MANAGING THE RISK OF HEALTHCARE ASSOCIATED INFECTION IN NHSScotland

Report of a Joint Scottish Executive Health Department and NHSScotland Working Group

April 2001

Contents

Executive Summary

There has been increasing concern in recent years about the risks to health when receiving treatment and care. A number of organisations have expressed disquiet about the rates of infections occurring in patients during their stay in hospital. Recent adverse publicity has focussed on consumer concerns regarding cleanliness in healthcare premises.

Studies have found that:

- an estimated 9% of hospital patients acquire an infection during their stay;
- the total cost to Scottish hospitals of such infections could be in the region of approximately £21.6 million per annum;
- risks are not only present in hospitals but also in primary healthcare and social settings;
- there is a potential risk of vCJD, the human form of BSE, being spread from person to person by surgical instruments.

In this context, the Scottish Executive Health Department set up a Working Group in November 2000 to produce guidance to NHSScotland about assessing and managing risks related to healthcare associated infection (HAI), decontamination and hospital cleanliness.

Several preliminary observations guided the Group's work. There is a need for:

- greater learning about risks and for this to be addressed in terms of organisational change, training and development, and learning from adverse events;
- guidance for Trusts on risk management processes in relation to HAI;
- standards to assess Trusts' performance when managing the risk of HAI;
- national arrangements to be made for monitoring risks, setting standards and ensuring compliance with the standards in relation to HAI.

The Working Group was asked to address the need to develop a comprehensive framework for managing such risks. To do this, the Group divided its work into the following three main tasks, which were taken forward by sub-groups:

I. Producing guidance on risk management processes related to HAI. This work was done with reference to the existing Scottish requirements of the Scottish Infection Manual, the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS), and the English NHS Controls Assurance model.

II. Producing draft standards for infection control, decontamination of re-usable medical devices and cleaning services. This involved review of existing relevant standards developed for England, where available, with regard to their appropriateness for use by NHSScotland. The draft standards are ready for professional validation, national piloting and implementation and serve as Annexes to this report.

III. Making recommendations on arrangements, at a local and national level, for monitoring risks, setting standards and ensuring and reporting on compliance with the standards. The Working

Group worked closely with the Clinical Standards Board for Scotland (CSBS), which has been charged with responsibility for taking this forward, to develop a framework for national implementation.

This report, compiled by the Working Group, draws together existing guidance and consensus on good practice into a single point of reference. It aims to provide both an overview of, and a more specific insight into, the main components of the risk management system for HAI.

It was concluded that an integrated approach, based on a generic model of risk management, would yield the most effective results. This applies not only in terms of the three areas identified within the HAI related standards, but also in respect of the local and national risk management processes which need to be established. The Working Group's key recommendations are summarised below, grouped according to the organisation with prime responsibility for taking them forward.

NHSScotland

1. There should be a common approach to the risk management of HAI with matching local and national components.

2. Risk management of HAI should be based on the Australian/New Zealand Standard 4360: 1999 model.

3. NHSScotland should promote an organisational culture which actively seeks openness and sharing of information on managing risk.

4. NHSScotland should adopt the outlined standards for:
   - Infection Control
   - Decontamination of Re-usable Medical Devices
   - Cleaning Services.

5. There should be effective feedback, at all levels, to facilitate a positive response to performance as assessed against HAI risk management standards.

NHS Trusts

6. Trust training and development programmes should contain the following elements:
   - personal development plans which specify risk management training needs;
   - an organisational training plan which ensures the development of skills related to risk management of HAI;
   - provision of a wide repertoire of training activities;
   - documented evidence of training and development related to HAI within clinical governance reporting processes.

7. Trusts should ensure that the risk management of HAI is integrated with CNORIS and clinical risk management structures and processes.

8. Trusts should ensure that the recommendations of the Scottish Infection Manual, HDL(2001)10 and CNORIS are in place.

9. Each Trust should designate a senior manager, as detailed in HDL(2001)10, to be responsible for monitoring the risk management of HAI and ensuring self-assessment of performance against standards takes place.

10. Infection Control Committees should have overall responsibility for HAI (i.e., infection control, decontamination of re-usable medical devices and cleaning services).

11. Trusts should review their Infection Control Team and ensure that it is sufficiently robust both in personnel and other resources to accommodate the wider remit with increased responsibilities and workload associated with HAI risk management processes.

12. Trust annual infection control programmes should be based on the risk management model contained within the AS/NZS 4360: 1999.

13. Trust Boards should produce an annual assurance statement based on an internal audit of HAI (i.e., infection control, decontamination of re-usable medical devices and cleaning services) risk management.

14. Trusts should use the HAI related standards (i.e., infection control, decontamination of re-usable medical devices and cleaning services) to self-assess performance in the risk management of HAI.

15. Trusts should submit an annual report to CSBS of the results of self-assessment against the HAI risk management standards (i.e., infection control, decontamination of re-usable medical devices and cleaning services).

Risk Management Executive, Willis Ltd.: Clinical Negligence and Other Risks Indemnity Scheme

16. CNORIS should adopt the HAI related standards (i.e., infection control, decontamination of re-usable medical devices and cleaning services) within Levels Two and Three standards.

Clinical Standards Board for Scotland

17. CSBS should ensure integration of the HAI related standards (i.e., infection control, decontamination of re-usable medical devices and cleaning services) with the CSBS Generic Standards.

18. CSBS should develop a risk matrix tool for assessing risks related to HAI.

19. CSBS should develop a methodology, based on the risk matrix and in consultation with NHSScotland, for setting, evaluating and verifying compliance with HAI risk management standards (i.e., infection control, decontamination of re-usable medical devices and cleaning services).

20. CSBS should establish a Healthcare Associated Infection Reference Group to ensure that standards are regularly evaluated and revised.

21. CSBS should produce an annual report covering the risk management of HAI.

Scottish Executive Health Department

22. SEHD should consider HAI related incidents in plans to take forward the recommendations contained within the Department of Health (England) report, "An organisation with a memory".

23. SEHD should, jointly with CSBS, SCIEH and NHS Trusts, develop key outcome indicators to measure the effectiveness of progress to reduce the risk of HAI.

24. SEHD should include findings from the monitoring of compliance with risk management standards and HAI key outcome indicators, when available, in the NHSScotland Performance Assessment Framework.

25. SEHD should agree with CSBS and regulatory bodies when the latter will become involved in seeking compliance with risk management standards.

Chapter 1

Introduction and Background

1.1 Introduction

In recent years there has been increasing concern about the risks to health from receiving treatment and care. There has also been disquiet expressed by a number of organisations about the rates of infections occurring in patients during their stay in hospital. The exact size of the problem and its implications for NHSScotland are difficult to quantify, however it has been estimated that:

- 9% of hospital patients acquire an infection during their stay[1];
- blood poisoning occurs in 3.6 patients per 1000 admissions to hospitals in the UK[2];
- the total cost to Scottish hospitals of healthcare associated infection (HAI) in hospitals is approximately £21.6 million per annum[3].

In addition, recent incidents have pointed to the risk of infection being present in care settings outside of hospitals[4,5]. The state of cleanliness of healthcare facilities has also stimulated adverse comment from a number of quarters[6]. More recently, attention has focussed on the potential risk of vCJD (the human form of BSE) being spread from one person to another by surgical instruments[7].

The NHSScotland health plan, "Our National Health: A plan for action, a plan for change"[8] makes clear the Scottish Executive's commitment to tackling these problems and to improving standards. It summarises the Scottish Executive Health Department's (SEHD) priorities for action. Key pledges are:

> *" We will take steps to strengthen and monitor infection control procedures in hospitals"*
>
> *" We will expect every NHS Trust to have acted on the recommendations of the Accounts Commission report "A Clean Bill of Health" by June 2001"*
>
> *"Every NHS Trust will be expected to have in place an infection control policy including elements specifically for domestic and catering staff"*
>
> *"Every healthcare system will be expected to deliver the service standards established by the Clinical Standards Board on food, cleanliness, infection control and other matters"*

A recent SEHD review[9] of decontamination in healthcare in Scotland found that evidence of an integrated approach to reduce the risk of infection is lacking in some NHS Trusts. This report highlighted the need to develop a comprehensive framework to manage the risks from infection, which should encompass:

- the capability of NHSScotland to assess and manage the risks of infection;
- the standards required to assess performance in managing these risks;
- the evidence that NHSScotland should provide to show it is doing its reasonable best to protect patients, staff, the public and other stakeholders against these risks.

A joint SEHD and NHSScotland Working Group was formed to make recommendations on the content of the framework, and how it should be established, and this report presents the key conclusions of that Working Group.

1.2 The Current Situation

1.2.1 Healthcare associated infection (HAI)

Infection can affect patients, staff and others in all healthcare settings, not just in hospitals. Because of this the Working Group adopted the term "Healthcare Associated Infection" instead of "Hospital Acquired" or "Nosocomial" infection, in order to encompass the broader application.

At any one time an estimated 9% of patients have acquired an infection during their stay in hospital[1]. A variety of microorganisms cause HAI, most of which are flora from human skin or the gastrointestinal tract, or from the environment. Rates of HAI vary, but are generally highest in surgical patients. The most common types of HAI are urinary tract infection (UTI), surgical site infection (SSI) and lower respiratory tract infections such as pneumonia. Table 1 presents estimates from the United States of the relative proportion of all HAI in hospitals and their relative impact.

