SCOTTISH EXECUTIVE

Health Department
Directorate of Performance Management & Finance

Dear Colleague

DECONTAMINATION - NHSSCOTLAND STERILE SERVICES PROVISION REVIEW GROUP (GLENNIE GROUP)

Purpose

1. This letter

- provides an update on progress to date;
- reiterates the deadlines for interim and full compliance;
- provides an update on the next steps in relation to the achievement of the decontamination technical requirements in Primary Care, Dental Hospitals and Independent Hospitals;
- provides an update on the decontamination of endoscopes;
- provides clarification and a reminder of the requirements on the risk categorisations for all types of CJD; and
- provides an update on Instrument Tracking Systems.

Background

2. Following a self assessment survey undertaken by NHS Trusts and Island NHS Boards of their decontamination practices and procedures, the Glennie Group published its report in August 2001. This report set Technical Requirements (TRs) compliance with which it is considered would minimise risks for potential transmission of CJD. The report also provided a framework for NHS Trusts, Island NHS Boards and the since formed NHS Unified Boards to follow to upgrade and/or reconfigure their decontamination processes to comply with the TRs. Further details on events that led to the establishment of the Glennie Group are contained in NHS HDL(2001) 10.

18th September 2003

Addresses

For action
Chief Executives, NHS Trusts
Chief Executives, NHS Boards
Common Services Agency
Scottish Ambulance Service
State Hospitals Board for Scotland
Directors of Finance,
NHS Boards and NHS Trusts
General Managers, Independent Hospitals
Chief Administrative Dental Officer, Dental Hospitals

For information
Chief Executive, NHS Quality in Scotland

The Director, Mental Welfare Commission for Scotland

Chief Executive, NHS Education for Scotland

Medical and Nursing Directors

Medical Director, SCIEH

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3. Decontamination is being addressed as part of the overall strategic approach to managing the risk of Healthcare Associated Infection (HAI). More details on these related initiatives are provided in NHS HDL(2002)82. (NHS HDLs can be viewed at (http://show.scot.nhs.uk/publications/pubindex.htm).

Progress to Date

4. Following the conclusion of the self assessment survey reported above, priority was given to those sites dealing with clinical procedures recognised as high risk (for CJD transmission), i.e. neurosurgery and 'back of eye' surgery. As a result of the hard work and dedication from staff in these sites, the interim Technical Requirements were achieved in 2002 for all high-risk acute sites.

Interim and Full Compliance

5. A deadline of 30 June 2002 was set for acute sites reprocessing instruments used for medium/low risk procedures to meet the interim technical requirements. To achieve interim compliance the replacement of many washer disinfectors was required. Due to the impossibility of getting the equipment procured and installed by 30 June, the deadline was extended to March 2003 but only for those sites included in the national procurement programme for washer disinfectors. Furthermore, this extended deadline was given only for the installation of washer disinfectors.

6. To date the majority of equipment has been installed and validated. There is however a number of sites still experiencing problems which have occurred as a result of the high level of demand on manufacturers. Scottish Healthcare Supplies (SHS) is currently working with the Scottish Centre for Infection and Environmental Health (SCIEH) to prioritise sites and negotiate steps to rectify the position with manufacturers.

7. To assess compliance against the interim TRs, SCIEH will undertake a review of Sterile Services Departments (SSDs) during the latter part of this year. Details of the visits will be provided in due course

8. SSDs should be aware that to achieve full compliance both registration with the Medicines and Healthcare products Regulatory Agency (MHRA), formerly the Medical Devices Agency (MDA), and accreditation by a notified body will be required. In order to achieve this SSDs need to be working in a compliant manner by the end of 2003 and must have in place, **prior to 31 March 2004**, a date on which an assessment will take place.

9. **The deadlines for compliance with the full technical requirements are as follows:**

	31 March 2004[Note 1]	**31 December 2004**[Note 2]
Acute Trusts and acute services of Integrated Trusts/Unified Boards/ Island Boards	high, medium and low risk	-
Golden Jubilee National Hospital	high, medium and low risk	-
Independent Hospitals[Notes 1 & 3]	medium and low risk	-
Primary Care Trusts and non-acute services of Integrated Trusts/Unified	medium risk	low risk

Boards / Island Boards		
Dental Hospitals	medium risk	low risk
Scottish Ambulance Service	medium risk	low risk

Note 1: See paragraph 10 below
Note 2: An action plan to achieve compliance with the full Technical Requirements must be submitted to SEHD by 31 March 2004.
Note 3: See paragraph 8 above.

