' are defined as those services that reprocess invasive medical devices for reuse through decontamination. Decontamination is the combination of processes (including washing, disinfection and sterilisation) used to make re-usable items safe for handling by staff and use on patients. The effective decontamination of re-usable medical devices is essential in reducing the risk of transmission of infectious agents.

1.1.3 As part of a major initiative by the Scottish Executive Health Department (SEHD) to address Healthcare Associated Infection (see 1.4.3), NHS trusts have been tasked with developing action plans to bring their decontamination processes for medical devices up to required standards by March 2004. This report reviews the current state of decontamination services in Scotland and, against that background, provides a framework within which NHS trusts can develop the required action plans.

1.1.4 The Framework covers the activity for all centralised sterile service departments (CSSDs), all locally processed acute sector activity, dental hospital activity, and minor procedures by general medical practitioners. It does not cover locally processed primary care trust (PCT) activity or dental activity in community healthcare facilities and by private or independent dental practitioners. Further data is being collected for these areas of activity and will be reported upon at a later stage.

1.1.5 The action plans above are to be with SEHD by the end of October 2001. A second report, in November, will make recommendations on service reconfiguration and resource implications for the acute sector managed services. The third report, early next year, will cover the issues of locally processed PCT and dental activity.

1.2 Need for Review

1.2.1 The Glennie Group was established following a recommendation by a working group led by Dr David Old, then Reader in Microbiology at the University of Dundee Medical School. Dr Old's Group reviewed NHSScotland's compliance with published guidance on the decontamination of medical devices, and the adequacy of the guidance. Similar to this report, its driver was a public health requirement to minimise the potential risk of person to person transmission of vCJD via re-usable surgical instruments.

1.2.2 To assist the Old Group, SEHD commissioned NHS Estates and the Scottish Centre for Infection and Environmental Health (SCIEH) to carry out a review of decontamination practices in healthcare premises in Scotland.

* A medical device is any instrument, apparatus, appliance, material or other article whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of: control of conception; diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or physiological process.

1.2.3 The Old Group's report 'The Decontamination of Surgical Instruments and other Medical Devices' was issued in February 2001 under cover of NHS HDL (2001) 10. It reported that, whilst there were examples of good practice, many decontamination processes fell below current standards. In some cases, practice was unacceptably poor. The Group's recommendations led to the establishment of two further working groups, namely the Glennie Group and the Carey Group that have linked interests.

1.2.4 The remit of the Carey Group, chaired by Richard Carey, Chief Executive of Highland Acute Hospitals NHS Trust, was to review and develop guidance and standards on managing the risk of Healthcare Associated Infection. The Group's work and report concentrated on the management action needed to identify, quantify, manage and, through the application of set standards, control risk in the areas of infection control, hospital cleaning services and the decontamination of medical devices.

1.2.5 The Carey Group subsequently produced draft decontamination standards. Management responsibility for these standards (and those for infection control and hospital cleaning) has passed to the Clinical Standards Board for Scotland (CSBS) and Trusts have been asked to undertake a baseline assessment of their compliance with these standards. The results will be fed back to CSBS who aim to collaborate in an UK-wide approval scheme for decontamination services for NHS trusts early in 2002.

1.2.6 The development and implementation of plans to reduce the potential risk of vCJD transmission through surgical instruments in the UK involves close collaboration among the four Health Departments. With regard to sterile service provision, the aim is to ensure a commonality of approach particularly with regard to standards and time-scales. This is driven in part by the recommendation of the Philips Inquiry into BSE that arrangements need to be in place for a synchronised approach to common problems of animal or human health.

1.2.7 The Glennie Group (membership at Appendix A.1) was established in December 2000 with a remit to identify:

- the nature and scope of current sterile service provision in NHSScotland.
- a framework for change with specific regard to achieving the required technical and operational standards in the most cost effective way possible.
- the means of achieving change.

1.2.8 The review rested on a self-assessment survey of decontamination practices and procedures across NHSScotland trusts undertaken in March 2001. The survey collected data on the management and operational aspects of service provision, which has been used for the Main Review that is reported further at Section 2 below.

1.2.9 Subsequent to the Main Review being commissioned, concerns were expressed by the UK Government's Spongiform Encephalopathy Advisory Committee (SEAC) about the higher theoretical risk of person to person transmission of vCJD through surgical instruments used in neurosurgery and posterior eye surgery.

1.2.10 To address the SEAC concerns, a more in-depth 'fast track' external assessment was made of the decontamination processes in the 10 units in Scotland that provide sterilisation services for the clinical activities concerned. The results of the assessment, and plans to remedy identified processing deficiencies, were presented to a sub-group of the Glennie Group (membership at Appendix A.2). The 'Fast Track' review is covered in more detail at Section 3 below.

1.3 Report Coverage and Next Steps

1.3.1 The Glennie Framework addresses the first two remit items at 1.2.7 above. It focuses mainly on the acute sector, which carries a high level of risk relative to vCJD, covering all centralised sterile service departments (CSSDs) activity, all locally processed acute sector activity, dental hospital activity, and minor procedures by general medical practitioners.

1.3.2 The Framework does not cover, in any great detail, locally processed primary care trust (PCT) activity nor dental activity in community healthcare facilities and by private or independent dental practitioners. Further data is being collected for these areas of activity and will be reported upon at a later stage.

1.3.3 The technical requirements and guidance contained in this report regarding the decontamination of surgical instruments relates to where the sterilisation phase includes the application of a time-temperature-pressure stage. Currently, flexible endoscopes undergo sterilisation utilising chemical methods. The Medical Devices Agency and the UK Health Departments are currently revising the guidance on the decontamination of endoscopes. Accordingly, this report does not cover in detail the provision of services to decontaminate such medical devices.

1.3.4 With regard to decontamination processes for dentistry, the Scottish Executive Health Department's Chief Dental Officer (CDO) has established a Group to consider the requirements for reducing the potential risk of transmission of vCJD through surgical instruments. Between the CDO and Glennie Groups, further work will be taken forward to review compliance with standards in primary care dentistry and the implications of developing remedial measures to meet agreed standards.

1.3.5 In considering the framework for developing and securing improvements in decontamination services, the Glennie Group has refrained from drafting a blue print for future service provision. Instead the Framework provides NHS trusts and Island Health Boards with data and a range of options on which to develop and cost local solutions to suit local circumstances. In so doing it seeks to encourage collaboration and joint working between trusts.

1.3.6 It is clear from survey work undertaken to date that most sterile service sites fail to meet the technical requirements (see Section 2.3 and Appendix D.1) to reduce the potential risk of transmitting vCJD. Therefore, as well as undertaking the CSBS baseline assessment mentioned at 1.2.5 above, acute trusts (initially) have been requested to prepare action plans to reach the set technical requirements for consideration by the Glennie Group in November 2001. The timing for similar action by primary care trusts, and covering general dental activities, will be determined later.

1.3.7 The Glennie Group plans to issue a second report in the latter part of 2001 that will summarise the acute trusts' proposals, make costed recommendations for reconfiguring decontamination services, and the pace of implementation. Similar action will be taken early in 2002 for the primary care sector.

1.4 Future Funding Considerations

1.4.1 The Group acknowledged that implementation of the finally agreed reconfiguration model will have resource implications. It was noted that health boards 'Indicative Revenue Allocations letter for 2002-03 & 2003-04' (6th April 2001) listed 'improving decontamination procedures' as a financial pressure to be taken into account when preparing future financial plans. Therefore, the Group considered that any resources made available should be:

- for capital and non-recurring revenue purposes only;
- limited to works that secure the Full Technical Requirement (per Appendix D);
- only for schemes offering best value.

1.4.2 In cases where central investment is approved, it will be necessary for trusts and health boards to follow the Health Department's normal business case criteria and procedures.

2. MAIN REVIEW

2.1 Review Methodology

2.1.1 NHS HDL(2001)10 dated 9th February 2001 circulated copies of 'The Decontamination of Surgical Instruments and Other Medical Devices' report (see 1.2.1 to 1.2.3 above). The HDL required trusts to designate a senior manager to have overall responsibility for risk assessment and management processes relating to decontamination, infection control, medical devices management and cleaning services. It also required them, by 31st March 2001, to:

- develop an action plan to ensure that appropriate arrangements are in place to oversee and improve, where necessary, decontamination processes;
- undertake an audit of decontamination practices to address any issues of potential risk to staff and/or patients;
- make an assessment of the age and condition of decontamination facilities and equipment in both central and local decontamination units.

2.1.2 To assist the review process, SEHD developed a questionnaire that sought information from all acute and primary care trusts under the following headings:

1. current management of decontamination practices and procedures.
2. risks associated with decontamination activities and how they were being managed.
3. decontamination equipment not associated with a Sterile Services Department.
4. operational and financial details relating to Sterile Service Providers.

2.1.3 Data from the duly completed questionnaires, authorised by trust Chief Executives, were summarised and collated by the Scottish Centre for Infection and Environmental Health (SCIEH). A synopsis of the outcome report is provided below.

2.2 Current Situation

2.2.1 There are 28 central sterile services departments (CSSDs) operating in Scotland, inclusive of the three Island Health Boards, three dental hospitals, Glasgow Victoria Linen processing unit and the commercial contractor Trust Sterile Supplies Ltd. (TSSL) based at Bellshill, Lanarkshire. A map of the locations is at Appendix B.1.

2.2.2 Only 4 of the 28 CSSDs are currently accredited to the required EN46002 quality standard (Appendix D.2 details), namely - Ayrshire Central Hospital (Irvine), Ninewells Hospital (Dundee), Victoria Hospital (Glasgow - linen processing unit) and TSSL, who currently provide decontamination services mainly to Lanarkshire Acute Hospitals Trust.

2.2.3 A further 3 CSSDs have committed investment to achieve EN46002 accreditation, namely - Foresterhill Hospital (Aberdeen), New Royal Infirmary (Edinburgh) and Falkirk Royal.

2.2.4 Excluding the Island Health Boards and TSSL, revenue costs are approximately £15 million per annum.

2.2.5 An estimated throughput of 37 million instruments is processed annually by approximately 450 whole time equivalents (WTEs) employed within NHSScotland.

2.2.6 A further (estimated) 32.3 million instruments are currently processed outwith CSSDs at local decontamination units (LDUs), i.e. 6.0 million instruments in the acute sector and 26.3 million in the primary care services managed by Primary Care Trusts.

2.2.7 The above figures exclude instruments processed locally by independent general medical and dental practitioners, currently estimated at 165 million instruments per annum.

2.2.8 The value of circulating stocks of instruments and theatre linen within NHS Scotland is currently unknown.

2.2.9 The majority of CSSDs currently operate significantly below optimum capacity of 70% - 80%.

2.2.10 Facilities are generally operated on a single day shift system 5 to 5.5 days per week with partially manned back and night shifts systems.

2.2.11 Staffing/productivity ratios differ between CSSDs with consequent variations in processing costs. The cost per item ranges between £1.11 and £0.16 against an average of £0.46.

2.2.12 Appendix C lists current activity levels and revenue costs by site, based on Trust provided information.

2.3 Assessment Criteria

2.3.1 The Group considered the two key issues relative to the future provision of decontamination activity were:

- Compliance with set Technical Requirements for managing the risk of vCJD transfer.
- Identification of nature and scope of future CSSD provision with specific regard to:
 - Location
 - Activity
 - Value for Money (VFM)
 - Technical Requirements

2.3.2 The Group was aware that a considerable number of legislative and best practice standards exist for decontamination of re-usable medical devices. However, the Group's primary concern was to address the potential risk of transmitting vCJD through such devices.