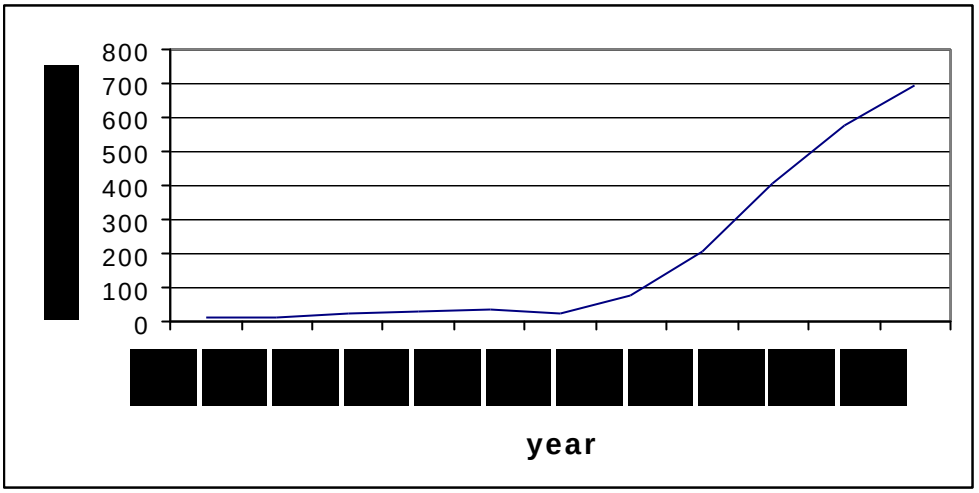
Table 1: **Estimates of the Extent of HAI in Hospitals (Based on US Experience[10,11])**

Healthcare Associated Infection	Proportion of all HAI (%)	Proportion of extra bed days (%)	Proportion of extra cost (%)	Proportion preventable? (%)
Urinary Tract Infection	45	11	13	38
Surgical Site Infection	29	57	42	35
Pneumonia	19	24	39	Surgery: 27 Medicine: 13
Bloodstream	2	4	3	35
Other	6	4	3	N/A

The incidence (i.e., the rate at which new cases occur) of HAI varies. In those undergoing surgery as in-patients, SSI rates are estimated to be 4%, the rate being different for different types of operation e.g., 15% after gastric operations and 3% after hip prosthetic surgery[12].

Damage to health from HAI can be wide ranging. A marker of the occurrence of serious infections is the isolation of bacteria from blood (bacteraemias). Bacteraemias are estimated to occur in 3.6 patients per 1000 admissions[2]. Organisms which are resistant to antibiotics give rise to particular concern. The most important of these, methicillin-resistant *Staphylococcus aureus* (MRSA) is estimated to be the cause of 25% of bacteraemias[13]. In recent years the number of MRSA isolates from blood samples examined at Scottish microbiological laboratories has increased dramatically, partly due to increased testing (see Figure 1).

Figure 1: **Trends in reports of blood isolates of MRSA received at the Scottish Centre for Infection and Environmental Health**



Common risk factors for HAI are the state of health of the patient (e.g., underlying chronic illness, concomitant infections, and poor nutritional status); other therapies (especially immuno-suppression) and the type of procedure performed (especially catheterisation and surgical operations classified as dirty[a]. It is estimated that between 15% and 30% of HAI can be prevented by better application of existing knowledge and realistic infection control practice[1] .

Reliable estimates of the occurrence of HAI in-patients being treated in primary care are not available[14]. Incidents related to HAI are, however, known to have occurred, particularly in dentistry. Increasing attention is being paid to potential HAI problems due to the earlier discharge of patients from hospital, some of whom may be incubating an infection[13]. The increasing variety of procedures including minor surgery performed in community settings and the number of cases with chronic infections (e.g., hepatitis C) being looked after by primary care practitioners are also important factors.

A recent risk assessment commissioned by Department of Health (DH) (England)[7] concluded that based on current knowledge, the risk of person to person spread of vCJD by surgical instruments cannot be ruled out as a public health problem. Good decontamination practice (i.e., cleaning, disinfection and sterilisation) of medical devices, although it does not eliminate it, was highlighted as the priority in reducing this risk.

The detailed review[9] of decontamination practice in a limited number of NHS and private healthcare facilities undertaken by SEHD, found examples of excellent practice, with modern well maintained, validated equipment in appropriate facilities with a controlled environment. This shows that good standards can be achieved. However, most of the sites assessed were deficient in a number of key areas. In general, decontamination processes in the sites visited in the review were found to have many shortcomings which could increase the likelihood of adverse health occurrences to both patients and staff.

There has been recent adverse publicity on hospital cleanliness. The Audit Scotland report "A Clean Bill of Health?"[15] reviewed standards of cleaning in Scottish hospitals, primarily as measured against recommended minimum frequencies for cleaning set by the Scottish Health Management Efficiency Group (SCOTMEG) in 1987, and by the costs and effectiveness of cleaning services. The Report

[a] An operation is classified as dirty if frank pus is encountered or the abdomen is opened for a perforated internal organ. An operation performed more than four hours after compound trauma would also be included in this group.

acknowledged the important contribution which cleaning services make to hospital hygiene and to the quality of care experienced by patients. The Report found that, in relation to the cleaning frequencies recommended by SCOTMEG, the majority of hospital wards included in the Audit Scotland survey either complied with the recommended frequencies or were over-cleaned. In a minority, however, cleaning frequencies appeared to be below the recommended level.

The Audit Scotland Report was also concerned about variations in costs of cleaning. It suggested that hospitals should develop comparative indicators of the quality of cleaning, and should take action to improve productivity. All hospitals needed to develop core indicators to allow meaningful comparison of cleaning standards.

1.2.2 Roles and responsibilities

Scottish Executive Health Department

The aim of the Scottish Executive Health Department is to set clear national priorities for NHSScotland and standards to be delivered in a local context. This entails putting in place a transparent process for holding the NHS to account[8].

SEHD established the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS)[16] with two main objectives. Firstly, it is designed to encourage a rigorous approach to risk management in NHSScotland by developing standards which integrate clinical and non-clinical risk. These draw upon acknowledged good practice within the healthcare sector. Secondly, CNORIS is intended to provide cost-effective financial risk pooling arrangements and a common system to deal with the consequences of claims against the service.

Health Boards and NHS Trusts (unified NHS Boards)

During 2001, there will be a single unified NHS Board established in each of the fifteen Health Board Areas which will replace the separate board structures of the existing NHS Health Boards and NHS Trusts[8]. NHS Trusts will retain their existing operational and legal responsibilities within the local health system. Responsibility for infection control is currently shared between Health Boards and Trusts, while managing the risk of HAI is primarily an NHS Trust responsibility. In this report the term "Trusts" refers both to current NHS Trusts and to the Island Health Boards (which have no Trusts). Further guidance will be forthcoming on the responsibilities of the new unified NHS Boards. For the purposes of this report recommendations have been made in terms of the existing structures. The proposed revised arrangements may have a bearing on how these recommendations are applied in the future. However, they should not affect the substantive content of the report.

The SEHD's "Scottish Infection Manual"[17] provides guidance on core standards for the control of infection in hospitals, healthcare premises and the community interface. Health Boards are responsible for ensuring that adequate standards of infection control are met by NHS Trusts in their area. The SEHD Manual recommends that all Trusts have Infection Control Committees (ICCs) and Infection Control Teams (ICTs), which are responsible for preparing infection control policies and monitoring compliance with standards (as specified by the Health Board).

The Clinical Standards Board for Scotland (CSBS)

This Board sets national standards and has developed a system of quality assurance and accreditation of clinical services[18]. As "Our National Health: A plan for action, a plan for change"[8] indicates, the CSBS is now the lead body for the development of standards related to HAI and will establish a system of quality assurance and accreditation in this area.

General Medical and Dental Practitioners – Primary Care Contractors

The issue of the accountability of primary care contractors is complex. For practical purposes, the precedent of CNORIS is quite clear in excluding primary care contractors from Trusts' coverage, except where a general dental practitioner (GDP) or general medical practitioner (GMP) is working as an employee of a Trust. Primary Care Contractors are therefore accountable for their own performance in this area. However, Primary Care Trusts have a role in monitoring services and ensuring that they are provided to an adequate standard.

Private Healthcare

Currently Health Boards formulate and monitor infection control standards for Private Hospitals and Nursing Homes. These functions will pass to the Scottish Commission for the Regulation of Care once that body is established following legislation.

The Scottish Centre for Infection and Environmental Health (SCIEH)

SCIEH is responsible for the national surveillance of communicable disease (including HAI), providing operational support to local agencies involved in the management of communicable diseases and conducting appropriate research into infection.

1.3 Review of NHSScotland Risk Assessment and Management Processes Related to Healthcare Associated Infection

The joint Scottish Executive/NHSScotland Working Group was established, under the leadership of Richard Carey (see Appendix 1 for full membership). The Group's remit was to provide guidance on:

1. How the senior management of NHSScotland should co-ordinate the following functions, to:
    - monitor the risks to human health from healthcare procedures and the environment in which they take place (especially those associated with inadequacies in infection control, cleaning services and decontamination of re-usable medical devices);
    - assess the potential for damage to human health from these;
    - develop a programme of control measures (including training);
    - co-ordinate their implementation;
    - evaluate their effectiveness.

2. Which standards should be monitored to ensure that NHSScotland organisations discharge these functions optimally.

3. What options are available to ensure compliance with these standards.

The Working Group met on four occasions. A number of sub-groups carried out in-depth examination of the main subject areas and formulated draft standards. Those working in related fields throughout the UK were consulted. The following report outlines the Working Group discussions and key recommendations.

Chapter 2

An Approach to the Risk Management of Healthcare Associated Infection

2.1 Risk and Healthcare

Health services make a significant contribution to improving health. Healthcare organisations strive to maximise their effectiveness by minimising the factors which might have an unfavorable effect on outcome. The chance of these factors impacting on outcome is known as risk. Risk is therefore defined as the chance of something happening that will have an impact on objectives. It is measured in terms of severity and probability (see Figure 2).

Figure 2: **Risk**

"Risk is the product of probability (*usually expressed as a percentage*) and severity (*usually expressed as a cost*) of occurrence

Often expressed as:

The risk of (what/how) to (what/whom) over (what cycle)".

The StPaul|HRRI

NHSScotland faces different types of risk: financial, organisational, and clinical. With regard to the latter, studies of hospitals in the UK and USA have found substantial rates – between 3% and 16% of admissions – of adverse events (defined as unintended injuries caused by medical management rather than the disease process)[19,20]. A large number of these may be preventable, and a significant proportion can lead to death or disability. The economic impact of adverse events on the NHS in England and Wales may be as great as £1 billion per annum[21].

Adverse events often occur as a result of errors but usually in association with failures in a system for delivering clinical care. It is now commonly recognised that preventing such events requires a change in NHS culture with a move from seeking to blame individuals, to analysing and acting on causes.