10. It is recognised that, in some instances of **new build SSDs**, the March 2004 deadline for full compliance will not be achieved. SSDs that anticipate failing to achieve this deadline **must, as soon as possible, notify the Department in order to negotiate an extension to the deadline**. Any requests for an extension must be made in writing (to Ross Scott) setting out the reasons why the deadline will not be achieved, how any medium risk work will be handled and what the extended deadline is likely to be. The request for an extension will be reviewed by SCIEH before a final decision is taken by the Department.

Acute Sector

11. The SCIEH visits referred to in paragraph 7 will assess the compliance status of all SSDs against the interim technical requirements and assess progress towards full compliance.

Dental Hospitals, Independent Hospitals and Primary Care

12. SCIEH has undertaken a baseline assessment of Dental and Independent Hospitals. The hospitals have been informed of the outcome and proposals for remedial action are in the process of being submitted to SEHD for review.

13. SCIEH undertook an exercise to update data on the number of Local Decontamination Units (LDUs) in the primary care sector in order to identify those who are reprocessing instruments used for medium risk procedures in respect of potential transmission of CJD. NHS Trusts, Island Boards and Unified Boards which intend to continue with LDUs will be required to comply with the Glennie TRs and, in the first instance, those undertaking reprocessing of instruments used for medium risk procedures will be visited by an auditor from SCIEH and assessed for compliance with the technical requirements.

14. To assist with the assessment of requirements for LDUs, key indicators for the low risk TRs are currently being developed. Work is still progressing on these but they are expected to be available later this month. In addition to this a brief consensus document giving guidance on appropriate equipment and facilities for LDUs has been commissioned from the Decontamination Technical Advisory Panel (DTAP). The intention is to hold a study day to discuss the guidance and key indicators before they are finalised. This study day will be held in October and further details will be issued by SCIEH in due course. Following this the documents will be launched at a training day to which managers and representatives of staff dealing with decontamination within the primary care sector will be invited.

15. Further details on the current situation regarding decontamination in the Primary Care and Dental Hospitals are contained in Annex A.

The Decontamination of Endoscopes

16. The Glennie technical requirements do not cover the decontamination of endoscopes but are limited to those instruments where decontamination involves the application of heat processes. Annex B provides an update on the current position.

17. The, MHRA (formerly the MDA) has published revised guidance on the Decontamination of Endoscopes (MDA DB2002(05) (http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf). The Joint TSE Working Group of the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee (ACDP/SEAC JWG) has recently published partially updated guidance on safe working and prevention of infection relating to CJD and related diseases (see http://www.doh.gov.uk/cjd/tseguidance/): a revised chapter on decontamination of endoscopes is expected later this year.

18. A draft European specification for endoscope washer disinfectors is still under consideration. It has been recognised that in choosing equipment it is important that sites are fully aware of the appropriate options in respect of equipment and facilities. To assist, DTAP has been commissioned to prepare a brief consensus document to inform in the short term, until more comprehensive guidance is available. Further details will be available by the end of 2003.

Risk Categorisations

19. 'Risk' is a widely used term, and it is important to distinguish between high risk procedures, high risk tissues, and high risk patients: see the ACDP/SEAC JWG document referred to in paragraph 17 for definitions relating to CJD. To avoid confusion about the appropriate requirements for instrument reprocessing, please note that the Glennie Risk Categorisation refers only to the potential for transmission of CJD and not to the risk of healthcare associated infection (HAI) in general. Instruments used in invasive procedures classified as low risk under the Glennie categorisation, can present a significant risk for other HAIs, and require to be reprocessed utilising validated decontamination processes. It should be noted that the recently published updated guidance of the ACDP/SEAC JWG has added olfactory epithelium to the list of tissues for which the risk of infectivity for CJD is considered "medium risk" (see Annex C).

20. The classification of the general infection risk associated with the decontamination of medical devices is published by the Microbiology Advisory Committee of the MHRA and is available on their website in the Microbiology Advisory Committee (MAC) Manual Part 1 Principles (http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf).

IT Systems for SSDs

21. At its meeting on 29 May, the Glennie Group discussed the need to ensure that SSD IT systems in use at sites throughout Scotland are either the same or at the very least compatible. This is particularly important where there is a need to provide contingency arrangements between sites.

22. DTAP hosted a one day seminar on 16 July on "IT Management Systems - Specification and Compatibility". The seminar included a presentation of the SCIEH guidance document on the preparation of a specification for IT management and traceability systems as well as feedback from a Trust who has already undertaken the process. A CD-ROM with copies of documents presented on the day and information on commercial systems was issued to delegates. A copy of the guidance document and the sample specification is available on the SCIEH website (http://www.show.scot.nhs.uk/scieh/).