2.3.3 Accordingly, the Group devised a Technical Requirements matrix that categorises clinical procedures into the risk ratings of High, Medium and Low, and allocated the legislative/advisory standards against them at 'Interim' and 'Full' levels and across the function headings of Equipment, Facilities, Staff and Management. The risk matrix relates specifically to CJD and does not mirror the Carey/CSBS risk classification as drawn from the Microbiological Advisory Committee Manual.

2.3.4 The Technical Requirements matrix is at Appendix D.1A with supporting guidance notes at D.1B. A Decontamination Standards and Guidance Note is provided at Appendix D.2.

2.3.5 The Group considered that all CSSDs must comply with the Full Requirement by no later than March 2004. But in between, CSSDs dealing with high risk instruments must reach the Interim Requirement by December 2001 and all other CSSDs by end March 2002. The situation for primary care trusts and dental practitioners will be addressed and reported later.

3. FAST TRACK REVIEW

3.1 Background

3.1.1 The need for a review of decontamination processes in neurosurgery and posterior ophthalmic procedures, ahead of considering the results of the Main Review, followed a SEAC decision that such procedures carry the highest potential risk of patient to patient transfer of vCJD from contaminated surgical instruments.

3.1.2 The term 'fast track' refers to the way in which the review group's recommendations for investment, to address the deficiencies found, were processed by the Health Department's Capital Investment Group (CIG). It allowed the plans to be considered ahead of any required business case submissions, which are required under the Department's normal capital investment approval procedures.

3.1.3 Ten sites, managed by seven trusts, provide decontamination services for the surgical procedures in question. The trusts concerned were:

- Highland Acute Hospitals NHS Trust
- Grampian University Hospitals NHS Trust
- Tayside University Hospitals NHS Trust
- Lothian University Hospitals NHS Trust
- North Glasgow University Hospitals NHS Trust
- South Glasgow University Hospitals NHS Trust
- Ayrshire & Arran Acute Hospital NHS Trust

3.1.4 The objectives of the Fast Track Review were to:

- identify deficiencies in processes in relation to key standards/requirements;
- define measures to achieve compliance with key standards with defined time scale;
- develop action plans to implement measures;
- review and approve action plans;
- co-ordinate action plans with outcome of Main Review;
- recommend to SEHD the resources required.

3.2 Review Methodology

3.2.1 All ten sites were visited by representatives of the assessment teams used in the earlier Old Group review (see 1.2.1 to 1.2.3 above). The criteria by which the sites were assessed are summarised at Appendix E.

3.2.2 The review revealed that only one trust (Ayrshire & Arran Acute) met the required standards. Accordingly, the other six were requested to produce costed action plans for bringing their processes up to the required standards, and to present their cases to a sub-group of the Glennie Group to assess the appropriateness and cost accuracy/effectiveness of the proposals.

3.3 Sub-group's Recommendations

3.3.1 The plans contained a range of proposals. They went from the provision of additional re-usable surgical instruments, to cover the extended turn round time that will result from ending LDU processes, to the procurement of new washer/disinfector equipment and minor building works, to ensure the adequate separation of clean and dirty processes.

3.3.2 The Group made recommendations to the Scottish Executive Health Department in respect of each trust. The Department accepted the recommendations overall and have separately pursued the cost and implementation issues in each case.

4. SERVICE RECONFIGURATION OPTIONS (THE FRAMEWORK)

4.1 Options Basis

4.1.1 All activity and financial information used in the options has been derived from the responses to the decontamination survey undertaken in March 2001 and incorporates fast track review data.

4.1.2 Data validation has been undertaken wherever possible and practicable.

4.1.3 The financial and operational assumptions utilised in the construction of the options are summarised at Appendix F.

4.1.4 Options for change in service configuration have been considered on the following activity scenarios, each level being related to the previous on a sequential basis:

Level 1: All current CSSD related activity including the three dental hospitals.

Level 2: All activity associated with Level 1 above plus transferring to CSSDs all localised acute hospital related activity undertaken in LDUs and activity associated with minor procedures undertaken by general medical practitioners.

Level 3: All the activity associated with Levels 1 and 2 above plus transferring to CSSDs all localised primary healthcare related activity managed by Primary Care Trusts (community dentistry and chiropody predominantly) and all activity associated with independent and private dental practitioners. Dental activity would be phased in first.

4.1.5 The key principle for all options is to make best use of the existing infrastructure by upgrading CSSDs where this is considered feasible. Where that is not the case, the options highlight possible new-build requirements.

4.1.6 Based on the information provided by trusts through the main and fast track reviews, it was established that only 10 of the 24 mainland NHS sites (per Appendix B.2) could feasibly be upgraded to the set Technical Requirements.

4.1.7 Additionally, it was considered that given the current state of 6 of CSSD sites in Glasgow, i.e. excluding linen services (Victoria) and dental hospital, future sterile service provision in Glasgow could only be accommodated through a new build solution, leasing or outsourcing.

4.1.9 Therefore, for the purposes of developing options, the Group considered that the future maximum number of mainland NHS CSSD sites should be 12, i.e. 10 upgrades and 2 new builds.

4.1.10 At this stage, no consideration was given to whether Public/Private Partnerships (PPP) leasing and outsourcing were the preferred routes for reconfiguration. That issue will be addressed by trusts when developing their business cases at the post-Framework stage, where major investment is required.

4.1.11 Instrumentation is a significant element within the options. By placing an emphasis on upgrading facilities where possible, and the operational need to reduce LDU processes, there will be a substantial need for additional instruments so there is no loss of turn round time at theatres.

4.1.12 The estimated cost for additional instruments is shown as Non Recurring Revenue Costs in the following option summaries. As indicated in Appendix F (point 5), the estimated costs are based on a broad formula. Given the range of clinical specialties covered, and the varying demands in terms of instrument numbers and quality, the cost estimate may differ significantly to the actual requirement under each option.

4.1.13 The (additional) Recurring Revenue Costs line in the following option summaries covers capital charges, supplies and staffing. As indicated at Appendix F (point 14) it is expected that staffing requirements will increase despite a reduction of sites. In general terms, the apportionment between the estimated capital charge and staffing/supplies costs is 35:65.

4.2 Options

OPTION LEVEL 1: CURRENT CSSD ACTIVITY

A. Upgrade All (that are capable of upgrade)

4.2.1 Of the 28 sites providing services, the three island health board sites have not been evaluated within the review process. Their review will be concluded later this year. The facilities operated by TSSL are compliant with required standards.

4.2.2 Based on the information provided by each trust in the survey, the Group established that of the 24 mainland sites only 10 are capable of being upgraded to the required standards. The position is summarised at Appendix B.2

4.2.3 CSSD services within Glasgow are currently provided on 6 different sites, namely Glasgow Royal Infirmary, Gartnavel, Stobhill, Southern General, Victoria and Yorkhill. In addition CSSD facilities are provided at the Glasgow dental hospital. Cumulatively these facilities process, i.e. have a throughput of, 10 million instruments per annum. The Victoria also processes linen for all hospitals utilising the 'Glasgow' system.

4.2.4 Environmental considerations mean that Glasgow can only be accommodated through a new build solution, leasing or outsourcing. To generate sufficient capacity and allow an appropriate level of back up it is suggested that two new facilities are required in Glasgow. An analysis of the current cost per item suggested the economies of scale from a single facility are insufficient to outweigh the operational risks associated with Glasgow having one very large facility.

4.2.5 The following analysis assumes a 2-site solution for North and South Glasgow, i.e. to facilitate sufficient capacity and an appropriate level of contingency provision and results in 12 'core' mainland NHSScotland CSSD facilities. The 12 facilities would be:

CSSD	Services Rationalised From
Ayrshire Central Hospital Irvine	No change
Borders General Hospital	No change
Dumfries General Hospital	No change
Ninewells Hospital	Strathcathro, Dundee Dental Hospital
New Royal Infirmary of Edinburgh	City Hospital, Edinburgh Dental Hospital, Western General Hospital
Falkirk Royal	No change
Foresterhill	No change
Glasgow North	Gartnavel, Stobhill, GRI, Yorkhill, Western General, Glasgow Dental Hospital
Glasgow South	Victoria, Southern General, Victoria Linen Processing
Inverclyde	No change
Raigmore	Belford and McKinnon
Woodend	No change

4.2.6 The exact configuration of Glasgow facilities would depend upon a locally developed business case. Appendix F1, F2 and F3 summarise the estimated costs for this option.

4.2.7 On the above basis, i.e. 10 upgrades and 2 new builds, including the fast track information, the 12 site configuration has an initial estimate cost as follows:

Net capital costs	£17,031,000
Non recurring Revenue Costs	£8,235,100
Recurring Revenue Costs	£2,152,500

B. Selective Upgrade (of sites capable of upgrade)

4.2.8 The options detailed below in relation to a selective upgrade of sites is intended to demonstrate the potential outcomes from a selection of collaborative approaches to service delivery. It will be necessary for trusts to consider collaborative approaches when preparing their proposals and business plans for future service delivery.

11 Sites: ('Core' 12 but exclude Inverclyde which would be serviced from South Glasgow)

Net capital costs	£16,831,000
Non recurring Revenue Costs	£8,443,900
Recurring Revenue Costs	£2,162,500

10 Sites: ('Core' 12 but exclude Inverclyde (as above) and Borders General Hospital which would be serviced from the New Edinburgh Royal Infirmary)

Net capital costs	£16,701,000
Non recurring Revenue Costs	£8,601,100
Recurring Revenue Costs	£2,199,500

9 Sites: ('Core' 12 but exclude Inverclyde, Borders General Hospital (as above) and Woodend which would be serviced from Foresterhill)

Net capital costs	£16,381,000
Non recurring Revenue Costs	£8,737,300
Recurring Revenue Costs	£2,217,500

OPTION LEVEL 2: CURRENT CSSD ACTIVITY PLUS LOCAL ACUTE ACTIVITY

4.2.9 Currently some 6 million instruments within the acute sector are processed outwith CSSDs and in LDUs. The table below details where such activity is undertaken. The activity figures are inclusive of minor procedures undertaken by general medical practitioners.

CSSD Area	Instruments per annum
Inverclyde	416,780
Ayrshire Central Hospital Irvine	0
Borders General Hospital	3,640
Dumfries General Hospital	409,292
Falkirk Royal	410,000

Foresterhill	1,033,136
New Royal Infirmary of Edinburgh	1,053,468
Glasgow North	338,000
Glasgow South	379,600
Ninewells	1,982,344
Raigmore	14,768
Woodend	0

4.2.10 If this activity was transferred to the host CSSD then the activity profiles for the 12-site option and the 9-site option would be as in the Table below. The 9 site option assumes that Inverclyde activity goes to South Glasgow, Borders General activity goes to the New Edinburgh Royal Infirmary and that Woodend activity goes to Foresterhill. Again, the pattern of service delivery would be subject to collaborative discussions between the relevant trusts, who may see other alternatives.