Infections usually form a large percentage of adverse events – in one study being second in incidence to drug complications[19]. A Scottish Office Department of Health report[3] estimated the total cost to Scottish hospitals of HAI in hospitals to be approximately £21.6 million per annum. This cost has been calculated on the basis of the resources used to treat those with HAI in hospitals and does not include the settlement of legal claims. The avoidable burden, i.e., the proportion which can be prevented by better application of existing knowledge and realistic infection control practice, of HAI in Scottish hospitals is estimated to be approximately £3.9 million per annum although there are considerable difficulties in costing. This estimate was based on HAI increasing length of stay by an average of two days. Other studies have found the excess stay in hospital to be considerably greater[13,22]. The true cost is likely to be substantially higher as these figures do not include treatment costs of HAI manifesting in the community, or costs to patients and their families or society.

Healthcare is only one industry which can place the public at risk of infection. Recent policy in the UK has sought to ensure that controls to reduce such risks are proportionate – i.e., comensurate to the risks involved – and equitable across different sectors of the economy[23] . The report of the BSE Inquiry has reinforced the need for Government Departments to monitor the implementation of measures designed to reduce the risks associated with the BSE/vCJD agent[24]. It is therefore a priority to ensure compliance with measures to control HAI and reduce the risk of vCJD, in ways which are comparable with how similar risks are dealt with in other industries.

2.2 The Risk of Healthcare Associated Infection

In the context of HAI, the principal risk involved is **the probability of patients, staff or others being exposed, while in a healthcare setting, to an infectious agent which damages their health**. The prime objective of risk management is to minimise this risk. Patients may be exposed to a microorganism likely to cause infection while receiving healthcare through, for example:

- direct person to person contact (particularly via hands, the main route of transmission of MRSA);
- medical devices (e.g., surgical instruments, catheters or needles introducing microorganisms into the body either through the device being contaminated or by transferring a microorganism from one organ or cavity where it does no harm to another where it does);
- airborne/droplet spread (e.g., from contaminated humidifiers or air conditioning or through droplets expelled by sneezing etc.);
- environmental contamination (e.g., from microorganisms present on floors, fittings, in dust etc.);
- food (e.g., from food contaminated with a pathogenic microorganism).

Exposure to a microorganism is most likely to occur when these factors occur in tandem in a specific setting:

- a high prevalence of the microorganisms causing HAI (e.g., a high carriage rate of a microorganism in a group of patients or staff);
- a concentration of compromised patients (e.g., those with broken skin or whose immune systems are depressed);
- the presence of potential routes of transmission.

Other factors influencing the likelihood of exposure to microorganisms causing HAI are, for example: anti-microbial prescribing, the technique employed in carrying out invasive procedures, bed occupancy/patient movement, decisions on medical device procurement and disposal and food hygiene practice in catering.

These various factors are regularly present in, or pertinent to, the healthcare setting. It is not always possible to identify people who are infectious, and to distinguish them from those who are not. Preventing exposure which can lead to HAI, therefore, involves all services and staff taking *Standard Precautions* for the control of infection as routine practice. Standard Precautions are designed to protect staff, patients and others from transmission of infection where the risk is known or unknown. They incorporate *Universal Precautions*, designed to prevent transmission of bloodborne infections, and *Body Substance Isolation*, designed to reduce the risk of transmission of infection from other body substances[17]. The principles of Standard Precautions include:

- good hand washing practice;
- appropriate use of personal protective equipment;
- effective decontamination of equipment and environment;
- safe use and disposal of sharps;
- safe handling and reprocessing of contaminated laundry;
- safe handling and disposal of healthcare waste;
- patient isolation where appropriate;
- patient personal care/hygiene (particularly related to blood, body fluids, secretions and excretions);
- aseptic technique for invasive procedures and care of invasive devices.

Since the concerns about vCJD have arisen, particular focus has also centred on:

- the effective decontamination of re-usable medical devices (i.e., cleaning, disinfection and sterilisation);
- the use of single use medical devices whenever possible;
- prohibiting re-use of devices designated as single use.

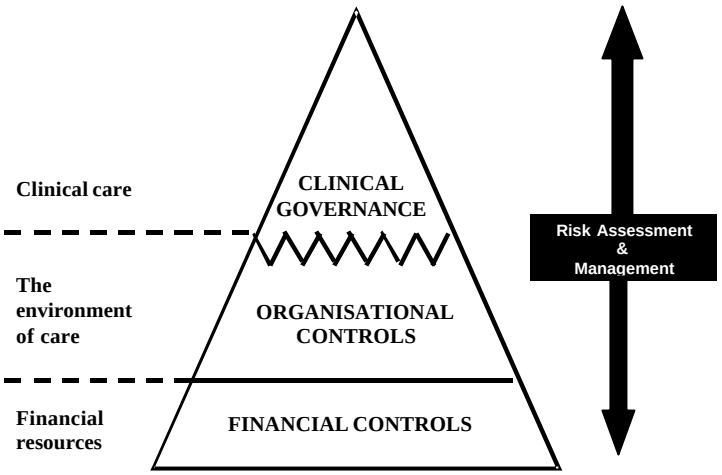
Standard precautions may be backed up by additional targeted controls based on an assessment of the risk of exposure in specific situations, for example in intensive care units.

2.3 A Model for Managing the Risk of Healthcare Associated Infection

Managing risk in the NHS usually involves three overlapping and complementary approaches: clinical risk management, organisational controls, and financial risk and liability controls (see Figure 3). Reducing HAI will involve elements of each. Organisational and financial risk management provide the platform for delivery of effective clinical care. These systems cannot, therefore, operate in isolation. When these broad areas of risk are actively managed, then the following benefits can be expected:

- a reduction in risk exposure through continuous risk assessment and targeted risk treatment;
- a reduction in the frequency and/or severity of HAI and related incidents, complaints, legal claims, staff absence and general loss;
- a demonstrable compliance with applicable laws, regulations and standards;
- an enhanced reputation through public disclosure of achievements in managing risk;
- increased public confidence in the quality of services.

Figure 3: **Managing Risk**

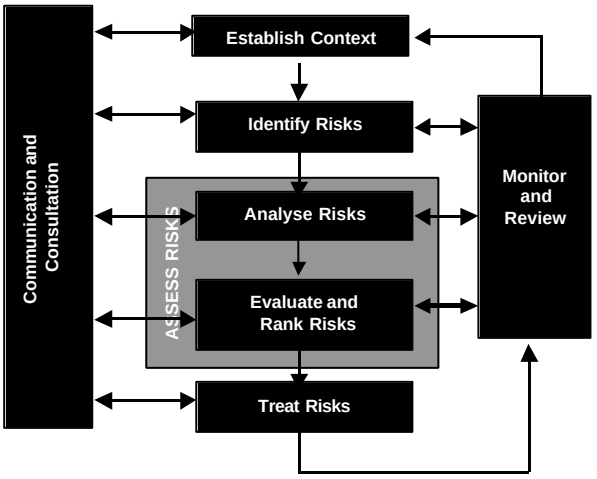


Controls Assurance Framework 1999

The Australia/New Zealand Standard (AS/NZS)4360:1999[25] on risk management provides a basic guide to how organisations should manage risk (see Figure 4). Six interrelated processes are involved:

1. communicating and consulting with relevant stakeholders on risks and related matters;
2. establishing the context for risk management;
3. identfying potential hazards;
4. assessing risks;
5. treating risks;
6. monitoring and reviewing the quality and effectiveness of risk management.

Figure 4: **A Model for Risk Management**



AS/NZS 4360:1999

The above model has been adopted by the NHS in England as part of the Controls Assurance Framework[26,27]. This model is accepted by CNORIS as a rigorous methodology for the management

of risk generally in NHSScotland. Its principles were endorsed by the Working Group as the template on which NHSScotland should base its approach to the risk management of HAI.

This model has application at two levels in NHSScotland: national and local. At national level arrangements should be made to:

- identify and analyse risks to health in healthcare settings;
- prioritise and set risk management standards;
- ensure an appropriate level of compliance for given standards;
- co-ordinate the risk management of HAI with CNORIS.

Locally, service providers in NHSScotland should be required to incorporate nationally set standards into local risk management and governance procedures. They should develop risk management processes based on the AS/NZS 4360: 1999 and integrate the risk management of HAI within their existing organisational framework and prioritised risk-based action plans.

2.4 The Way Ahead

When considering how NHSScotland should take forward the development of better systems to manage the risk of HAI based on the AS/NZS 4360: 1999, the Working Group highlighted four areas as priorities:

- learning about risks;
- NHS Trusts' risk management processes related to HAI;
- standards for assessing NHS Trusts' performance in managing the risk of HAI;
- NHSScotland national risk management processes related to HAI.

2.5 Summary of Recommendations

- There should be a common approach to the risk management of HAI with matching local and national components.
- Risk management of HAI should be based on the Australian/New Zealand Standard 4360: 1999 model.

Chapter 3

Learning About Risk

" Culture is: how things are done around here"[28]

3.1 Introduction

Health care provision is by nature a significant risk activity, and risk is part of everyday life for all staff working in the NHS. In the past risk management has been seen to be mainly a health and safety issue. However, with a greater emphasis on quality controls in patient care and clinical effectiveness, the term risk management has come to cover a much broader range of issues. Effective management of risk therefore requires a fundamental shift in attitude by organisations and their staff.

Risk management is about reducing the probability of negative patient outcomes or adverse events by systematically assessing, reviewing and then seeking ways to prevent, occurrence. Fundamentally risk management involves clinicians, managers and healthcare provider organisations identifying the circumstances of practice that put patients at risk of harm, and then acting to prevent and control these circumstances and thereby manage and reduce risks.

Infection is an unintended, unwelcome, often damaging consequence of healthcare. When it is serious it can have devastating effects. When things go wrong, in healthcare or any activity, there can be a tendency to blame individuals. However HAI and other types of adverse events often happen repeatedly due to the recurrence of the same set of circumstances. Improving safety therefore needs clinicians and managers to look in more depth at where systems have failed, learn from this and apply the lessons learnt.

There is now a recognition that the NHS needs to re-think how its component organisations and individuals learn through unplanned occurrences, whether or not they result in an adverse outcome for the patient or others[29,30]. The DH (England) report "An organisation with a memory"[31] has highlighted the following areas as key for development:

- unified mechanisms for reporting and analysis when things go wrong;
- a more open culture in which errors or service failures can be reported and discussed;
- systems for ensuring that, where lessons are identified, the necessary changes are put into practice;
- a much wider appreciation of the value of the 'system' approach in preventing, analysing and learning from errors.