23. It has been agreed that SCIEH will establish a "community of interest" group to develop a nationally agreed approach to the introduction of compatible IT systems into sites.

Instrument Tracking Systems

24. Full traceability through SSD processing to individual patients will require identification of individual instruments. A suitable identification system must be:

- suitable for use with all types of reusable device,
- suitable for marking of existing instruments,
- fast and reliable to read,
- durable,
- without adverse effect on the performance or life of the devices.

25. At the moment none of the commercially available systems have been demonstrated to meet these basic requirements. This matter is under constant review by SCIEH and advice on suitable systems will be published when these become available.

Coding systems for trays and supplementary instruments

26. In order to ensure that sites can provide contingency support to neighbouring SSDs it is essential that the codes used to identify particular sets of theatre instruments, supplementary instruments etc cannot be confused. Consideration is to be given to adopting a 'site identification code' that will ensure a unique identity for trays. This will be considered by the 'community of interest' group (see 23 above) being established by SCIEH.

Coding system for instruments

27. A nationally agreed code for identification of instruments may be desirable. This will be considered also by the 'community of interest' group (see 23 above) being established by SCIEH.

SSD consultative group

28. Following the IT seminar (see 22 above) there was a consensus from those present that an SSD consultative group should be established to discuss matters of common interest in relation to decontamination. The Glennie Group agreed that SCIEH should establish such a group and manage meetings approximately quarterly.

Contracts with Private Providers

29. To ensure that decontamination services provided to NHSScotland are all of the same standard SSDs using private providers or other NHS Bodies should ensure and seek assurance that the services being provided comply with the Glennie Technical Requirements as well as the requirements of the Medical Devices Regulations.

Action

30. Chief Executives of NHS Boards and Trusts should ensure that this HDL is circulated to:

- Sterile Supplies Unit Managers
- Senior Managers with responsibility for risk assessment and management of decontamination as defined in HDL(2001)10.

Yours sincerely

JOHN ALDRIDGE
Director of Performance Management and Finance

ANNEX A

DECONTAMINATION: PRIMARY CARE AND DENTAL

Introduction

The following text summaries the current situation regarding decontamination processes in the primary care sector. The primary care sector for these purposes is defined as:

- Community Hospitals or other clinical units directly managed by Primary Care or Integrated NHS Trusts or NHS Boards which carry out low risk procedures as defined in the Glennie Group Report;

- Community Health Services directly managed by Primary Care NHS Trusts or NHS Boards which provide services which carry out low risk procedures as defined in the Glennie Group Report, principally community dental and chiropody/podiatry but may also include certain family planning or other services;

- Independent contractor services which carry out principally low risk procedures i.e. general dental and general medical services;

- Private primary care services which carry out low risk procedures principally dental and chiropody/podiatry services.

Community Hospital or other clinical units directly managed by Primary Care or Integrated NHS Trusts or NHS Boards

SCIEH will lead an assessment of local decontamination units which undertake reprocessing of instruments used for medium risk procedures once the development of new assessment documentation has been completed.

Community Health Services directly managed by Primary Care NHS Trusts or Integrated NHS Trusts or NHS Boards

Community Dental Clinics are included in the Decontamination review led by the University of Glasgow and SCIEH (see below). A methodology for the on-going assessment of these services will be developed from the pilot. It is expected that the tool will also be appropriate for chiropody/podiatry and other community health services. A date for the assessment of these services has still to be agreed and will be notified in due course. In the interim, Trusts should ensure that decontamination procedures meet the Glennie interim requirements and in particular that they follow the "The Protocol for Local Decontamination of Surgical Instruments" contained within the Glennie Report (HDL(2001)66).

Where a new facility is being planned then the plans should be submitted to the Decontamination Technical Advisory Panel (DTAP) for comment and verification. DTAP are also available to advise and assist on the development of the plans in the first instance.

Independent Contractor Services

An Expert Advisory Group has been carrying out an assessment of the risk of CJD associated with procedures carried out on oral tissues. This risk assessment was published in July 2003 (see http://www.doh.gov.uk/cjd/dentistryrisk/index.htm). The overall conclusion is that risk of CJD transmission in General Dental Practice procedures is small, **as long as decontamination procedures are satisfactory in terms of current Glennie TRs**. As in hospital surgery, the key consideration in minimising any risk of transmission is assuring the efficacy of instrument decontamination, even though current methods cannot remove such risks completely. In line with existing SEAC advice, potential risks can be further reduced by the introduction of more single-use instruments where appropriate, especially of difficult-to-clean items.