	Current Activity Base	Local Acute Activity	Revised Activity Base	12 Site Maximum Capacity	9 Site Maximum Capacity	12 Site Utilised	9 Site Utilised
Inverclyde Royal Hospital	2,244,000	416,780	2,660,780	4,488,000	0	59%	
Ayrshire Central Hospital	2,849,099	0	2,849,099	5,698,198	5,698,198	50%	50%
Borders General Hospital	379,000	3,640	382,640	758,000	0	50%	
Crichton Royal Hospital	1,753,000	409,292	2,162,292	2,700,000	2,700,000	80%	80%
Falkirk Royal Infirmary	1,635,000	410,000	2,045,000	3,270,000	3,270,000	63%	63%
Foresterhill Hospital	2,864,000	1,033,136	3,897,136	5,728,000	5,728,000	68%	75%
Woodend Hospital	417,000	0	417,000	525,000	0	79%	
Raigmore Hospital	1,763,000	14,768	1,777,768	3,286,000	3,286,000	54%	54%
New Royal Infirmary	4,841,500	1,053,468	5,894,968	7,500,000	8,000,000	79%	78%
North Glasgow Facility	6,652,000	338,000	6,990,000	7,000,000	8,000,000	100%	87%
South Glasgow Facility	3,138,000	379,600	3,517,600	7,000,000	8,000,000	50%	77%
Ninewells Hospital	5,201,000	1,982,344	7,183,344	9,000,000	9,000,000	80%	80%
	33,736,599	6,041,028	39,777,627	56,953,198	53,682,198		
				69.84%	74.10%		

4.2.11 Irrespective of the number of CSSDs maintained, to allow the local acute activity to be processed centrally, the following estimated costs would be incurred. These are additional to the costs detailed under Level 1 above.

Capital costs	£3,000,000
Non recurring Revenue Costs	£337,850
Recurring Revenue Costs	£2,028,110

4.2.12 The capital investment requirement is attributable entirely to the extension of Ninewells, Dundee. This investment is required to allow Ninewells to operate at an acceptable capacity level. It could be possible to eliminate the need for capital investment if the work currently undertaken at Ninewells on behalf of Fife Acute Trust, approximately 2 million instruments per annum, was transferred to an alternative provider. However, the table above demonstrates that, even if 12 sites are maintained, without significant capital investment no single provider could take on an additional 2 million instruments and maintain acceptable capacity levels.

4.2.13 The recurring revenue cost comprises £1,728,000 direct staffing and supplies costs plus £300,000 of capital charges. It has been assumed that the transfer of local acute work will not result in the release of staff time from individual wards and departments therefore each CSSD will need to increase staffing levels proportionately with increased workload.

OPTION LEVEL 3: CURRENT CSSD ACTIVITY PLUS LOCAL ACUTE ACTIVITY PLUS PRIMARY HEALTH CARE ACTIVITY PLUS INDEPENDENT/PRIVATE DENTAL ACTIVITY

4.2.14 Currently approximately 26.3 million instruments within the primary health care sector are processed outwith CSSDs. Of this total over 10.0 million is associated with community dental activity. In addition, a further 164 million instruments are processed annually by independent/private dental practitioners. Clearly, the framework of CSSDs identified above would not be capable of processing the additional instrumentation associated with the three areas of dental activity.

4.2.15 If the 12-site solution is adopted then it would be possible to process a maximum of 17.175 million instruments centrally. This would leave a balance of up to 173 million instruments to be processed by alternative means. However, in order to maintain an appropriate contingency within the system, it is considered that no CSSD should operate at above 80% of maximum capacity. This would reduce the number of primary health care sector and independent/private dental sector instruments that could be processed centrally to approximately 5.8 million or a little over 3.5% of the total.

CSSD Area	Maximum Capacity	Revised Activity Base	Spare Capacity
Inverclyde Royal Hospital	4,488,000	2,660,780	1,827,220
Ayrshire Central Hospital	5,698,198	2,849,099	2,849,099
Borders General Hospital	758,000	382,640	375,360
Crichton Royal Hospital	2,700,000	2,162,292	537,708
Falkirk Royal Infirmary	3,270,000	2,045,000	1,225,000
Foresterhill Hospital	5,728,000	3,897,136	1,830,864
Woodend Hospital	525,000	417,000	108,000
Raigmore Hospital	3,286,000	1,777,768	1,508,232
New Royal Infirmary	7,500,000	5,894,968	1,605,032
North Glasgow Facility	7,000,000	6,990,000	10,000
South Glasgow Facility	7,000,000	3,517,600	3,482,400
Ninewells Hospital	9,000,000	7,183,344	1,816,656
Total	56,953,198	39,777,627	17,175,571

4.2.16 It has been estimated that the cost of upgrading all local facilities associated with primary care trust activity in order to achieve compliance with the Technical Requirements would be approximately £28,000,000. This assumes that local facilities are capable of being upgraded, which experience suggests would not be the case. The upgrading costs for facilities associated with independent and private dental practitioners have not been calculated at this time but are likely to be prohibitive. Other options may need to be explored, including the introduction of single use instruments.

4.3 Options: Key Points Summary

Level 1 Options

- A maximum number 10 CSSDs are capable of being upgraded to meet the required standards.
- Glasgow requires a maximum of two facilities (new build/ leased) or at least an element of contracting out.

- ❑ To ensure acceptable operational capacity is achieved there should be a maximum of 12 CSSDs and a minimum of 9.
- ❑ Capital requirements range from £17.031 million for 12 sites to £16.381million for 9 sites.
- ❑ Investment in additional instrumentation and non-capital equipment of approximately £8.5 million is required.
- ❑ Recurring revenue costs of approximately £2 million per annum will be incurred.

Level 2 Options

- ❑ All locally processed acute sector activity can be accommodated within the Level 1 options.
- ❑ Inclusion would incur additional capital costs of £3 million, non-recurring revenue of £0.338 million, and recurring revenue of £2.028 million.

Level 3 Options

- ❑ Locally processed primary health care sector activity and activity associated with independent and private dental practitioners cannot be accommodated within Level 1 and 2 options.
- ❑ Only 3.5 percent of the activity can be accommodated.

4.4 Preferred Option

4.4.1 As indicated previously, it is not a function of this report to make a firm recommendation on any one option. This reflects the complexity and completeness of the data and the extent to which reliance must, at this stage, be placed on assumptions and estimates. It also reflects the strong view of the Group that in order for the required reconfiguration to be implemented effectively and timeously, it must have NHS trust ownership and support.

4.4.2 Rather, the aim of this report is twofold. Firstly, to set the technical requirements through which the potential risk of person to person transmission of vCJD through medical devices is minimised. And secondly, to provide a database, from a very comprehensive survey of decontamination practices across the whole of NHSScotland, from which trusts can develop plans for bringing their sterile service provision up to the appropriate level of Technical Requirement within a specified timeframe.

4.4.3 However, the Group considered it should identify a preferred option on which discussions for local solutions can be based. The Group's considerations in this regard were as follows.

4.4.4 Consideration was given to whether reconfiguration should be based on upgrading existing facilities, where possible, or to opt for a comprehensive new build programme coupled to possible private sector provision. The latter will, in either event, be a consideration for trusts as they develop action plans for meeting the Technical Requirements. The Group noted that, whilst virtually all CSSDs are currently below requirements, many were not far from attaining them. In these cases it would make little economic or financial sense to walk away from recent investment and/or an infrastructure that, with upgrading, has the capacity to handle current acute sector demands, which is where the high clinical risk for vCJD transmission exists.

4.4.5 Capacity was another consideration. The view taken was that no CSSD should operate at higher than 80% capacity (on average) to allow for production downtime e.g. pre-planned maintenance, breakdowns etc., and spare capacity contingency. Clearly, as the number of possible sites reduces then the pressure on the 80% threshold increases so reducing flexibility in the system to deal with unforeseen processing difficulties. This pointed to the consideration of costs for upgrading anything between 12 and 9 sites.

4.4.6 The net capital costs of all options range between £17 million and £16.4 million. For non recurring costs the range is £8.2 million and £8.7 million with recurring costs of around £2.2 million for all options. The Group considered that with such close margins there was little in funding terms to influence their decision.

4.4.7 In light of these considerations, the Group concluded that, particularly given the capacity and contingency considerations, the 12 site option was its preferred model.

4.5 Recommendations

- All posterior ophthalmic and neurosurgical re-usable instrumentation must be processed locally in line with the 'Protocol for Local Decontamination of Surgical Instruments' (Appendix D.3) with immediate effect.
- All posterior ophthalmic and neurosurgical re-usable instrumentation should transfer to CSSDs that meet the Interim Technical Requirements (TR) set out in Appendix D.1 and E by the end of December 2001.
- All other acute sector sites must comply with the Interim TR by end of March 2002.
- All reconfigured CSSDs/sites must comply with the Full TR no later than March 2004 and within individually set timescales.
- All acute trusts to prepare a local action plan that details how they will progress to the Interim TR, and subsequently the Full TR, for submission to the SEHD by end October 2001.
- All proposals should be considered on a 'full life cycle' basis, i.e. where single use instrumentation is introduced the impact on disposal and the environment must be inclusive.
- Where the action plan has a capital/non-recurring investment proposals, it should be supported by an Interim Agreement submission.
- Any central resources made available should be:
 - for capital and non-recurring revenue purposes only;
 - limited to works that secure the Full TR;
 - for schemes offering best value and align to Framework options or offer viable alternatives.
- All agreed investment proposals to be processed in accordance with SEHD's Capital Investment procedures and within a stipulated timescale.
- Further work is undertaken for the remaining activity associated with primary care trusts and independent and general dental practitioners.

GROUP MEMBERSHIP LISTINGS

1. Sterile Services Provision Review Group

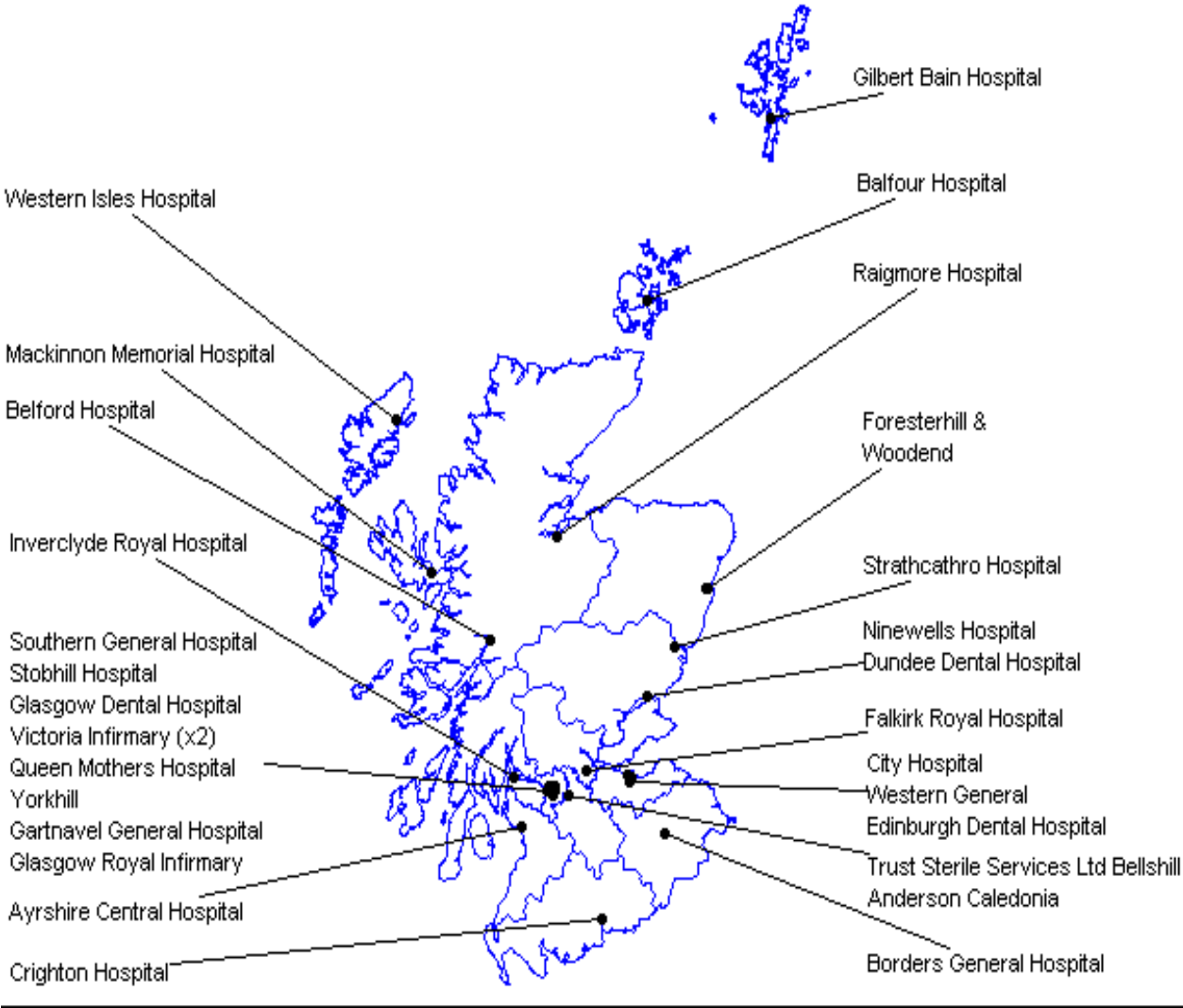
Mr John Glennie, Chief Executive, Borders Acute Hospital NHS Trust (Chairman)
Mr Sandy Agnew, Support Services Manager, Ayrshire & Arran Acute Hospitals NHS Trust
Mr Gordon Muir, CSSD Manager, Tayside University Hospitals NHS Trust
Mr Kenny Walker, Technical Development Manager, Grampian Primary Care NHS Trust
Dr Andrew Smith, Specialist Registrar, Glasgow Dental Hospital and School
Mr Gerry O'Brien, Assistant Director of Finance, Borders Acute Hospital NHS Trust
Mr Jim Devine, UNISON, Scottish Partnership Forum
Mrs Susan Russell, GMB, Scottish Partnership Forum
Dr Martin Donaghy, Senior Medical Officer, SEHD
Mr Eddie McLaughlan, Assistant Director, NHSScotland Property & Environment Forum Executive
Mr Ron Eunson, Authorised Person Sterilisers, Scottish Healthcare Supplies
Mr Chris Naldrett, Head of Policy Implementation & Development, SEHD Finance Directorate
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Survey/Review analysis and report: Ms Ann Smith, SCIEH