3.2 Organisational Learning

The concept of organisations as learning systems has emerged in recent years with the popularisation of the concept of the 'learning organisation'. The development of NHSScotland as a learning organisation is a pivotal theme in "The Strategy for Education Training and Life Long Learning"[32]. Creating a learning culture is recognised as integral to service planning and quality. However, as has

all too often been demonstrated, the culture of the organisation is capable of blunting or significantly altering the intended impact of risk management strategies.

The culture of any given organisation is inevitably complex, accommodating as it does various group values, desires, philosophies and relationships. Individuals and groups often perceive risks differently. Getting a whole organisation, with all its disparate internal groups, to share the same values, desires and objectives is extremely difficult. The introduction of Clinical Governance to the NHS is about creating a culture where the delivery of the highest possible standard of clinical care is understood to be the responsibility of everyone working in the organisation. It is built upon partnership and collaboration within health care teams and between individual health care professionals and managers.

Improving patient safety through effective risk management strategies is a key component of the clinical governance agenda. In order to achieve the desired outcomes of improved quality of patient care and public reassurance of standards of care, there is a need to identify the reasons why some events lead to learning while some do not, and to take steps to address what has been described as 'organisational forgetting'[33]. There is often a tendency to be preoccupied with how learning at the organisational level occurs and perhaps to lose sight of the significance of how individuals learn or do not. Organisational learning is dependent upon a collective infrastructure where structures and processes support the activity of learning, embedding the lessons learnt into the organisational culture and practices. Central to a positive risk management culture is the promotion of an open communication system where learning rather than apportioning blame is the goal[34].

Looking at the past record of the NHS in dealing with adverse events, it has been found that:

- history appears to repeat itself;
- human error is often the consequence – not the cause – of failure;
- staff are not trained or are acting beyond their competence;
- equipment may be used inappropriately;
- the final act is often the end of a long chain of failure;
- warnings are ignored;
- the NHS appears not to learn effectively. [31]

The renewed focus on quality within "Our National Health: A plan for action a plan for change"[8] provides an opportunity to address these issues. The Chief Medical Officer has stated his support for the key recommendations contained within the report, and discussions are currently underway as to how NHSScotland intends to take this forward. Among the necessary measures will be the development of risk assessment and incident recording systems which will increase understanding and improve practice. In order that individuals do not work in isolation to improve practice, investment is required in staff training and development in analysing and learning from adverse events, setting standards, monitoring them and ensuring compliance.

Integrated Care Pathways supported by detailed protocols are increasingly being recognised as an important system for improving the quality and effectiveness of patient care[35]. Guidelines, either national or local, may be built into the pathway. Variances are recorded and analysed, and the resulting information can be used to make changes in the system to improve the quality of patient care and improve compliance with good practice guidelines and Clinical Governance.

3.3 Training and Development

Training and development is central to ensuring that all NHS staff are equipped with the necessary skills, knowledge and attitudes, and to make sure that current infection control practice, including decontamination practice and environmental hygiene in healthcare premises, is of a high standard. Well-trained staff minimise risks both to themselves and to the patient. The approach to training and development must be seen as evolutionary and dynamic, and must be sensitive to changing circumstances.

Staff require access to a repertoire of courses/learning activities that are responsive to local needs and build upon standards for infection control. This should also include more effective use of information technology and open learning, taking account of an appropriate combination of learning settings and the availability of suitable learning resources and clinical skills programmes, so as to widen access to learning for all staff. Appropriate training on infection control issues should form part of the induction process and ongoing staff development and should be simple, clear and relevant to the policies of the healthcare organisation. Evidence that demonstrates supervision, monitoring and evaluation of the effectiveness of training must be available within all health care premises.

In particular NHS Trusts should ensure that the following are in place:

- organisational and personal development plans which specify training requirements for the risk management of HAI as determined by Trust Human Resource strategy, with current and future training needs being identified at annual appraisal;
- mechanisms at Trust Board level that will ensure training needs are identified in response to managing the risk of HAI, and in particular in response to incidents associated with infection control;
- a wide repertoire of training activities, which will enable all staff to access learning and identify their role in reducing the risk of HAI, for example:
    - open learning materials
    - study guides/learning packages
    - computer assisted learning programmes
    - clinical skills programmes
    - training days with specialist infection control input
- the capability to produce evidence that supervision and monitoring of training and development on HAI is encompassed within the Clinical Governance reporting processes.

The introduction of a formal risk management programme will raise awareness of risk. The recent establishment of the NHSScotland Risk Management Network will facilitate the development of skills in this area. The CNORIS web site (**www.cnoris.com**) provides a means of direct communication between individuals and organisations, facilitating exchange of good practice and early notification of developments in the wider area of risk management both in the UK NHS and International Healthcare.

3.4 Adverse Events Systems

The DH (England) report[31] recommends that a new national mandatory system be established to record and analyse adverse events in health care, change culture and ensure lessons learnt in one part of the NHS are properly shared with the whole of the health service. A number of systems already exist in NHSScotland which can to varying extents be seen as mechanisms for learning from adverse health care events, but collectively they have limitations. Many focus on the event, the people involved, the situation, technology and the outcome while issues relating to the culture and context are rarely considered. There is evidence of change as a result of the systems and while lessons are identified, often 'true active' learning does not take place.

There is limited evidence of good practice related to infection control adverse events which is readily accessible in NHSScotland. This may reflect a failure to record what might be seen as 'minor' infringements of infection control practice. Approaches taken to identify and control other more commonly recorded events need to be equally applied to infection related issues.

Current discussions on how NHSScotland should progress the issues raised in "An organisation with a memory"[31] will consider how to capture incidents associated with infection control in systems developed for adverse events. In particular they should address the need to provide guidance on how organisations can learn from these incidents and ensure that lessons learned impact positively on the risk management of HAI. Two examples of good practice were identified.

Example of Good Practice

Use of Statistical Process Control (SPC) Charts at Glasgow Royal Infirmary Hospitals

Trigger Event: The recognition that there was an uncontrollable level of MRSA acquired in hospital (>50 new cases per month) and that current infection control action was not working.

Action: The Infection Control Nurse (ICN) explored methods of quality control and discussed the problem with an expert in the use of industrial quality control tools. It was decided to introduce SPC charts which involved feedback to staff in wards with a MRSA problem, of the incidence of new MRSA acquisitions. SPC charts are statistical graphs that provide real-time feedback to practitioners, display data chronologically in an easy-to-interpret manner, and help detect increases or decreases in the acquisition rate.

Implementation: The Infection Control Team (ICT) set up the SPC chart system using retrospective data (25 months) initially, then prospective data. Each ward was provided with a SPC chart every month as a proxy for performance of infection control practices. Fishbone charts detailing the factors involved in transmission of MRSA were also developed by the ICT[1] to assist with staff education and training.

Review and Feedback: The SPC charts can help determine whether the MRSA rate is stable over time, and are considered to help identify deficiencies in adherence to standard infection control practices. The charts indicate when the situation is out-of-control, i.e., there is a statistically significant difference in the rate of acquisition.

Learning: Using SPC charts has resulted in responsibility for MRSA control being assigned to and accepted by wards who continuously review practice with reference to the fishbone chart and initiate change where necessary, particularly when increased transmission is detected. Ward staff are motivated to maintain good infection control practice. New acquired cases have been reduced by 50% comparing results for 1999 to those for 2000.

New Action: Implementation of SPC charts has been extended to cover 36 clinical areas. The Infection Control Team has now successfully used SPC charts in the control of both MRSA and *Clostridium difficile*. A paper describing the findings of this initiative has been submitted for publication.

[1]Curran E T, MRSA: Monitoring Quality, British Journal of Infection Control (2000) Vol 2: 1, 20-23.

Example of Good Practice

Use of Hazard Analysis Critical Control Point (HACCP)[1] to Reduce an Increased Incidence of Endophthalmitis in Lanarkshire Acute Hospitals NHS Trust

Trigger event: An increased incidence of endophthalmitis following intra-ocular surgery in excess of that normally expected (reported range 0.07% - 0.5%, median incidence 0.01%)

Action: All aspects of patient care were examined in detail by a multidisciplinary team using the Hazard Analysis Critical Control Point (HACCP) approach. A standard methodology was agreed and used to review each component of care from pre-operative assessment to post-operative administration of topical medication. Endophthalmitis is one of the most serious complications of intraocular surgery. Early post-operative infections are commonly caused by 'commensal' flora of the conjunctiva and eyelid. Exogenous sources such as contaminated fluids or instruments, the theatre environment, and the surgeon, are known risk factors and were considered in the HACCP.

Implementation: A detailed and referenced best practice protocol was developed for each component of care following group discussions, staff interviews, literature review, observation of practice etc. Differences between current and best practice were identified and recorded. Resource requirements and training needs were noted for each protocol. Management were informed of these and action was taken to introduce the protocols, including the need for audit assistance and suggestions of how and when the training should take place.

Review and Feedback: After introduction of the protocols ongoing audit was initiated and any variances identified, recorded and fed back. Detailed information is now available to inform any investigation of infection or other complication. Information on each case is fed back to all clinicians.

Learning: Evidence based practice is now provided at every stage of patient care. The training needs of all staff have been fulfilled leading to improved patient care and staff confidence. Greater appreciation of the roles of others within the care team has been identified by many disciplines involved. There is improved record keeping and auditing of practice allowing detailed examination if a case of infection or other complication does occur. A reduction in the infection rate to within the range normally expected has been achieved.

New Action: The detailed protocols were used to support the formation of an Integrated Care Pathway for patients undergoing intra-ocular surgery. A statistical tool[2] was developed to assist early recognition if the number of cases of endophthalmitis is becoming higher than expected.

1. Baird DR, Henry M. Liddell KG, Mitchell CM, Sneddon JG: in press – Journal of Hospital Infection
2. Allardice GM, Wright E, Peterson M, Miller JM: in press - Journal of Hospital Infection

3.5 Summary of Recommendations

- NHSScotland should promote an organisational culture which actively seeks openness and sharing of information on managing risk.

- Trust training and development programmes should contain the following elements:
  - personal development plans which specify risk management training needs;
  - an organisational training plan which ensures the development of skills related to risk management of HAI;
  - provision of a wide repertoire of training activities;
  - documented evidence of training and development related to HAI within clinical governance reporting processes.
- SEHD should consider HAI related incidents in plans to take forward the recommendations contained within the Department of Health (England) report, "An organisation with a memory".