The Infection Research Group at University of Glasgow Dental School and SCIEH are undertaking an assessment of General Dental Practices' decontamination processes in order to provide an evidence base for change. This study has developed a tool for assessing decontamination processes in primary care settings. The results from this work will allow a risk assessment to be made, a Framework for change to be compiled and the resource implications of upgrading primary care decontamination processes to the technical requirements of the Glennie Group to be estimated.

It is expected that the results will also be pertinent to General Medical Services including Dental practices and GPs. The results of the study will be reviewed by the Glennie Group. An interim review has been submitted on the findings from the first 50 sites surveyed. A working group led by the Chief Dental Officer, has reported on decontamination (see report on http://www.scotland.gov.uk/consultations/health/decontamination.pdf). On-going assessment of independent contractor services should be linked to the development of quality accreditation systems for these services.

Dental Hospitals

Dental Hospitals will be categorised as low risk providing they can demonstrate that they only undertake low risk procedures. Dental Hospitals must review their processes and have them verified by an external auditor to ensure no medium risk work is being undertaken.

A short life working group dealing with decontamination issues in dental hospitals has been set up. This group (with representatives from Glasgow, Dundee and Edinburgh) held its first meeting on 21 August and is due to meet again on 10th September.

Where a new facility is being planned, the plans should be submitted to the DTAP for comment and verification. DTAP are also available to advise and assist on the development of the plans in the first instance.

Private Primary Care Services

It is expected that many of the conclusions from the work on independent contractor services will be transferable to this sector. Discussions are due to commence with the Regulation of Care Commission on the monitoring of HAI related standards in this sector.

ANNEX B

UPDATE ON THE DECONTAMINATION OF ENDOSCOPES

Introduction

The decontamination of endoscopes is not part of the Glennie Group Remit.

The Joint TSE Working Group of the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee (ACDP/SEAC JWG) has recently published partially updated guidance on safe working and prevention of infection relating to CJD and related diseases (see http://www.doh.gov.uk/cjd/tseguidance/): a revised chapter on decontamination of endoscopes is expected later this year.

Medicines and Healthcare products Regulatory Agency (MHRA) (previously MDA) Guidance on Endoscopes

The Medicines and Healthcare products Regulatory Agency published revised guidance on the decontamination of endoscopes (MDA DB2002(05) which updated previous guidance issued in 1996. The 2002 bulletin reflects changes in the availability of disinfectants since 1996 and Trusts should be aware that the major brand of glutaraldehyde has been withdrawn.

The bulletin **emphasises the importance of effective cleaning, traceability and the need for users to follow manufacturers' instructions**. The bulletin does not address the issues related to CJD as the Joint TSE Working Group is considering them. Accessories other than single-use items must be kept together with a single endoscope, forming a unique set.

ACDP/SEAC Joint TSE Working Group

The Working Group has formed a sub-group, which is developing a stand-alone annex to the updated guidance "TSEs: Safe Working and the Prevention of Infection". It will also be included in the forthcoming guidance on CJD Incidents. The annex will cross-refer to the forthcoming MHRA Device Bulletin.

The JWG has considered two questions:

- what additional steps should be taken for endoscopes used on patients defined as at risk of a TSE?

- when an endoscope has been used on a patient who went on to develop CJD what are the relative risks to subsequent patients?

The Group has reviewed information on both flexible and rigid endoscopes. With regard to guidance on decontamination processes in general, it has been provisionally agreed that no additional advice is necessary for rigid endoscopes without lumens, which are autoclavable, including solid laryngoscope blades (although further options here are single use sheaths or single use blades).

For endoscopes, in all cases, **adequate manual cleaning, in accordance with the manufacturers' instructions, prior to further decontamination is the most important element in any reprocessing regimen**. Accessories for endoscopes should be, wherever possible, single use providing that this does not compromise clinical outcome. This is particularly important for channel cleaning brushes and the valve on the biopsy/instrument channel port used with flexible endoscopes.

ANNEX C

GLENNIE TECHNICAL REQUIREMENTS FOR DECONTAMINATION PROCESSES

Clinical procedures* **Categorisation by risk for all types of CJD**
High Risk • 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. **Medium Risk** • Other procedures involving the eye, including 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. • Procedures that involve contact with olfactory epithelium. **Low Risk** • All other invasive procedures including other anaesthetic procedures and procedures involving contact with the cerebral fluid.

* Further risk assessment to be undertaken on categorisation of dental tissues that are currently considered as low risk. (See http://www.doh.gov.uk/cjd/dentistryrisk/index.htm and http://www.scotland.gov.uk/consultations/health/decontamination.pdf).