2. 'Fast Track' Review Group for Neurosurgical and Posterior Eye Surgical Procedures

Mr John Glennie (Chairman)
Dr Jeff Jay (Ophthalmologist)
Mr Ken Lindsay (Neurosurgeon)
Mr Sandy Agnew
Mr David Hurrell (Healthcare Science Ltd)
Miss Mary Henry (SCIEH)
Ms Sandra Campbell (SMO, SEHD)
Dr Martin Donaghy (SMO, SEHD)
Chris Naldrett (SEHD and Group Secretary)

MAP OF EXISTING CSSDs



Appendix B.2

**TABLE DETAILING UPGRADE STATUS
OF ALL CENTRAL CSSD SITES**

C S S D	HOST TRUST	CAPABLE OF UPGRADE
Inverclyde Royal Hospital	Argyll & Clyde Acute NHS Trust	Yes
Ayrshire Central Hospital	Ayrshire and Arran Acute NHS Trust	Yes *
Borders General Hospital	Borders Acute NHS Trust	Yes
Crichton Royal Hospital	Dumfries & Galloway Acute NHS Trust	Yes !
Falkirk Royal Infirmary	Forth Valley Acute NHS Trust	Yes **
Forresterhill Hospital	Grampian Acute NHS Trust	Yes **
Woodend Hospital	Grampian Acute NHS Trust	Yes
Belford Hospital	Highland Acute NHS Trust	No
McKinnon Hospital	Highland Acute NHS Trust	No
Raigmore Hospital	Highland Acute NHS Trust	Yes
City Hospital	Lothian Acute NHS Trust	No **
Western General	Lothian Acute NHS Trust	No **
Gartnavel General Hospital	North Glasgow NHS Trust	No
Glasgow Royal Infirmary	North Glasgow NHS Trust	No
Stobhill Hospital	North Glasgow NHS Trust	No
The Southern General	South Glasgow NHS Trust	No
The Victoria Infirmary CSSD	South Glasgow NHS Trust	Yes *
The Victoria Infirmary TSSU	South Glasgow NHS Trust	No
Ninewells Hospital	Tayside Acute NHS Trust	Yes *
Strathcathro	Tayside Acute NHS Trust	No
The Queen Mother's Hospital	Yorkhill NHS Trust	No
Glasgow Dental Hospital	North Glasgow NHS Trust	No
Dundee Dental Hospital	Tayside Acute NHS Trust	No
Edinburgh Dental Hospital	Lothian Acute NHS Trust	No
Trust Sterile Supplies Limited	Contract with Lanarkshire Acute Trust	Yes *
Gilbert Bain Hospital	Shetland Isles Health Board	?
Balfour Hospital	Orkney Isles Health Board	?
Western Isles Hospital	Western Isles Health Board	Yes

Explanatory notes on next page.

NOTES

- * Upgraded sites currently accredited to EN46002.
- ** Sites in the process of upgrade to become accredited to EN46002 (NB City Hospital and Western General moving to New Build Royal Infirmary site).
- ? Upgrade status to be identified.
- ! Intended to move Crichton activity to new build provision within D & G Royal Hospital. No timescale established.

Appendix C

TABLE OF REVENUE COSTS (£) AND ITEM THROUGHPUT IN 2000/2001

Central Facility	Host Trust	Existing Revenue Costs	Annual Activity
Inverclyde Royal Hospital	Argyll and Clyde Acute NHS Trust	677000	2244000
Ayrshire Central Hospital	Ayrshire and Arran Acute NHS Trust	716000	2849099
Borders General Hospital	Borders Acute NHS Trust	265710	379000
Crichton Royal Hospital	Dumfries and Galloway Acute NHS Trust	266000	1753000
Falkirk Royal Infirmary	Forth Valley Acute NHS Trust	674480	1635000
Foresterhill Hospital	Grampian Acute NHS Trust	1065586	2864000
Woodend Hospital	Grampian Acute NHS Trust	153620	417000
Belford Hospital	Highland Acute NHS Trust	43000	83000
McKinnon Hospital	Highland Acute NHS Trust	20000	37000
Raigmore Hospital	Highland Acute NHS Trust	855046	1643000
City Hospital	Lothian Acute NHS Trust	2750000	4512000
Gartnavel General Hospital	North Glasgow NHS Trust	569000	1941000
Glasgow Royal Infirmary	North Glasgow NHS Trust	987000	1170000
Stobhill Hospital	North Glasgow NHS Trust	306000	1514000
The Southern General	South Glasgow NHS Trust	339529	2008000
The Victoria Infirmary CSSD	South Glasgow NHS Trust	1350049	
The Victoria Infirmary TSSU	South Glasgow NHS Trust	294000	1130000
Ninewells Hospital	Tayside Acute NHS Trust	3237474	4664000
Strathcathro	Tayside Acute NHS Trust	118725	234000
The Queen Mother's Hospital	Yorkhill NHS Trust	141000	1187000
		<u>1482921</u>	<u>32264099</u>
Glasgow Dental Hospital	North Glasgow NHS Trust	88338	840000
Dundee Dental Hospital	Tayside Acute NHS Trust	32000	303000
Edinburgh Dental Hospital	Lothian Acute NHS Trust	35000	329500
		155338	1472500
		<u>14984557</u>	<u>33736599</u>
Total Mainland Sites			

Notes

1. City Hospital line includes Western General, Edinburgh (£500,000 and 96,560 instruments per annum)
2. Excludes Island HBs and TSSL

TECHNICAL REQUIREMENTS FOR DECONTAMINATION PROCESSES

Clinical procedures* Categorisation by risk for all types of CJD
<p>High risk procedures</p> <ul style="list-style-type: none">• All procedures that involve piercing the dura, or contact with the trigeminal and dorsal root ganglia, or the pineal and pituitary glands.• Procedures involving the optic nerve and retina.
<p>Medium risk procedures</p> <ul style="list-style-type: none">• Other procedures involving the eye, including the conjunctiva, cornea, sclera and iris.• Procedures involving contact with lymphoreticular system (LRS).• Anaesthetic procedures that involve contact with LRS during tonsil surgery (for example laryngeal masks).• Procedures in which biopsy forceps come into contact with LRS tissue.
<p>Low risk procedures</p> <ul style="list-style-type: none">• All other invasive procedures including other anaesthetic procedures and procedures involving contact with the cerebrospinal fluid.

* Further risk assessment to be undertaken on categorisation of dental tissues that are currently considered as low risk.

Appendix D.1A

DECONTAMINATION: TECHNICAL REQUIREMENTS			
Risk Category	Function	Interim Requirements (indicators to demonstrate that requirements are met are presented in Appendix D.1B)	Full Requirements
High	Equipment	<ul style="list-style-type: none"> • Compliance with SHTM 2010 (sterilisers) • Compliance with SHTM 2030 (washer disinfectors must be part of decontamination process; manual cleaning limited to pre-clean, in accord with manufacturers' instructions, before washer-disinfecter processing) 	<p>Interim requirement plus:</p> <ul style="list-style-type: none"> • Compliance with SHTM 2031 (Clean Steam for Sterilization) • Compliance with BS EN 554 Sterilization of medical devices – validation and routine control of sterilization by moist heat • Accreditation to Article 12 or Annex V of the Medical Devices Regulation 1994 • Compliance with ISSM Quality Standards and Recommended Practices for Sterile Departments
	Facilities	<ul style="list-style-type: none"> • Physical separation of clean and dirty processes in accordance with SHPN 13 (Guidance on sterile services department) 	<p>Interim requirement plus:</p> <ul style="list-style-type: none"> • Space and design of whole facility to follow SHPN 13 (sterile services department) • Compliance with BS5925 Class L (Environmental cleanliness in enclosed spaces) • Compliance with SHTM 2025 (Ventilation in healthcare premises)
	Staff	<ul style="list-style-type: none"> • All personnel carrying out decontamination processes have documented training needs assessment and record of training received 	<p>Interim requirement plus:</p> <ul style="list-style-type: none"> • Compliance with BS EN 46002 (General standard on quality system requirements) and BS EN 724 (Guidance on complying with EN 46002) • Accreditation to Article 12 or Annex V of the Medical Devices Regulation 1994.