Chapter 4

NHS Trusts' Risk Management Processes Related to Healthcare Associated Infection

4.1 Introduction

As discussed in Chapter 2, the Working Group recognised that there should be a common risk management process for NHSScotland. This process should take place at two levels: national and local. Local responsibility for managing the risk of HAI primarily lies with NHS Trusts. GMPs and GDPs working as independent contractors have responsibility for reducing the probability of patients and staff being exposed to pathogenic microorganisms while receiving care or working in their premises.

This chapter provides an indication of how the AS/NZS 4360: 1999 model for risk management should be implemented in NHS Trusts. Given the diversity of services provided by NHS Trusts, how this model applies to specific Trusts will vary significantly. This chapter therefore, outlines broad processes and structures which should be adapted to fit local needs as appropriate.

4.2 Risk Management in NHS Trusts

4.2.1 Clinical Negligence and Other Risks Indemnity Scheme

From 1 April 2000 CNORIS was introduced throughout NHSScotland with the following aims:

- to encourage systematic risk management encompassing clinical and non-clinical risk;
- to provide cost-effective financial risk pooling arrangements and claims management;
- to complement other initiatives for improving standards.

Their work is supported by the introduction of clinical and non-clinical standards, which are being developed at three levels. Level One standards concentrate on ensuring that the correct management systems are in place whilst the corresponding standards for Levels Two and Three will focus on embedding of these systems into the day to day activities of the organisation. Accreditation in these risk management standards will help Trusts to provide evidence of their commitment to quality, and also impact upon the Trust's contribution to the financial risk pooling arrangements to meet the cost of claims against the service. Within the standards at Levels Two and Three, specific reference will be made to infection control and related issues.

Trusts are currently at different stages in the process of implementing Level One standards, which in broad terms focus on the following areas:

- risk management strategy, and framework for implementing risk management policies;
- risk assessment and prioritised risk action planning;
- monitoring and review of performance management;
- processes for managing, recording and analysing complaints, comments and adverse events;

- information on the risks and benefits of treatment and informed consent;
- operational risks – clinical and non-clinical;
- record keeping – clinical and non-clinical;
- human resources, recruitment, induction and lifelong learning.

4.2.2 Scottish Infection Manual

The Scottish Infection Manual sets out the role and responsibilities of health boards, hospitals and other health care providers in relation to infection control matters.

This document recognises that the range and type of NHS Trust in Scotland and the variety of health care services which they provide creates difficulty in giving prescriptive advice on the arrangements for infection control services. Certain basic organisational structures can however be recommended for the majority of Trusts. These include that:

- the Chief Executive of every Trust is responsible for ensuring that effective arrangements for infection control are in place;
- every Trust should have an infection control committee (ICC);
- every Trust should have an infection control team (ICT) which reports to the Chief Executive and has the primary responsibility for all aspects of infection prevention and control within the Trust.

4.2.3 Current risk management approach in Trusts

Discussions took place between Working Group members and a number of groups. Examples of current risk management structures were received from a cross section of Trusts within Scotland.

The Working Group concluded that NHS Trusts current risk management processes require further development to integrate measures related to HAI. NHS Trusts need to clarify their internal structures and processes in reference to the following areas:

- accountability for risk management;
- risk management structures;
- risk management processes;
- monitoring of risk management;
- reporting on risk management.

4.3 NHS Trust Structures and Processes for Managing the Risk of Healthcare Associated Infection

4.3.1 Accountability for the risk management of HAI

Trust Boards should have their responsibility for the risk management of HAI clearly defined. This requires clear lines of accountability for infection control, decontamination of re-usable medical devices and cleaning services, throughout the organisation and leading to the Trust Board.

In line with the recent Health Department Letter (HDL) on decontamination[36] Trusts should have appointed a senior manager (either an executive director or directly accountable to an executive director) who has overall responsibility for the risk management of HAI. The ICC should have an explicit, extended remit which includes all aspects of the risk management of HAI, including infection control, decontamination of re-usable medical devices and cleaning services.

4.3.2 Risk management structures related to HAI

NHS Trusts should ensure that their organisational structure includes clear indication of which individuals and groups have responsibility related to risk management policy and procedures, monitoring standards and line management for operational services. The structure should demonstrate how committees or groups with the following remits are linked:

- Infection Control
- Health and Safety
- Risk Management
- Clinical Governance

The creation of unnecessary additional new groups should be avoided to guard against the danger of 'piecemeal working' on the same topics by separate committees. The roles and remits of each group should be clearly detailed.

The structure of the ICC should be appropriate to the organisation. Some organisations have found that smaller operational ICCs reporting to the main Trust ICC work well. The ICC should have agreed terms of reference and accountability arrangements and should meet at least four times a year. Minutes of the ICC should be circulated to all clinical directors/managers and relevant committees, for example, clinical governance and risk management committees. The ICC should provide advice and support to the ICT.

Trusts should review their ICT and ensure that it is sufficiently robust both in personnel and other resources to accommodate the wider remit, with increased responsibilities and workload, which will result from implementing the risk management processes related to HAI. It is likely that many ICTs will require to be strengthened considerably.

4.3.3 Risk management processes related to HAI

Trusts should establish processes which integrate, as far as possible, mechanisms for clinical risk management, risk management associated with CNORIS and that related to HAI. They should establish processes which cover the key components of the AS/NZS 4360: 1999 risk management model.

Based on a recorded assessment of risk, each ICT should produce an organisation-wide annual programme for the risk management of HAI. The programme should clearly state:

- the main risks which will be addressed during the year;
- the control measures to be implemented for each identified risk;
- how the adequacy and effectiveness of these control measures will be monitored.

The programme should be developed and produced in full consultation with relevant key stakeholders, including the ICC, health professionals and senior managers. The programme should be approved by the Trust Board through the relevant risk management structure.

The ICC should endorse all local infection control policies, procedures, and guidance, as well as provide advice and support on the implementation of risk reduction policies and monitor the progress of the annual infection control programme in reducing the risk of HAI.

4.3.4 Monitoring of risk management related to HAI

NHS Trusts in Scotland currently comply, or are working towards compliance, with standards as set out by CNORIS. This is an essential step to ensure that a general risk management framework exists. This framework should be expanded to incorporate the above proposals in order that Trusts can monitor, assess and control risks associated with HAI.

The system in place for control of infection should be monitored and reviewed by the Senior Manager (as indicated in HDL (2001)10), who reports to the Trust Board on what improvements to the system are required. S/he should be responsible for ensuring that mechanisms are in place for the self-assessment of performance against standards as described in Chapter 5.

The ICC will review the detailed issues surrounding infection control. The ICC and ICT, supported by internal audit, should carry out an annual audit based on the risk management standards (see next Chapter) to provide evidence to the Trust Board that an effective system of risk management of HAI is in place.

Other relevant committees will play a significant role in monitoring and reviewing those aspects of the risk management of HAI which relate to their functions. They may also provide information in this regard for the Trust Board.

4.3.5 Reporting on risk management re lated to HAI

In line with recommendations on good practice in corporate gorvernance[37], HAI risk management standards should be exposed to the same rigorous internal audit as finance and be the subject of an annual statement of their effectiveness. Reports from audits of performance against HAI risk management standards should be presented for consideration to the relevant Trust committee with responsibility for internal audit. They should submit an annual assurance statement on audit findings for consideration and approval by the Trust Board.

A comprehensive annual infection control report should be produced by the ICT, reviewed by relevant Trust committees and presented to the Trust Board. The annual infection control report should contain, as a minimum, information on the following:

- main risks identified from annual risk assessment;

- progress of the infection control programme in reducing risk;
- a review of reported incidents including reports from external agencies e.g., environmental health departments;
- surveillance and monitoring data;
- education and training undertaken;
- results of audit of performance against risk management and other standards;
- recommendations on measures to reduce risk.

The Trust Board should include in its annual report the assurance statement, information from the report of the ICT and the findings of external verification of compliance with risk management standards (see Chapter 6).

4.4 Summary of Recommendations

- Trusts should ensure that the risk management of HAI is integrated with CNORIS and clinical risk management structures and processes.
- Trusts should ensure that the recommendations of the Scottish Infection Manual, HDL(2001)10 and CNORIS are in place.
- Each Trust should designate a senior manager, as detailed in HDL(2001)10, to be responsible for monitoring the risk management of HAI and ensuring self-assessment of performance against standards takes place.
- Infection Control Committees should have overall responsibility for HAI (i.e., infection control, decontamination of re-usable medical devices and cleaning services).
- Trusts should review their Infection Control Team and ensure that it is sufficiently robust both in personnel and other resources to accommodate the wider remit with increased responsibilities and workload associated with HAI risk management processes.
- Trust annual infection control programmes should be based on the risk management model contained within the AS/NZS 4360: 1999.
- Trust Boards should produce an annual assurance statement based on an internal audit of HAI (i.e., infection control, decontamination of re-usable medical devices and cleaning services) risk management.

Chapter 5

Standards for Assessing NHS Trusts' Performance in Managing the Risk of Healthcare Associated Infection

5.1 Introduction

The key objective of setting standards for risk management is to enable organisations to improve their performance in reducing risk. With regard to HAI, the challenge therefore, is to set realistic standards which are within the reach of most parts of NHSScotland, but stretch those whose performance does not meet statutory, mandatory or good practice requirements. Ultimately, by meeting standards, healthcare within NHSScotland will become safer.

In England, the NHS "Controls Assurance" system of risk management and control was introduced in 1999[26]. Controls Assurance is designed to provide evidence that NHS organisations are doing their 'reasonable best' to manage risk so as to meet their objectives and protect patients, staff, the public and other stakeholders against risks of all kinds. The standards developed for Controls Assurance reflect potential areas of significant risk and are based on existing statutory, mandatory and best or good practice requirements. One of the fundamental assumptions of Controls Assurance is that all statutory and mandatory requirements with which NHS organisations need to comply indicate a risk of some sort. These requirements exist because they are designed to control a risk that could threaten the organisation, the people, or the environment. Best practice or good practice guidance exists to advise on accepted, although not always 'evidence based', options for dealing with potential risks. Thus 'non-compliance' with standards and 'risk' are synonymous in the context of Controls Assurance. Several Controls Assurance standards relate to the areas of risk which the Working Group addressed.