DECONTAMINATION: TECHNICAL REQUIREMENTS			
Risk Category	Function	Interim Requirements (indicators to demonstrate that requirements are met are presented in Appendix D.1B)	Full Requirements
High (Continued)	Management	<ul style="list-style-type: none"> • Senior member of staff with documented responsibility for decontamination processes and capable of assessing and treating risks associated with ineffective decontamination processes and documented evidence of appropriate training. • Senior Manager with overview in accord with HDL 2007(10) • Steps taken to introduce systems which enable the tracing of sets of surgical instruments to the patients on whom they have been used and links this information with records of their decontamination 	<ul style="list-style-type: none"> • Qualified Manager (e.g. Member of ISSM or equivalent) in charge of Central Units • Compliance with BS EN 46002 (General standard on quality system requirements) • SHTM 2010 Sterilization Overview and management responsibilities • SHTM 2030 Washer-Disinfectors Overview and management responsibilities • SHTM 2031 Clean steam for sterilisation • MDA Device Bulletin DB 9801 Medical Device and Equipment Management for Hospital and Community based Organisations • Full implementation of systems which enable the tracing of sets of surgical instruments to the patients on whom they have been used and links this information with records of their decontamination

Risk Category	Function	Interim Requirements (Indicators to demonstrate that requirements are met are presented in Appendix D.1B)	Full Requirements
Medium	Equipment	<ul style="list-style-type: none"> Ability to demonstrate that washer disinfectors are fit for purpose, operating effectively, maintained adequately, and tested and validated in line with current guidance Compliance with SHTM 2010(sterilizers) Surgical instruments, if neither washer disinfectors nor ultrasonic washer are reasonably practical 	<p>Interim requirement plus:</p> <ul style="list-style-type: none"> Compliance with SHTM 2030 (washer disinfectors must be part of decontamination process; manual cleaning limited to pre-clean, in accord with manufacturers' instructions, before washer-disinfector) Accreditation to Article 12 or Annex V of the Medical Devices Regulation 1994 Compliance with SHTM 2031 (clean steam for sterilisation) Practice and procedures to follow ISSM Quality Standards and Recommended Practices for Sterile Service Departments BS EN 554 Sterilization of medical devices – validation and routine control of sterilization by moist heat
	Facilities	<ul style="list-style-type: none"> Physical separation of clean and dirty processes 	<p>Interim requirement plus:</p> <ul style="list-style-type: none"> Space and design of whole facility to follow SHPN 13 (Guidance on sterile services department) Compliance with BS5925 Class L (Environmental cleanliness in enclosed spaces) Compliance with SHTM 2025 (Ventilation in healthcare premises)
	Staff	<ul style="list-style-type: none"> All personnel carrying out decontamination processes have documented training needs assessment and record of training received 	<p>Interim requirement plus:</p> <ul style="list-style-type: none"> Compliance with BS EN 46002 (General standard on quality system requirements) and BS EN 724 (Guidance on complying with EN 46002) Accreditation to Article 12 or Annex V of the Medical Devices Regulation 1994

Medium (Continued)	Function	Interim Requirements (indicators to demonstrate that requirements are met are presented in Appendix D.1B) <ul style="list-style-type: none"> • Senior member of staff with documented responsibility for decontamination processes and capable of assessing and treating risks associated with ineffective decontamination processes and documented evidence of appropriate training • Senior Manager with overview in accord with HDL 2001(10) • Steps taken to introduce systems which enable the tracing of sets of surgical instruments to the patients on whom they have been used and links this information with records of their decontamination 	Full Requirements <p>Interim requirement plus:</p> <ul style="list-style-type: none"> • Qualified Manager (e.g. Member of ISSM or equivalent) in charge of CSSD • Compliance with BS EN 46002 (General standard on quality system requirements) • SHTM 2010 Sterilization: Overview and management responsibilities • SHTM 2030 Washer-Disinfectors Overview and management responsibilities • SHTM 2031 Clean steam for sterilisation • MDA Device Bulletin DB 9801 Medical Device and Equipment Management for Hospital and Community based Organisations • Full implementation of systems which enable the tracing of sets of surgical instruments to the patients on whom they have been used and links this information with records of their decontamination.
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Risk Category	Function	Interim Requirements	Full Requirements*
Low	Equipment	<ul style="list-style-type: none"> Ability to demonstrate that washer disinfectors are fit for purpose, operating effectively, maintained adequately, and tested and validated in line with current guidance Compliance with SHTM 2010 (sterilisers) Compliance with Protocol on the Local Decontamination of Surgical Instruments if neither washer disinfectors nor ultrasonic washer not reasonably practical 	<p>Interim requirement plus:</p> <ul style="list-style-type: none"> Compliance with SHTM 2030 (if use of washer disinfectors not reasonably practicable then utilisation of ultrasonic washer indicated)
	Facilities	<ul style="list-style-type: none"> Effective separation of clean and dirty processes in accord with Protocol on the Local Decontamination of Surgical Instruments 	As interim requirements
	Staff	<ul style="list-style-type: none"> All personnel carrying out decontamination processes have documented training needs assessment and record of training received 	Training needs and records as part of a formal quality assurance system
	Management	<ul style="list-style-type: none"> Senior member of staff with documented responsibility for decontamination processes and capable of assessing and treating risks associated with ineffective decontamination processes Senior Manager with overview in accord with HDL 2001(10) if decontamination taking place in NHS Trust 	<p>Interim requirement plus:</p> <ul style="list-style-type: none"> MDA Device Bulletin DB 9801 Medical Device and Equipment Management for Hospital and Community based Organisations

Key Indicators for Demonstration that Interim Technical Requirements Are Met

The key indicators outlined below provide an indication of the level of compliance with the technical requirements. At this time indicators are provided for the 'High' and 'Medium' risk interim requirements only.

The indicators should be interpreted as identifying key issues in relation to the requirements and are not intended to form an exhaustive list. For clarity of presentation, the indicators are presented in a concise form. The relevant guidance material should be consulted to provide context and understanding. Specialist advice should be sought where necessary.

To ensure compliance with the Technical Requirements, at least the following must be in place.

HIGH RISK

Equipment

Porous Load Sterilizers

- the steam supply system must be in accordance with design guidance in SHTM 2010 Part 2;
- the sterilizer must be commissioned, validated and tested annually, quarterly, weekly and daily (SHTM 2010 Part 3);
- the sterilizer must be fitted with a chart recorder or data logger, independent of the controller, recording chamber temperature and pressure (BS EN285; SHTM 2010 Part 2);
- the sterilizer must be subject to documented planned preventative maintenance (PPM), (SHTM 2010 Part 3);
- the steam quality must meet the physical conditions specified in SHTM 2010 Part 3 (< 3.5% non condensable gases (NCG), >0.95 dryness value (DV), <25° superheat);
- evidence must be available that the sterilizer installation, tests and operation have been audited at least annually by Authorised Person (Sterilizers) (AP(S));
- all sterilizers must have a plant history file/sterilizer process log (SHTM 2010 part 4).

Bowl and Instrument Sterilizer – Main Steam (N.B. Dropped instrument use only)

- the steam supply must be in accordance with design guidance in SHTM 2010 Part 2;
- the sterilizer must be commissioned, validated and tested annually, quarterly, weekly and daily as per SHTM 2010 Part 3;
- the sterilizer must be fitted with chart recorder or data logger as per SHTM 2010 Part 2
or
a documented procedure must be in place requiring operator to observe and record, temperature, on independent temperature gauge, to verify attainment of sterilizing temperature for each cycle;

- the sterilizer must be subject to documented PPM (SHTM 2010 Part 3);
- evidence must be available that the sterilizer installation, tests and operation have been audited at least annually by an Authorised Person (Sterilizers) (AP(S));
- all sterilizers must have a plant history file/sterilizer process log (SHTM 2010 part 4).

Benchtop Bowl and Instrument Sterilizer (N.B. Dropped instrument use only)

- sterile water for irrigation, changed daily, must be used for raising steam;
 - the sterilizer must be fitted with independent chart recorder or data logger as per SHTM 2010 Part 2;
- or*
- a documented procedure must be in place requiring operator to observe and record temperature, on independent temperature gauge, fitted to machine to verify attainment of sterilizing temperature;
- the sterilizer must be commissioned, validated and tested annually, quarterly, weekly and daily as per SHTM 2010 Part 3;
 - the sterilizer must be subject to documented PPM, (SHTM 2010 Part 3);
 - evidence must be available that the sterilizer installation, tests and operation have been audited at least annually by an AP(S);
 - all sterilizers must have a plant history file/sterilizer process log (SHTM 2010 part 4).

Other Sterilizers

- ethylene oxide / LTSF / gas plasma / dry heat - seek advice from an AP(S) as per SHTM 2010.

Washer disinfectors

- the washer disinfectant must be designed and constructed to ensure segregation of dirty items from cleaned items and to ensure that aerosols and leaks do not contaminate the environment;
- the washer disinfectant must be fitted with temperature recorder, independent of controller, to record the temperature during the disinfection stage;
- final rinse water must be produced by reverse osmosis or de-ionisation;
- the washer disinfectant must be commissioned, validated and tested annually, quarterly, weekly and daily in accordance with SHTM 2030 Part 3 to establish, at least:
 - cleaning efficacy for chamber and load carrier;
 - cleaning efficacy for test load;
 - cleaning efficacy for 'in-use' loads;
 - thermal disinfection.

Ultrasonic cleaners

- must be fitted with lid;
- must be capable of being drained and re-filled easily to permit change of water at not more than 4 hourly intervals;
- must be tested on installation, and weekly, using the aluminium foil erosion test to ensure continued ultrasonic activity.

Manual washing

- at least two sinks (one for washing and one for rinsing) dedicated to use for cleaning medical devices must be provided.

Process

General

- there must be a documented procedure designed to ensure that processed devices are clean and sterile including procedures for inspection for cleanliness, and records of items rejected and reworked;
- records of each load processed through each decontamination stage must be maintained (i.e. cleaning, disinfection and sterilization);
- records must be kept of load items placed in each cycle;
- there must be a documented procedure for review of cycle record and load condition prior to release of sterile product and a documented record of sterile product release.

Cleaning

- all cleaning must be carried out in accordance with the instructions provided by the manufacturer of the device to be cleaned;
- whenever practicable, automated washer disinfector with thermal disinfection process must be used;
- when using stand alone ultrasonic cleaner or ultrasonic irrigators with no disinfection stage, the device must, where possible, be cleaned in a washer disinfector after ultrasonication;
- manual cleaning, when required as pre-cleaning or when specified as the only permissible cleaning method, must be carried out in accordance with the Protocol for local decontamination of surgical instruments in Appendix D.3;
- there must be a documented procedure for loading the washer disinfector including, when necessary, disassembly of items and connection of lumened devices for irrigation of the channel;
- there must be a documented procedure for review of cycle record and load condition (inspection for cleanliness and dryness) prior to release of product for re-assembly, packaging and subsequent sterilization.

Washer Disinfectors

- weekly testing for protein residues by one of the methods in SHTM 2030 or a validated equivalent test must be carried out.

Benchtop Bowl and Instrument Sterilizer (N.B. Dropped instrument use only)

- there must be records demonstrating that reservoir and chamber are drained daily and refilled with sterile water for irrigation;
- there must be a documented procedure requiring the operator to observe and record attainment of the required temperature on an independent temperature gauge

or

the sterilizer must be fitted with chart recorder or data logger as per SHTM 2010 Part 2.

Facilities

- there must be physical separation of clean and dirty processes - this requires a physical barrier (wall) between dirty and clean areas with double ended (pass through) washer disinfectors. When manual cleaning is used a pass-through drying cabinet may also be necessary. Separation by segregated workflow alone is insufficient;
- the area must be physically segregated from both clinical activity and clean area for assembly and packing of devices;
- at least two sinks (one for washing and one for rinsing) dedicated to use for cleaning medical devices must be provided;
- appropriate inspection equipment e.g. magnifiers, and task lighting must be available.

Staff

- there must be documented records of training and acquisition of required skills for:
 - TP(S) carrying out annual tests;
 - MP(S) or TP(S) carrying out quarterly and weekly tests and maintenance;
 - operator carrying out daily tests and housekeeping;
 - operator/supervisor releasing sterile product.
- there must be evidence that all staff operating a sterilizer or washer disinfectant have been trained in the nature of loads that may be processed and the correct method of loading;
- there must be evidence that staff have been adequately trained in all relevant operational procedures;
- a Microbiologist (Sterilizers) must be appointed for each decontamination facility.

Management

- there must be a senior member of staff with documented responsibility for decontamination processes and capable of assessing and treating risks associated with ineffective decontamination processes, and with documented evidence of appropriate training;
- there must be a senior manager with overview in accordance with HDL 2001(10);
- steps must be taken to introduce systems which enable the tracing of sets of surgical instruments to the patients on whom they have been used and link this information with records of their decontamination.