5.2 Defining Healthcare Associated Infection Risk Management Standards for NHSScotland

Setting appropriate standards was an important part of the remit of the Working Group and a Sub-group was established to progress this area. It was composed of professionals with a broad range of expertise in the subject areas. They reviewed:

- the applicability of Controls Assurance standards to NHSScotland;
- the overlap between risk management and other types of standards;
- a template for risk management standards;
- the suitability of the standards as a tool for self-assessment by Trusts.

It was recognised that there is an urgent need for NHSScotland to adopt standards for the risk management of HAI. Because of this the production of standards based on existing work was considered the most suitable way forward. However, the need to pilot and consult on the standards produced was recognised.

5.3 Review of Controls Assurance Standards Related to Healthcare Associated Infection

The Working Group thought it desirable that the Controls Assurance standards should be considered for their appropriateness to NHSScotland because:

- they were developed specifically for NHS services;
- there were obvious benefits in creating a system which allows benchmarking with the NHS in England;
- sharing specialist expertise on setting risk management standards is advantageous to NHSScotland.

There are currently nineteen Controls Assurance standards. No Controls Assurance standard exists for cleaning services. The Working Group considered that the following Controls Assurance standards were appropriate to risk management of HAI by NHSScotland and should be subjected to in-depth review:

(1) Infection Control

(2) Decontamination of Re-usable Medical Devices

(3) Medical Devices Management

Much of the evidence base for the Controls Assurance standards i.e., United Kingdom statutory, mandatory and best or good practice requirements are equally applicable to Scotland. The extensive review undertaken by the Sub-group included:

- identifying equivalent Scottish guidance – statutory and mandatory;
- obtaining, reviewing and updating all reference material;
- cataloguing reference material used as evidence base (listed on first page of each draft standard – see Annexes 1, 2 & 3);
- amending standards where considered appropriate, to accord with Scottish requirements and to update guidance without introducing significant disparity.

The in-depth review identified an overlap between two of the standards i.e., decontamination of re-usable medical devices, and medical devices management. The criteria within the management of medical devices standard which have relevance in relation to re-usable medical devices are also adequately dealt with within the decontamination of re-usable medical devices standard. The remaining criteria in the medical devices management standard deal mainly with management issues which, whilst important, do not fall within the remit of the Working Group. It was considered unnecessary therefore, to include the management of medical devices standard in the suite of draft standards produced by the Working Group.

As no Controls Assurance standard for cleaning services existed a new one had to be developed. To maintain consistency with other HAI risk management standards, the Controls Assurance standard template was used.

There were reservations about the Controls Assurance weighting system in scoring compliance with standards and the Working Group were unable to endorse it as it lacked an evidential basis. It was

agreed that compliance with an individual standard criterion should be recorded in a *Yes, No, Not Applicable* format with an additional explanation narrative for *Not Applicable* or *Non-compliant* responses. To reduce the risk of HAI, Trusts must be able to compare their own performance over time and also with other Trusts. Work is required to develop further a validated benchmarking scoring system.

Based on the in-depth review undertaken by the sub-group, the Working Group concluded that the standards (see below) as amended should be utilised for assessing NHSScotland Trusts' performance in managing the risks of HAI, subject to a piloting and consultation process:

- Infection Control (see Annex 1);
- Decontamination of Re-usable Medical Devices (see Annex 2);
- Cleaning Services (see Annex 3).

5.4 Overlap with Other Standards

The standards considered are not typical clinical standards but adopt more of a quality assurance model and reflect potential areas of significant risk to the organisation. Their principal purpose is to assess how effectively an organisation is managing risk. As such they mainly relate to the organisational structures and processes needed to identify, assess and treat specified risks.

The infection control standard relates to measuring the quality of Trusts' infection control structures and procedures in this area. This standard will refer to, and overlap with:

- clinical standards related to aspects of therapeutic, diagnostic and other interventions such as antimicrobial prescribing, catheterisation, care of surgical wounds etc., which should be developed and monitored following the CSBS Quality Assurance and Accreditation scheme.
- organisational standards related to risk management of other areas, which impact on infection such as healthcare waste, food hygiene, health and safety etc;
- CNORIS Standards – the draft Infection Control, Decontamination of Re-usable Medical Devices and Cleaning Services standards should be adopted by NHSScotland within CNORIS Levels Two and Three Standards.

5.5 Self-assessment by NHS Trusts

The standards are designed principally to facilitate self-assessment. They are also designed to be both measurable and auditable. The template for the standards is:

- a front page – identifying the title of the standard, a statement of the standard to be achieved, an overview of the standard and key references which form the 'evidence-base' for the assessment criteria within the standard;
- audit criteria which, when taken together, indicate whether the standard has been fully, partially, or not achieved. Guidance is provided to help in the assessment of whether the criteria are fulfilled plus the source(s) from which they were derived along with examples of data the organisation should collect and record to enable verification of their achievement;

- an assessment matrix which will allow the generation of a 'benchmark' against which progress can be measured;
- an action planning pro-forma to allow listing of key actions necessary to rectify any weaknesses identified from self-assessment.

Self-assessment should be the honest opinion of the Trust of their current position in relation to the standards. Trusts need to develop an internal process for self-assessment. This should encompass:

- guidance on how individual departments review their own performance in these areas;
- a mechanism for ongoing review of local self-assessment;
- development of costed action plans for remedial action to ensure compliance with standards;
- collation of information for Trust and national reporting requirements;
- feedback to both local and national stakeholders.

5.6 Piloting and Consultation

The draft standards produced by the Working Group have been developed without wider consultation with NHSScotland stakeholders. The standards should be piloted in at least one NHS Trust. There should also be consultation with stakeholders. The need for consultation and piloting is particularly important in relation to the cleaning services standard which, unlike the other two, as a newly developed standard has not been subjected to consultation within the service or validated by use elsewhere. However, it is recognised that, due to the need for urgent action to reduce the risk of HAI it will be necessary to introduce the standards as soon as possible and gather feedback on their appropriateness through Trusts' experience in using them. This will be the beginning of a process of joint working between NHS Trusts and the CSBS to develop, improve and extend them.

5.7 Summary of Recommendations

- NHSScotland should adopt the outlined standards for:
  - Infection Control
  - Decontamination of Re-usable Medical Devices
  - Cleaning Services.
- Trusts should use the HAI related standards (i.e., infection control, decontamination of re-usable medical devices and cleaning services) to self-assess performance in the risk management of HAI.
- CNORIS should adopt the HAI related standards (i.e., infection control, decontamination of re-usable medical devices and cleaning services) within Levels Two and Three standards.
- CSBS should ensure integration of the HAI related standards (i.e., infection control, decontamination of medical re-usable devices and cleaning services) with the CSBS Generic Standards.

Chapter 6

NHSScotland National Risk Management Processes Related to Healthcare Associated Infection

6.1 Introduction

Three national agencies will play a key role in ensuring the effectiveness of risk management of HAI in NHSScotland:

- The Scottish Executive Health Department
- The Clinical Standards Board for Scotland
- The Scottish Centre for Infection and Environmental Health

The following proposals on how risk management should be undertaken nationally apply mainly to the CSBS but also have implications for SEHD and SCIEH.

6.2 National Risk Management Processes Related to Healthcare Associated Infection

6.2.1 Risk assessment – creation of a matrix tool

Risk management standards need to enjoy the widest possible consensus of support if they are to be effective. Because risks are not equal in their frequency and severity, there must be a way to indicate to those working in NHSScotland which risks are the most significant. This will help explain the rationale behind the action undertaken nationally to ensure controls are in place.

Local risk management structures and processes need to be complemented by an appropriate national system whose function will include external review of risk management performance in relation to HAI and intervention when appropriate. The purpose of the latter should be to ensure that remedial action is taken if local systems are failing. The level of external intervention to seek compliance with standards should be related to the level and nature of risk required to be managed. Thus a key national function is to indicate clearly to the service when external intervention to seek compliance with standards will occur. For this purpose a risk matrix should be developed, as the basis for prioritising risks and thus defining the level at which external, national intervention to ensure compliance with standards will be required. One system for classifying risks could be:

- **negligible** (i.e., not warranting active compliance management);
- **tolerable** (i.e., requires management to 'as-low-as-reasonably possible', and compliance with standards to be internally managed and externally verified);
- **intolerable** (i.e., required management 'at-all-costs', and standards to be externally enforced with sanctions for non-compliance).

This approach recognises the trade off between compliance and accountability that exists. Internal systems of risk management based on self assessment against standards usually achieve high compliance at a relatively low cost and should be the bedrock of the system. However, they can suffer from low accountability. National systems are high cost but afford higher accountability. The latter is appropriate only where the consequences of non-compliance are sufficiently high (i.e., '**intolerable**') that enforcement with sanctions is necessary.

CSBS should develop a risk assessment process for prioritising risk management standards and as the basis for deciding appropriate methods of ensuring compliance with them.

6.2.2 Setting risk management standards

The Working Group has developed draft risk management standards. CSBS should continue with their development and implementation, including the formulation of a CSBS action plan for their introduction.

Currently the CSBS is undertaking consultation on generic standards, which complement clinical standards and help ensure that care is safe and effective. The two key areas of risk management and risk environment are identified under the standard: *"All patients receive safe and effective care and treatment based on available evidence"*. The new standards on infection control, decontamination of re-usable medical devices and cleaning services should feed into these.

The CSBS should establish a Healthcare Associated Infection Reference Group to ensure that standards are regularly evaluated and revised so they remain relevant and up to date. This group should include representatives from relevant organisations, including:

- Professional bodies and Colleges
- Health Councils
- Voluntary/consumer organisations
- Health Boards and NHS Trusts

The standards should be continuously improved and developed, and if appropriate, extended. One of the greatest challenges is to collect appropriate outcome measures which indicate the effectiveness (or otherwise) of compliance with the standards. Close collaboration with SCIEH on the findings of the forthcoming national HAI surveillance programme will be required. The process of evaluating standards should include input from CNORIS.

A SEHD Working Group (a Sub-Group of the Advisory Group on Infection) is working to develop a system for the surveillance of HAI for NHSScotland. In England there will be a mandatory requirement on NHS Trusts to notify MRSA infections, with results to be published from April 2002. This will be discussed further in Scotland.