Key Indicators for Demonstration that Interim Technical Requirements Are Met

MEDIUM RISK

Equipment

Porous Load Sterilizers

- the steam supply system in accordance with design guidance in SHTM 2010 Part 2;
- the sterilizer must be commissioned, validated and tested annually, quarterly, weekly and daily as per SHTM 2010 Part 3;
- the sterilizer must be fitted with a chart recorder or data logger, independent of the controller, recording chamber temperature and pressure (BS EN285; SHTM 2010 Part 2);
- the sterilizer must be subject to documented PPM, (SHTM 2010 Part 3);
- the steam quality must meet the physical conditions specified in SHTM 2010 Part 3 (< 3.5% non condensable gases, >0.95 dryness value, <25° superheat);
- evidence must be available that sterilizer installation, tests and operation have been audited at least annually by an AP(S);
- all sterilizers must have a plant history file/sterilizer process log (SHTM 2010 part 4).

Bowl and Instrument Sterilizer – Main Steam (N.B. for sterilization at point of use)

- the steam supply must be in accordance with design guidance in SHTM 2010 Part 2;
- the sterilizer must be commissioned, validated and tested annually, quarterly, weekly and daily as per SHTM 2010;
- the sterilizer must be fitted with a chart recorder or data logger as per SHTM 2010 Part 2;
or
there must be a documented procedure requiring operator to observe and record temperature, on independent temperature gauge, fitted to machine to verify attainment of sterilizing temperature for each cycle;
- the sterilizer must be subject to documented PPM, (SHTM 2010 Part 3);
- there must be evidence that sterilizer has been audited at least annually by an AP(S);
- all sterilizers must have a plant history file/sterilizer process log (SHTM 2010 part 4).

Benchtop Bowl and Instrument Sterilizer (N.B. for sterilization at point of use)

- sterile water for irrigation, changed daily, must be used for raising steam;
- the sterilizer must be fitted with a chart recorder or data logger as per SHTM 2010 Part 2;
or
there must be a documented procedure requiring operator to observe and record temperature, on independent temperature gauge, fitted to machine to verify attainment of sterilizing temperature;

- the sterilizer must be commissioned, validated and tested yearly, quarterly, weekly and daily as per SHTM 2010 Part 3;
- the sterilizer must be subject to documented PPM, (SHTM 2010 Part 3);
- there must be evidence that the sterilizer installation, tests and operation have been audited at least annually by an AP(S);
- all sterilizers must have a plant history file/sterilizer process log (SHTM 2010 part 4).

Other Sterilizers

- ethylene oxide / LTSF / gas plasma / dry heat - seek advice from an AP(Sterilizers) as per SHTM 2010.

Washer disinfectors

- must be fitted with a temperature indicator or recorder, independent of controller to monitor the temperature during the disinfection stage;
- the washer disinfectant must be commissioned, validated and tested annually, quarterly, weekly and daily in accordance with SHTM 2030 to establish, at least:
 - cleaning efficacy for chamber and load carrier;
 - cleaning efficacy for test load;
 - cleaning efficacy for 'in-use' loads;
 - thermal disinfection.

Ultrasonic cleaners

- must be fitted with lid;
- there must be a procedure to ensure change of water at not more than 4 hourly intervals;
- Ultrasonic cleaners must be tested on installation, and weekly, using the aluminium foil erosion test to ensure continued ultrasonic activity.

Manual washing

- at least two sinks (one for washing and one for rinsing) dedicated to use for cleaning medical devices must be provided.

Process

General

- there must be a documented procedure designed to ensure that processed devices are clean and sterile;
- there must be records of each load processed through each decontamination stage (i.e. cleaning, disinfection and sterilization);
- records must be kept of load items placed in each cycle;
- there must be a documented procedure for review of cycle record and load condition prior to release of sterile product. Documented record of sterile product release.

Cleaning

- all cleaning must be carried out in accordance with the instructions provided by the manufacturer of the device to be cleaned;
- whenever practicable automated washer disinfector with thermal disinfection process must be used;
- when using stand alone ultrasonic cleaner or ultrasonic irrigator with no disinfection stage, the device must, where possible, be cleaned in a washer disinfector after ultrasonication;
- manual cleaning, when required as pre-cleaning or when specified as the only permissible cleaning method, must be carried out in accordance with the Protocol for local decontamination of surgical instruments in Appendix D.3;
- there must be a documented procedure for loading the washer disinfector including, when necessary, disassembly of items and connection of lumened devices for irrigation of the channel;
- there must be a documented procedure for review of cycle record and load condition (inspection for cleanliness and dryness) prior to release of product for re-assembly, packaging and subsequent sterilization.

Washer Disinfectors

- weekly testing for protein residues by one of the methods in SHTM 2030 or a validated equivalent test must be carried out.

Benchtop Bowl and Instrument Sterilizer (N.B. for sterilization at point of use)

- there must be records demonstrating that reservoir and chamber are drained daily and refilled with sterile water for irrigation;
- a documented procedure requiring operator to observe and record attainment of required temperature on independent temperature gauge;
or
the sterilizer must be fitted with chart recorder or data logger as per SHTM 2010 Part 2.

Facilities

- there must be physical separation of clean and dirty processes - this requires a physical barrier (wall) between dirty and clean areas with double ended (pass through) washer disinfectors. When manual cleaning is used a pass-through drying cabinet may also be necessary. Separation by segregated workflow alone is insufficient;
- the area must be physically segregated from both clinical activity and clean area for assembly and packing of devices;
- at least two sinks (one for washing and one for rinsing) dedicated to use for cleaning medical devices must be provided;
- appropriate inspection equipment e.g. magnifiers, and task lighting must be provided.

Staff

- there must be documented records of training and acquisition of required skills for:
 - TP(S) carrying out annual tests;
 - MP(S) or TP(S) carrying out quarterly and weekly tests and maintenance;
 - operator carrying out daily tests and housekeeping;
 - operator/supervisor releasing sterile product.

- evidence must be available that all staff operating a sterilizer or washer disinfectors have been trained in the nature of loads that may be processed and the correct method of loading;
- evidence must be available that staff have been adequately trained in all relevant operational procedures;
- a Microbiologist (Sterilizers) must be appointed for each decontamination facility.

Management

- there must be senior member of staff with documented responsibility for decontamination processes and capable of assessing and treating risks associated with ineffective decontamination processes, and documented evidence of appropriate training;
- there must be senior Manager with overview in accord with HDL 2001(10);
- steps must be taken to introduce systems which enable the tracing of sets of surgical instruments to the patients on whom they have been used and link this information with records of their decontamination.

DECONTAMINATION STANDARDS AND GUIDANCE

The standards and guidance summarised below comprise the principal references relevant to the achievement of the technical requirements detailed in Appendices D.1 and D.1A.

British Standards

Independently accredited compliance with BS EN ISO 9002, and BS EN 46002 is essential for decontamination units which are required to be registered as manufacturers under the Medical Devices Regulations. 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. Harmonised European standards, e.g. EN 554, afford a presumption of compliance to the relevant essential requirements given in Annex 1 of the Medical Devices Directive. All healthcare facilities should be complying with these standards and hospitals were advised of this in Medical Devices Bulletin 18a.

British Standards such as BS 5295 (clean rooms), 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.

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 sterilise 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

Scottish Health Technical Memoranda (SHTM)

SHTMs are produced to provide healthcare facilities with a framework of best practice in the choice, purchasing, installation, validation, and 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.

SHTM 2010 Sterilization

Scottish Health Technical Memoranda (SHTM) 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. SHTM 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 sterilising 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.

SHTM 2025 Ventilation in healthcare premises

SHTM 2025 provides guidance on the legal requirements, design implications, maintenance and operation of specialist ventilation in all types of healthcare premises. SHTM 2025 is published in four volumes:

1. *Overview and management responsibilities* – provides an overview of ventilation in healthcare premises and considers the overall responsibility of managers of healthcare premises. It outlines legal obligations and clinical needs with respect to ventilation, summarises the technical aspects and concludes with guidance on the management of systems.
2. *Design considerations* – does not set out to give detailed instruction and design but highlights the overall requirements that should be applied to the design up to the contract documentation.
3. *Validation and verification* – gives general advice for ensuring that the installed equipment has been formally tested and certified as to contract. The importance of correctly setting to work and commissioning the completed installation is emphasised. The handover procedure including the provision of documentation and training is set out.
4. *Operational management* – provides information to those responsible for overseeing the day-to-day operation and maintenance. Safe systems of work, record keeping and legal obligations are included.

SHTM 2030 Washer-disinfectors

SHTM 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 uses, 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.

SHTM 2031 Clean steam for sterilization

SHTM 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 SHTM 2010 Sterilization.

1. Planning/Building notes

SHPN 13 Sterile services department

Scottish Hospital Planning Note 13 provides guidance for the planning and design of a sterile services department, with particular requirements for cleaning, disinfecting and sterilising, storage and materials handling and good manufacturing practice.

Health Building Note 13 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.

2. Guidance produced by the Medical Devices Agency

DB2000(05): Guidance on the Purchase, Operation and Maintenance of Vacuum Benchtop Steam Sterilizers

This bulletin is supplementary to DB9804 and provides guidance on the purchase, operation and maintenance of benchtop steam sterilizers that have a forced air removal system to provide Type B or Type S sterilization cycles. These sterilizers are marketed as vacuum benchtop steam sterilizers or porous load benchtop steam sterilizers. It also covers periodic testing.

DB2000(04): Single-Use Medical Devices: Implications and Consequences of Reuse

This bulletin replaces DB9501 and draws attention to the hazards and risks associated with reprocessing and reusing single-use medical devices. It covers the legal issues and regulatory requirements of such actions. It also considers the implications of damage to the materials or construction of the device and inadequate decontamination procedures.

DB2000(02): Medical Devices and Equipment Management: Repair and Maintenance Provision

This bulletin builds on and provides additional guidance to that contained within MDA Bulletin DB9801, covering the management of the repair and maintenance process, and setting out good practice for the organisation that carried it out.

DB9804: The Validation and Periodic Testing of Benchtop Vacuum Steam Sterilizers

This bulletin provides guidance for owners, managers and users of vacuum benchtop steam sterilizers in order to minimise risks to patients and operators. It gives details of daily and weekly tests and checks needed, and test protocols for medical physicists and Test Persons (sterilizers).

DB9801: Medical Device and Equipment Management for Hospital and Community-based Organisations

This bulletin replaces HEI 98 and emphasises training and maintenance as being the two factors with the greatest impact on the safe use of medical devices. It highlights user knowledge and skills as having major implications for safety and outlines the need for both generic and specific training. Planned preventative maintenance, which follows manufacturer's guidance, is also emphasised in ensuring that devices are safe and reliable.

DB9801 Supplement 1: Checks and Tests for Newly-delivered Medical Devices

DB9607: Decontamination of endoscopes

This bulletin is concerned with those problems associated with the decontamination of endoscopes and their accessories. Attention is drawn to areas of particular concern and advice and guidance offered to both users and manufacturers (of both the devices and the processing equipment) in resolving these issues. It also draws together existing advice, with particular reference to disinfectant contact times, upon which those personnel with responsibility for decontamination and infection control may base their processing procedures.

DB9605: The Purchase, Operation and Maintenance of benchtop steam sterilizers

This bulletin is aimed at all owners and users of small benchtop steam sterilizers and should be of particular interest to: General Practitioners, community healthcare workers, dental practitioners, podiatrists, and staff in operating theatres, Intensive Care Units, Day Surgery Units, Accident & Emergency departments and Out-patient departments. It is also relevant to tattooists and acupuncturists. It contains advice regarding the purchase, installation and validation, periodic testing, maintenance, technical aspects, safety considerations, legal and insurance considerations as relevant to this equipment.