SEHD should develop key outcome indicators related to HAI in the national surveillance system planned for NHSScotland. The indicators should measure the effectiveness of progress to reduce the risk of HAI. The full participation of CSBS, SCIEH and Trusts in the development of key outcome indicators is important. Consultation and comparability at a UK level is also important.

6.2.3 Undertaking external review of performance against these standards

The findings from Trusts' submissions of self-assessment against the standards should be collated by CSBS to assess the overall level of performance in NHSScotland and review which specific audit criteria for standards require external verification. This should be done by assessing:

- the level of performance against standards;
- the incidence of healthcare outcomes which risk management processes are required to reduce;
- the level of risk to the public occurring as a result of failure to achieve the standard (the risk matrix should be used for this purpose).

Based on this approach, an appropriate verification mechanism should be employed to review further and validate the measure of performance against each given standard. Given the differences in technical and clinical content within the three different standards, it may be that the verification methodology will be different for each standard. It will be for the CSBS to define these further.

As indicated previously, the assessment against the risk matrix should be used to define the method of external verification. The method of external verification will also be determined in part by a decision on what action is required to ensure compliance with a standard. A range of options for compliance mechanisms is outlined in Table 2. They may be formal or informal.

***Table 2*: Options for External Compliance Mechanisms**

1. **Peer review**– e.g., the CSBS quality accreditation scheme for clinical services
2. **Consumer inspection** – e.g., the current "Virgin" initiative on food, cleaning and other hotel services in English hospitals.
3. **Healthcare industry accreditation** – e.g., the CPA scheme for diagnostic laboratories.
4. **Formal professional review** – e.g., medical colleges' accreditation of training schemes.
5. **Local NHS inspection** – e.g., that undertaken by Health Boards in relation to private nursing homes.
6. **National NHS inspection** – e.g., that proposed for the Regulation of Care Commission for private health and social care.
7. **External formal audit** – e.g., the type undertaken by Audit Scotland.
8. **Statutory inspection** – e.g., that undertaken by local authorities in relation to food safety.
9. **Statutory investigation** – e.g., that undertaken by the Health and Safety Executive.

The CSBS should define the appropriate external verification and compliance mechanism for each of the three standards.

6.2.4 Reporting findings

NHS Trusts should be required to make an annual submission to the CSBS. The submission should take the form of a report on the self-assessment of compliance with risk management standard criteria based on a core dataset.

CSBS should report to Trusts the results of the external verification of their own self-assessment of performance against standards. CSBS should also report back, through the unified NHS Boards to Trusts how their performance compares with other Trusts. Despite the formation of unified NHS Boards, Trusts will remain the statutory employer of staff with responsibility for clinical governance.

Monitoring of risk management is only effective if it can improve the performance of those working to reduce the risk of HAI. There must be local and national feedback loops which ensure the following:

- NHS Trusts should demonstrate local mechanisms to feed back the findings of risk management audits and the external verification of performance against the risk management standards.
- CSBS should feed back to Trusts the findings of external verification of performance against risk management standards in a way which facilitates a positive response. The feedback should prioritise areas of non-compliance and where improvement needs to take place.
- CSBS should provide appropriate feedback to SEHD to facilitate the management of NHSScotland's risks and liabilities.
- NHS Trusts should feed back to the SEHD, information on levels of compliance and the costs of ensuring compliance with standards.

For accountability purposes it is essential that performance in this area, as measured against the relevant standards, is reported adequately to the Trust Board, the CSBS and SEHD. It is recognised that Trusts will not be able to demonstrate full compliance with the HAI risk management standards in the first instance. As indicated in Chapter 4, NHS Trusts should be expected in their annual reports to produce a statement of their self-assessed performance against standards and the steps they are taking to remedy any deficiencies. The assurance statement should be based on their return to CSBS.

CSBS should publish an annual report covering the risk management of HAI, which will include the results of the verification of Trusts' self-assessment against standards, in line with their current practice on national reporting. CSBS should alert NHS Trusts about information put into the public domain about Trust performance against risk management standards, in order to facilitate the handling of relevant communication issues.

In addition, CSBS should develop methods to share information about HAI related risk management good practice. This will also help in the development of national and local education and training in this area.

6.2.5 National accountability

Currently SEHD is developing a performance assessment framework. It is expected that in time the findings of monitoring of compliance with risk management standards (both external and internal) and the HAI key outcome indicators will be incorporated into this framework.

With regard to ensuring that remedial action is taken in response to findings, areas of major concern should be raised by the CSBS with SEHD for use in performance management and accountability review systems and for immediate action where necessary. If a serious problem is identified during external verification, the CSBS should advise the NHS Trust concerned and the SEHD immediately. SEHD needs to specify to the CSBS on the basis of what findings, formal statutory and regulatory bodies will be required to be involved in ensuring compliance with risk management standards. This specification also needs to be agreed by the major regulators of the healthcare industry. This should define what action will be taken in the event of non-compliance with a risk management standard defined as **intolerable** .

6.3 Summary of Recommendations

- CSBS should develop a risk matrix tool for assessing risks related to HAI.
- CSBS should develop a methodology, based on the risk matrix and in consultation with NHSScotland, for setting, evaluating and verifying compliance with HAI risk management standards (i.e., infection control, decontamination of re-usable medical devices and cleaning services).
- CSBS should establish a Healthcare Associated Infection Reference Group to ensure that standards are regularly evaluated and revised.
- SEHD should, jointly with CSBS, SCIEH and NHS Trusts, develop key outcome indicators to measure the effectiveness of progress to reduce the risk of HAI.
- Trusts should submit an annual report to CSBS of the results of self-assessment against the HAI risk management standards (i.e., infection control, decontamination of re-usable medical devices and cleaning services).
- There should be effective feedback, at all levels, to facilitate a positive response to performance as assessed against HAI risk management standards.
- CSBS should produce an annual report covering the risk management of HAI.
- SEHD should include findings from the monitoring of compliance with risk management standards and HAI key outcome indicators when available in the NHSScotland Performance Assessment Framework.
- SEHD should agree with CSBS and regulatory bodies when the latter will become involved in seeking compliance with risk management standards.

Appendix 1: MEMBERSHIP OF THE WORKING GROUP

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Appendix 3: GLOSSARY OF KEY TERMS AND ABBREVIATIONS

GLOSSARY

Adverse event	-	An unfavourable incident or situation, which occurs in a particular place during a particular interval of time.
Aseptic technique		A method of carrying out sterile procedures so that there is the minimum risk of introducing infection.
Assurance statement	-	A written declaration of confidence in an organisation.
Audit	-	The examination or evaluation of a specified quantity or quality.
Bacteraemia	-	When bacteria are present in the bloodstream.
Benchmarking	-	Use of a standard or point of reference for the purpose of comparison, usually in the context of improving performance.
Catheterisation	-	The insertion of a hollow tube (a catheter) into an organ of the body – for example the bladder, either for investigational purposes or to give some form of treatment. Performed under strict sterile conditions.
Cleaning	-	A process which physically removes contamination but does not necessarily destroy microorganisms. The reduction of microbial contamination is not routinely quantified and will depend upon many factors, including the efficiency of the cleaning process and the initial bioburden. Cleaning removes microorganisms and the organic material on which they thrive. It is a necessary pre-requisite of effective disinfection or sterilisation.
Clinical Governance	-	Corporate accountability for clinical performance.
Compliance	-	The degree to which Trusts adhere to risk management standards.
Controls Assurance	-	The system of management of risk which is used in NHS (England) based on best governance practice and Internal Control. It exists to inform NHS (England) boards about significant risks within the organisation for which they are responsible. It is intended to assist staff to identify risks, to help them to determine unacceptable levels of risk, and to decide on where best to direct resources to eliminate or reduce those risks. The use of self-assessment techniques is fundamental to the process in ensuring that objectives are met and risks are properly controlled.
Cost	-	Cost of activities, both direct and indirect, involving any negative impact, including money, time, labour, disruption, goodwill, political and intangible loss.

GLOSSARY – continued

Decontamination	-	A process which removes or destroys contamination and thereby prevents microorganisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Three processes of decontamination are commonly used; cleaning, disinfection and sterilisation.
Disinfection	-	A process used to reduce the number of viable microorganisms but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection may not achieve the same reduction in microbial contamination levels as sterilisation.
Endophthalmitis	-	Inflammation of tissues inside the eye. The inflammation can be caused by, for example, bacteria, fungi, viruses or protozoa. This is a rare complication of any eye surgery.
Hazard	-	A source of potential harm or a situation with a potential to cause loss.
Healthcare associated infection	-	Infection acquired in the hospital or other healthcare setting.
Incidence (of infection)	-	Rate at which new cases occur.
Integrated Care Pathway (ICP)		Locally determined and agreed multidisciplinary practice based on guidelines and evidence, where available, for a specific patient/client group. ICPs form all or part of the clinical record, document the care given and facilitate the evaluation of outcomes for continuous quality improvement.
Intraocular	-	Within the eye.
Likelihood	-	Used as a qualitative description of probability or frequency.
Loss	-	Any negative consequence, financial or otherwise.
Mandatory (guidance)	-	Compulsory (guidance) but not required by law.
Monitor	-	To check, supervise, observe critically, or record the progress of an activity, action or system on a regular basis in order to identify change.
Performance Assessment Framework	-	The method used within NHSScotland to measure performance of Trusts and Health Boards (NHS Unified Boards) against agreed indicators.
Primary Care	-	NHSScotland healthcare provision outwith hospitals, for example, general medical practitioner and general dental practitioner services.

GLOSSARY – continued

Probability	-	Probability is the chance or likelihood of a specific event or outcome measured by the ratio of specific events or outcomes to the total number of possible events or outcomes. Probabilities may vary in value from 0 (no chance) to 1 (certain). It is sometimes expressed as a percentage.
Risk	-	The chance of something happening that will have an impact upon objectives. It is measured in terms of the severity of the consequence and frequency.
Risk Assessment	-	The process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria.
Risk Management	-	The culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects.
Risk Management Process	-	The systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk.
Risk Reduction	-	A selective application of appropriate techniques and management principles to reduce either likelihood or an occurrence or its consequences, or both.
Self-assessment	-	The honest opinion of the Trusts of their current position in relation to risk management standards.
Stakeholders	-	Those people and organisations who may affect, be affected by or perceive themselves to be affected by a decision or activity.
Standard	-	Required level of quality.
Statutory	-	Required by law.
Sterilisation	-	A process used to render an object free from viable microorganisms including viruses and bacterial spores.
Verification	-	Checking or confirmation of the truth or accuracy of something (e.g., self-assessment).