3. Guidance produced by the Institute of Sterile Services Management

Quality Standards and Recommended Practices for Sterile Service Departments (SSD)

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.

PROTOCOL FOR LOCAL DECONTAMINATION OF SURGICAL INSTRUMENTS

- 1. Background**
- 2. Management of Surgical Instruments**
 - 2.1 General Information
 - 2.2 Acquisition and disposal of surgical instruments
- 3. Reprocessing of Medical Devices**
 - 3.1 Automated Cleaning
 - 3.2 Manual Cleaning
 - 3.3 Disinfection
 - 3.4 Inspection
 - 3.5 Packaging
 - 3.6 Sterilization
 - 3.7 Storage
 - 3.8 Transportation
- 4. References**

1. Background

Recent work undertaken by a Working Group established by the Scottish Executive Health Department has shown that there is a significant amount of reprocessing of re-decontamination surgical instruments in clinical areas as opposed to central processing units. The Group's report, '*The Decontamination of Surgical Instruments and other Medical Devices*', also states that wherever possible, decontamination processes should be automated.

Automated cleaning methods provide a number of advantages over manual methods. This includes the provision of efficient, reproducible processes, which can be more easily controlled and validated than manual methods. They provide protection for the user by reducing the exposure to chemicals and micro-organisms. Certain methods of automated cleaning also provide simultaneous cleaning and disinfection of items.

All reprocessing of surgical instruments should be undertaken outside of the clinical environment where possible, and preferably in Central Decontamination Units.

The preferred methods of decontamination, for the reasons stated above, are, in order of preference:

1. Central automated decontamination.
2. Local automated decontamination.
3. Local manual decontamination.

The above pre-supposes that all other good practice measures are in place.

This protocol has been developed to provide advice and guidance to ensure that decontamination, and in particular manual cleaning, is undertaken in a safe and effective manner.

The advice and guidance contained within this protocol is drawn from current published advice and is referenced throughout. This document should be read in conjunction with such other guidance as is necessary. It is not a substitute for published guidance.

2. Management of Surgical Instruments

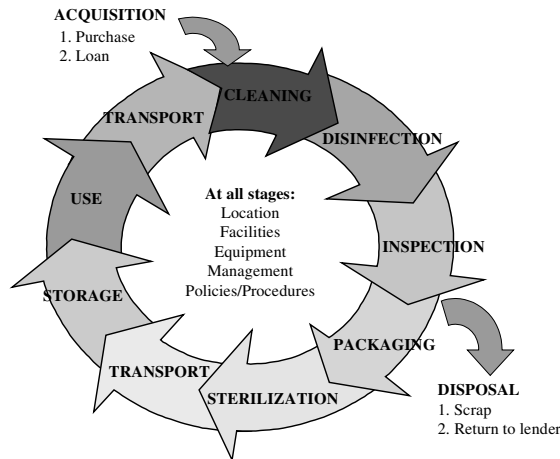
2.1 General Information

Cleaning of re-useable surgical instruments is an essential pre-requisite to ensure effective disinfection and/or sterilization. The presence of organic matter on surgical instruments can inhibit disinfectant or sterilant contacting microbial cells and thereby reduce its activity and effectiveness. Surgical instruments and associated accessories should be decontaminated immediately following use, or as soon as is reasonably practicable. It is essential that, where devices have to be transported outside the clinical unit to the processing centre, regular collections are made and all items are appropriately containerised to prevent damage during transit, and to ensure staff safety.

All re-useable surgical instruments that are used in the clinical environment should be decontaminated without exception. For example, it is unacceptable to process only those instruments that come into direct patient contact. All instruments and instrument trays, opened in the clinical environment, should be decontaminated between uses.

The following pages contain key advice applicable to the reprocessing of surgical instruments where undertaken locally. Effective decontamination requires the control and monitoring of all stages of the life-cycle process shown in Figure 1.

Figure 1: Life-cycle of re-useable surgical instruments



At all stages, it is imperative that decontamination issues relating to the environment, equipment, facilities, management and policies/procedures are taken into account.

2.2 Acquisition and disposal of surgical instruments

Organisations should have a documented policy for the purchase of re-useable medical devices (including surgical instruments). This is to ensure that equipment purchased is fit for the intended purpose, compatible with existing equipment, easy to clean, and that the processes by which decontamination is to be achieved is available within the organisation. Advice is given in MDA DB 9801: Medical Device and Equipment Management for Hospital and Community-based Organisations. All manufacturers of CE marked re-useable medical devices (including surgical instruments) are required to provide 'information on the appropriate processes to allow re-use, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized.' (Medical Devices Directive 93/42/EEC Annex 1 ER 13.6h).

Users should refer to this information to ensure the compatibility of the processes employed in the cleaning of surgical instruments. Safety concerns relating to the compatibility of medical devices and their accessories with cleaning, disinfecting and sterilizing agents was issued as SAN (SC) 96/10. Devices designated for single-use must not be re-used under any circumstances. Further advice is given in MDA DB 2000(04).

The Advisory Committee on Dangerous Pathogens (ACDP) / Spongiform Encephalopathy Advisory Committee (SEAC) guidance, 'Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection' and NHS MEL 1999 (65), 'Variant Creutzfeldt Jakob Disease (vCJD): Minimising the risk of transmission', recommends that where surgical instruments have been used on patients suspected of having Transmissible Spongiform Encephalopathies (TSEs), such as vCJD, the instruments should be quarantined in accordance with the above MEL, pending confirmation of diagnosis.

2.3 Processing environment and equipment requirements

The area to be used for manual cleaning should be dedicated for the purpose and not shared with other activities. This may be achieved by dedicating a zone to the cleaning process and segregating dirty from clean by appropriate work flow patterns and practices.

The following should be provided as appropriate:

- personal protective equipment (PPE) for staff undertaking manual cleaning, e.g. gloves, face masks, waterproof apron, and goggles or visors (the latter must be used when operating jet guns). A first aid kit and eye wash bottle should also be available nearby;
- a dedicated sink (not hand wash basin), to contain water/detergent mixture for cleaning instruments;
- where practicable, a second dedicated sink for rinsing items;
- cleaning materials, including appropriate detergents;
- a supply of cleaning implements and accessories, i.e. brushes/cloths etc, as recommended by the instrument manufacturers or local policy, which are themselves routinely decontaminated or discarded at a frequency detailed in a documented local policy;
- clean, disposable, absorbent, non-shedding cloths for hand drying items, or a mechanical drying facility.

The environment (i.e. air and surfaces) within which instruments are prepared for sterilization requires an appropriate level of particulate and microbiological control. The purpose of environmental control is to minimise the possibility of re-contamination and as such Microbiological/Infection control advice as to the appropriateness of the reprocessing environment should be sought in every case.

3. Reprocessing of Medical Devices

3.1 Automated Cleaning

Automated cleaning is preferred to manual cleaning due to the reproducibility and control of the process. This type of process is also more readily validated than manual cleaning. The process may involve a disinfection element such as in the use of a washer-disinfector or may consist of ultrasonic cleaning.

The process used should be appropriate to the equipment being cleaned and the type of contamination being removed.

Advice should be sought in relation to automated cleaning processes and procedures from the Authorised Person (Sterilizers) and Microbiologist (Sterilizers).

3.2 Manual Cleaning

Manual cleaning would normally be undertaken either by employing immersion or non-immersion techniques depending on the construction of the device.

Immersion Method – Procedure for manual cleaning

To minimise the risk to personnel undertaking manual cleaning, splashing and the creation of aerosols must be avoided.

The following is recommended:

- a. fill the clean sink (not hand wash basin) with water and detergent (detergent dilution and water temperature should be in accordance with manufacturer's instructions and/or local documented policy/procedures);
- b. wearing protective clothing, dismantle or open the instrument to be cleaned and fully immerse it in the solution in order to displace trapped air and to ensure penetration of the lumen if hollow instruments are being cleaned. Consideration should be given to the use of a protein-enzyme dissolving solution when cleaning medical devices with lumens or complex parts;
- c. brush, wipe, agitate, irrigate, jet wash or hand spray the item to dislodge and remove all visible soil, taking care to ensure the item remains under the surface of the water at all times to prevent the creation of aerosols;
- d. remove the item from the sink and drain any excess detergent prior to placing it in the second sink (if available) to rinse in clean water;
- e. rinse the item thoroughly with clean water or water jet gun under the surface of the water;
- f. remove and drain the item before drying using the method recommended by the manufacturer;
- g. complete all necessary documentation to record the item being processed and details of the method employed.

NOTE:

- 1) The wash temperature is of particular importance when using enzymatic detergents.
- 2) If either the cleaning solution or the rinse water becomes obviously soiled or contaminated, it should be changed and the process repeated.
- 3) Cleaning materials should be disposed of, in the appropriate waste containers, following use, in accordance with local policy.
- 4) Jet guns should only be connected to the cold water supply.

Non-immersion methods

This type of manual cleaning is appropriate for certain equipment where items will become compromised by soaking in aqueous solution, e.g. electrical and electronic equipment. These items should be cleaned in accordance with manufacturer's instructions. See also the advice given in *'Sterilization, Disinfection and Cleaning of Medical Equipment'*, Part 2 Section 4, by the Microbiology Advisory Committee (MAC).

Factors affecting manual cleaning

Due to the lack of acknowledged methods available to users to test the efficacy of manual cleaning processes, the following are important factors for successful cleaning;

- a. water temperature. It is important to be aware that protein coagulates at 35°C and water above this temperature must not be used for initial immersion of devices prior to cleaning;
- b. detergent concentration;

- c. nature of soil and method of removal;
- d. accessibility of fluid to the item.

Advice on assessing the efficacy of the cleaning process should be sought from the local Microbiologist/Infection Control Officer.

Over and above these factors is staff training and competency and this should be reflected in local policy statements.

3.3 Disinfection

Disinfection, as opposed to sterilization, is intended to reduce the number of viable micro-organisms and may not necessarily inactivate certain viruses and bacterial spores. Disinfection can be achieved by a number of means, dependent upon the nature of the surgical instrument being cleaned but is usually achieved by an automated washing process or by chemical means (reference SHTM 2030). Chemical disinfection should only be employed where no practical alternative exists. Disinfection is recommended for contaminated equipment prior to handling and inspection, before packaging and sterilization.

3.4 Inspection

Following cleaning, all instruments should be carefully examined for organic material and/or damage (under magnification where appropriate). Inspection, maintenance or testing of items must be carried out by trained persons in accordance with the manufacturer's instructions and/or local policy. Where practicable the inspection and functional testing of surgical instruments should be carried out by a person not responsible for cleaning the item. Those persons carrying out these tasks have a responsibility for ensuring that the items are fit for reuse. Records of all work performed, including functional testing, should be maintained.

3.5 Packaging

Where products are to be packaged, the materials used should be compliant with the relevant European Standards (BS EN 868) (Reference SHTM 2010). The methodology employed for packaging within the department should be documented.

3.6 Sterilization

Where items are to be sterilized following cleaning and/or disinfection the following should be taken into account:

- the process used (e.g. steam sterilization);
- the type of cycle (e.g. pre-vacuum/porous load);
- any relevant cycle parameters (e.g. 134-137°C for a minimum holding time of 3 minutes).

Non vacuum benchtop sterilizers in which air is passively displaced by steam will only reliably sterilize devices that are **not** wrapped and are **not** hollow, e.g. cannulated items (refer to Medical Devices Agency guidance DB 9804 June 1998).

MDA DB 9605 states that '*Dentists should note that benchtop steam sterilizers represent the best means available for prevention of cross-infection via dental handpieces in situations where porous load sterilization facilities are not available.*' Although handpiece lumens might not be sterilized, they will be subjected to disinfecting conditions that experts consider should be sufficient to inactivate HIV, HBV and HCV.

The sterilizer must be validated for the loads that the user intends to process, and only those loads should be processed in it, e.g. a sterilizer that is capable of sterilizing the lumen of a dental handpiece might fail to do so if the handpiece is wrapped.

3.7 Storage

The environmental conditions of the areas designated for storage and distribution should ensure the integrity of all materials and products, i.e. clean, dry, well ventilated and secure. The accommodation should afford adequate protection to prevent contamination or deterioration of the product. Items with damaged packaging should not be used. Stock rotation should be used for storage, i.e. FIFO (First in, First out).

3.8 Transportation

If the processed item is to be returned to the user it should be transported in a clean, secure transit container which protects the items from damage.

3.9 Record keeping

The Consumer Protection Act (1987)(6), in particular Product Liability, has implications for the reprocessing of devices used for patient care. In particular, it is essential to maintain adequate records that demonstrate how a particular device was processed, a description of the methods employed and details of available trained personnel with copies of training records. The organisation should have the ability to demonstrate how instruments have been processed e.g. a log of personnel involved in the cleaning and operation of the decontamination equipment, with cycle number (where applicable).

4. References

Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health, Medical Devices Agency.
MEL 1999(65) Variant Creutzfeldt Jakob Disease (vCJD): Minimising the risk of transmission.
Medical Devices Directive 93/42/EEC Annex 1ER 13.6, h
SHTM 2010 Sterilizers.
SHTM 2030 Washer-disinfectors.
Safety Action Notice (SC) 96/10 Medical Equipment Compatibility with Johnson and Johnson NU-Cidex.
HDL (2001)10 Decontamination of Medical Devices.

'FAST TRACK' REVIEW: ASSESSMENT CRITERIA FOR ACTION PLANS

1. The standards to be achieved were divided into three distinct areas:

- ❑ **Equipment** – compliance with SHTM 2010, 2030 & 2031 (that cover specification and verification requirements for washer/disinfectors (W/Ds) and sterilisers, and steam purity requirements);
- ❑ **Facilities** – must have an effective separation of clean and dirty processes with appropriate levels of air conditioning, i.e. a 'Class L Clean Room';
- ❑ **Procedures** – must have appropriate staff training programmes and recording systems, and a suitably appointed decontamination lead officer. Eventual EN46002 compliance is one end point;
- ❑ **Management** – must have appointed senior manager with an overview of decontamination, infection control and cleaning services.

2. The following were regarded as key measures by which the above standards would be assessed:

Local Decontamination Units (LDUs)

- ❑ By end December 2001 the use of LDUs for decontamination of N&O surgical instruments should end and transfer to CSSDs that meet the above standards. (LDU provision can be retained for 'dropped instruments' and instrument pre-cleaning where that was a manufacturer's requirement.)
- ❑ In the interim, steps should be taken to improve practice in line with DH NHS Estates 'Protocol for Local Decontamination of Surgical Instruments (2001)'.

Central Units

- ❑ By end of December 2001, equipment and facilities must be upgraded (or well on the way to becoming upgraded) to the required standards, and documented staff training in place.

Instrumentation

- ❑ Additional requirements must be consistent with anticipated activity and turnaround needs, and in line with current instrument costs.
- ❑ For ophthalmic activity, the aim should be to have all instruments, i.e. not just 'back of the eye' instruments, processed centrally.

Interface with likely Glennie Group recommendations for all other decontamination services

- ❑ Proposals sit comfortably with, and ideally take a positive step towards, initial thoughts on service reconfiguration per the forthcoming 'Glennie Framework'.
- ❑ Proposals should demonstrate VFM and minimise possible write-off of short term investments.

SEHD/FD
May 2001

KEY OPERATIONAL AND FINANCIAL ASSUMPTIONS

- 1 No CSSD should operate at higher than 80% capacity.
- 2 Trays have been converted to instruments via:
 - One Tray = 39.9 instruments
 - One Ward Pack = 10 instruments
 - One Supplementary = 1 instrument.
- 3 Dental Hospital activity has been converted to standard activity by multiplying total instruments by 0.25.
- 4 Victoria linen processing unit will transfer to Glasgow South facility.
- 5 Additional instruments have been allowed for at £10,000 per theatre or £120,000 whichever is higher.
- 6 Transport costs have been calculated at £50,000 per annum per site serviced.
- 7 Transport trolleys have been allowed for at 3 per theatre.
- 8 Capital costs for new builds have been based on Healthcare Construction price guide.
- 9 Equipment costs have been validated using information from SHS.
- 10 Upgrade costs from Trusts have been assumed to be correct.
- 11 Capital charges have been assumed to be 10% of capital investment.
- 12 LDU upgrading costs have been calculated at £20,000 per facility.
- 13 Investment detailed on Appendix F.1 for EN285 is not required.
- 14 An overall increase in staff numbers is projected due to transfer of local acute work and impact of quality systems therefore no redundancy costs built in.
- 15 No allowance made for equipment write off unless advised through Fast Track submissions.

Appendix F.1

Capital Investment to Achieve Standard Compliance											
Gross Expenditure	12 Sites			11 Sites			10 Sites			9 Sites	
	Compliance Investment EN46002	EN285	Compliance Investment EN46002	EN285	Compliance Investment EN46002	EN285	Compliance Investment EN46002	EN285	Compliance Investment EN46002	EN285	
Ayrshire Central Hospital	235,000	400,000	235,000	400,000	235,000	400,000	235,000	400,000	235,000	400,000	
Borders General Hospital	636,000	312,000	636,000	312,000	636,000	312,000	636,000	312,000	636,000	312,000	
New RIE	0	50,000	0	50,000	0	50,000	0	50,000	0	50,000	
Falkirk Royal Infirmary	200,000	364,000	200,000	364,000	200,000	364,000	200,000	364,000	200,000	364,000	
Foresterhill Hospital	579,500	200,000	579,500	200,000	579,500	200,000	579,500	200,000	579,500	200,000	
North Glasgow Facility	6,600,000	0	7,200,000	0	7,200,000	0	7,200,000	0	7,200,000	0	
Inverclyde Royal Hospital	1,400,000	435,000	1,400,000	435,000	1,400,000	435,000	1,400,000	435,000	1,400,000	435,000	
Ninewells Hospital	686,000	561,000	686,000	561,000	686,000	561,000	686,000	561,000	686,000	561,000	
Raigmore Hospital	490,000	230,000	490,000	230,000	490,000	230,000	490,000	230,000	490,000	230,000	
South Glasgow Facility	6,600,000	0	7,200,000	0	7,200,000	0	7,200,000	0	7,200,000	0	
Woodend Hospital	320,000	230,000	320,000	230,000	320,000	230,000	320,000	230,000	320,000	230,000	
	17,746,500	2,782,000	17,546,500	2,347,000	17,280,500	2,035,000	16,960,500	1,805,000	16,701,000	2,035,000	
Funding Already Committed Locally											
Borders General Hospital	136,000	0	136,000	0	136,000	0	136,000	0	136,000	0	
Foresterhill Hospital	579,500	0	579,500	0	579,500	0	579,500	0	579,500	0	
	715,500	0	715,500	0	715,500	0	715,500	0	715,500	0	
Net Additional Funding Requirement	17,031,000	2,782,000	16,831,000	2,347,000	16,701,000	2,035,000	16,381,000	1,805,000	16,381,000	1,805,000	

Appendix F.2

NON-RECURRING REVENUE COSTS TO ACHIEVE COMPLIANCE

	12 Sites Non Recurring Costs	11 Sites Non Recurring Costs	10 Sites Non Recurring Costs	9 Sites Non Recurring Costs
Inverclyde Royal Hospital	0	208,800	208,800	208,800
Borders General Hospital	0	0	157,200	157,200
Woodend Hospital	0	0	0	136,200
Belford Hospital	136,200	136,200	136,200	136,200
McKinnon Hospital	136,200	136,200	136,200	136,200
Garthnavel General Hospital	348,000	348,000	348,000	348,000
Glasgow Royal Infirmary	278,400	278,400	278,400	278,400
Stobhill Hospital	169,800	169,800	169,800	169,800
The Southern General	243,600	243,600	243,600	243,600
The Victoria Infirmary TSSU	165,600	165,600	165,600	165,600
Strathcathro	144,600	144,600	144,600	144,600
The Queen Mother's Hospital	157,200	157,200	157,200	157,200
Fast Track Sites	1,420,400	1,420,400	1,420,400	1,420,400
	<u>3,200,000</u>	<u>3,408,800</u>	<u>3,566,000</u>	<u>3,702,200</u>
Glasgow Dental Hospital	3,011,700	3,011,700	3,011,700	3,011,700
Dundee Dental Hospital	1,011,700	1,011,700	1,011,700	1,011,700
Edinburgh Dental Hospital	1,011,700	1,011,700	1,011,700	1,011,700
	<u>5,035,100</u>	<u>5,035,100</u>	<u>5,035,100</u>	<u>5,035,100</u>
Total Mainland Sites	<u>8,235,100</u>	<u>8,443,900</u>	<u>8,601,100</u>	<u>8,737,300</u>

Appendix F.3

RECURRING COSTS TO ACHIEVE COMPLIANCE												
Central Facility												
Host Trust												
			12 Sites		11 Sites		10 Sites		9 Sites			
			Recurring Costs	EN285	Recurring Costs	EN285	Recurring Costs	EN46002	EN285	Recurring Costs		EN46002
Inverclyde Royal Hospital		Argyll and Clyde Acute NHS Trust	140,000	43,500	50,000			50,000			50,000	
Ayrshire Central Hospital		Ayrshire and Arran Acute NHS Trust	23,500	40,000	23,500	40,000		23,500	40,000		23,500	40,000
Borders General Hospital		Borders Acute NHS Trust	50,000	31,200	50,000			50,000			50,000	
Falkirk Royal Infirmary		Forth Valley Acute NHS Trust	20,000	36,400	20,000	36,400		20,000	36,400		20,000	36,400
Foresterhill Hospital		Grampian Acute NHS Trust		20,000		20,000			20,000			20,000
Woodend Hospital		Grampian Acute NHS Trust	32,000	23,000	32,000	23,000		32,000	23,000		32,000	23,000
Belford Hospital		Highland Acute NHS Trust	50,000		50,000			50,000			50,000	
McKinnon Hospital		Highland Acute NHS Trust	50,000		50,000			50,000			50,000	
Raigmore Hospital		Highland Acute NHS Trust	49,000	23,000	49,000	23,000		49,000	23,000		49,000	23,000
City Hospital		Lothian Acute NHS Trust		5,000		5,000		37,000	5,000		37,000	5,000
Gartnavel General Hospital		North Glasgow NHS Trust	710,000			760,000					760,000	
Glasgow Royal Infirmary		North Glasgow NHS Trust	50,000			50,000		50,000			50,000	
Stobhill Hospital		North Glasgow NHS Trust	50,000			50,000		50,000			50,000	
The Southern General		South Glasgow NHS Trust	710,000			760,000					760,000	
Victoria Infirmary CSSD		South Glasgow NHS Trust										
Victoria Infirmary TSSU		South Glasgow NHS Trust	50,000			50,000		50,000			50,000	
Ninewells Hospital		Tayside Acute NHS Trust	68,000	56,100	68,000	56,100		68,000	56,100		68,000	56,100
Strathcathro		Tayside Acute NHS Trust	50,000			50,000		50,000			50,000	
Queen Mother's Hospital		Yorkhill NHS Trust	50,000			50,000		50,000			50,000	
			2,152,500	278,200		2,162,500	203,500	2,199,500	203,500		2,217,500	180,500