ABBREVIATIONS

AS/NZS	-	Australian/New Zealand Standard
BSE	-	Bovine Spongiform Encephalopathy
CNORIS	-	Clinical Negligence and Other Risks Indemnity Scheme
CPA	-	Clinical Pathology Accreditation
CSBS	-	Clinical Standards Board for Scotland
DH	-	Department of Health (England)
GDP	-	General Dental Practitioner
GMP	-	General Medical Practitioner
HACCP	-	Hazard Analysis Critical Control Point
HAI	-	Healthcare Associated Infection
HDL	-	Health Department Letter
IC	-	Infection Control Committee
ICD	-	Infection Control Doctor
ICN	-	Infection Control Nurse
ICT	-	Infection Control Team
MEL	-	Management Executive Letter (Health Department)
MRSA	-	Methicillin-resistant *Staphylococcus aureus*
NHS	-	National Health Service
SCIEH	-	Scottish Centre for Infection and Environmental Health
SCOTMEG	-	Scottish Health Management Efficiency Group
SEHD	-	Scottish Executive Health Department
SPC	-	Statistical Process Control
SSI	-	Surgical site infection
TICC	-	Trust Infection Control Committee
UTI	-	Urinary tract infection
vCJD	-	Variant Creutzfeldt Jakob Disease
UK	-	United Kingdom

INFECTION CONTROL

STANDARD

There is a managed environment, which minimises the risk of infection, to patients, staff and visitors.

OVERVIEW

This standard was originally produced by the Controls Assurance Team, NHS Executive (England). It has been reviewed and adapted for Scotland. The standard draws largely on existing guidance. Where the "key source" of a criterion is the Scottish Infection Manual, NHS MEL/HDL or CMO letter, this is cited as "Scottish Executive Health Department".

Prevention and control of infection is part of the overall risk management strategy within the healthcare environment and an integral part of the management of antibiotic resistance. A proportion of healthcare associated infection is preventable

Evidence from the literature pertains mainly to hospital-acquired infection but could be relevant to the primary care setting. Evolving clinical practice presents new challenges in infection prevention and control, which need continual review and assessment.

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CRITERION 1

Board level responsibility for infection control is clearly defined and there are clear lines of accountability for infection control matters throughout the organisation, leading to the board.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

The Chief Executive is responsible for ensuring that effective arrangements for infection control are in place.

Clear lines of accountability throughout the organisation should be established defining the relationships between the Risk Management Committee/Group, Clinical Governance Committee, Infection Control Committee and Infection Control Team.

The following specific arrangements should be in place:

- ❑ The infection control programme is developed with the support of the board and approved by it.
- ❑ The Chief Executive and Risk Management Committee/Group receive the annual report on the infection control programme which is presented to the board.
- ❑ The Chief Executive, or a deputy with authority to make appropriate decisions on the Chief Executive's behalf, works closely with the Infection Control Team.
- ❑ A senior manager (i.e., either a member of the trust board or directly accountable to a member of the Trust board) is designated as having overall responsibility for risk assessment and management processes relating to infection control/decontamination/cleaning services.
- ❑ Senior management support is provided for infection control emergencies out of hours.
- ❑ The Chief Executive and the Risk Management Committee/Group are informed of any serious problems or issues relating to infection control issues.

Examples of verification:

- ➢ Accountability arrangements chart
- ➢ Minutes of Risk Management Committee/Group
- ➢ Board minutes
- ➢ Records of untoward events

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

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CRITERION 2

There is an Infection Control Committee that endorses all infection control policies, procedures, and guidance, provides advice and support on the implementation of policies, and monitors the progress of the annual infection control programme.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

The membership of the Infection Control Committee (ICC) should include:

- ❑ The senior manager responsible for infection control/decontamination/cleaning services.
- ❑ The Infection Control Team (ICT).
- ❑ The Chief Executive or a nominated senior manager with authority to represent him or her.
- ❑ The Consultant in Public Health Medicine (Communicable Diseases and Environmental Health) for the Health Board in which the hospital is situated.
- ❑ A representative of the Occupational Health Service.
- ❑ An Infectious Disease Physician where there is one.
- ❑ Nurse Executive Director or nominated representative(s).
- ❑ Senior clinical medical staff representatives nominated by the Medical Director.
- ❑ Chief Pharmacist or representative.
- ❑ Other identified representatives, from, for example, Sterile Services Department, Estates Department, Facilities Management, etc.
- ❑ Appropriate representatives from other hospitals/areas covered by the ICC.

The structure of the ICC should be appropriate to the organisation. Some organisations have found that smaller, operational ICCs reporting to the main ICC work well. The ICC should have agreed Terms of Reference and Accountability arrangements and should meet at least four a year. Minutes of the ICC should be circulated to all clinical Directors/managers and relevant committees, for example, clinical governance and risk management committee/group. The ICC should provide advice and support to the ICT.

Examples of verification:

- ➢ Terms of reference/Membership/Accountability arrangements
- ➢ Minutes of Infection Control Committee
- ➢ Circulation list for minutes

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

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CRITERION 3

There is an appropriately constituted and functioning Infection Control Team.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

The Infection Control Team (ICT) includes:

- ❑ The infection control doctor(s) (ICD).
- ❑ The infection control nurse(s) (ICN).
- ❑ A consultant medical microbiologist if the ICD is from another speciality.

The ICT should be supported, as appropriate, by adequate secretarial, IT and audit staff.

The responsibilities of each member of the ICT are clearly defined and the contracted sessions per week for the ICD are defined and agreed.

Members of the ICT must have appropriate training in infection control and provide evidence of relevant continuing professional development (CPD).

The ICT liaises with the Trust occupational health department(s) when dealing with:

- ❑ Infection control advice relating to the health and safety of Health Care Workers.
- ❑ Infection control advice relating to the transmission of infection from Health Care Workers to patients, other members of the organisation's staff and visitors.

The ICT should ensure that advice on infection control is available on a 24-hour basis.

The ICT liases with the local Consultant in Public Health Medicine (CD&EH) when dealing with:

- ❑ Outbreaks within the acute and primary care settings.
- ❑ Issues relating to infection within primary care settings.
- ❑ Areas of work requiring the involvement of environmental health officers.

Examples of verification:

- ➢ Infection control policy
- ➢ ICT membership

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

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CRITERION 4

Prevention and control of infection is considered as part of all service development activity.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

Infection control advice should be provided by the Infection Control Team (ICT), particularly in relation to the following:

- ❑ The development of policies relating to engineering and building services for the Trust and to the purchase of medical devices/equipment.
- ❑ Early stage planning for advice relating to engineering and building works and the purchase of medical devices/equipment.
- ❑ All stages of the contracting process for hotel and other services which have implications for infection control, e.g., cleaning, laundry, clinical waste, catering.

Examples of verification:

- ➢ Planning meeting minutes
- ➢ Reports
- ➢ Policies
- ➢ Procurement specifications

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CRITERION 5

An organisation wide annual infection control programme with clearly defined objectives is produced by the Infection Control Team.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

The ICT should develop and produce an annual infection control programme in full consultation with relevant key stakeholders, including the Infection Control Committee, health professionals and senior managers. The programme should be approved by the board through the relevant Risk Management structure.

Identified priorities arising from the infection control programme should be incorporated within the relevant annual business plan(s).

The programme should be kept under regular review by the ICC and ICT and modified as necessary.

The programme should include reference to audit of the implementation of, and compliance with selected infection control policies.

The annual infection control report should outline the progress of the infection control programme.

Examples of verification:

- Documented programme
- Meeting minutes identifying consultation
- Annual business plan(s)

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 6

Written policies, procedures and guidance for the prevention and control of infection are implemented and reflect relevant legislation and published professional guidance.

INFORMATION

Key Source: Scottish Executive Health Department, Medical Devices Agency, EPIC Project, Health and Safety Executive.

Guidance:

Policies, procedures and guidance should be approved by the ICC. Each directorate, department or service should have a current copy of the approved policies, procedures and guidelines pertinent to its activities.

Key policies should be in place, including:

- ❑ Standard infection control precautions comprising Universal (blood & body fluid) precautions and Body Substance Isolation.
- ❑ Handwashing.
- ❑ Prevention of occupational exposure to blood-borne viruses (BBVs), including prevention of sharps injuries.
- ❑ Management of occupational exposure to BBVs and post exposure prophylaxis.
- ❑ Safe handling and disposal of healthcare waste.
- ❑ Laundry.
- ❑ Outbreaks of communicable infections and ward/hospital closure.
- ❑ Isolation of patients.
- ❑ Use of indewellng urethral catheters.
- ❑ Insertion and maintenance of central venous catheters.
- ❑ Antimicrobial prophylaxis and therapy prescribing.
- ❑ Control of MRSA, VRE and other antimicrobial resistant micro-organisms.
- ❑ Control of tuberculosis, including multi-drug resistant tuberculosis.
- ❑ Single use and single patient use devices and other health care products.
- ❑ Decontamination and reprocessing of re-usable medical devices.
- ❑ Collection, packaging, handling delivery and disposal of laboratory specimens.
- ❑ Occupational health policies for prevention and management of communicable infections in health care workers, including those infected with BBVs.
- ❑ Handling of medical devices in procedures carried out on known/suspect CJD patients and on patients in risk categories for CJD as defined in the ACDP/SEAC guidance (including disposal/quarantining procedures).
- ❑ Control of Viral Haemorrhagic Fevers.
- ❑ Last Offices.

All polices should be clearly marked with a review date.

Examples of verification:

- ➢ Directorate/Dept./Service policy collection

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 7

There is an annual programme for the audit of infection control policies and procedures.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

There should be a written programme for the audit of infection control policies and procedures.

The annual programme should include a timetable stating which key infection control policies, procedures and guidelines are to be reviewed or written that year.

The audit should check that all policies are clearly marked with a review date.

Audit results should be fed back to stakeholders and be included in the Infection Control Annual Report.

Examples of verification:

- Written audit programme

RESPONSE

	YES	NO	N/A
COMPLIANT?			

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CRITERION 8

Timely and effective specialist microbiological support is provided for the infection control service.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

The microbiology laboratory should be CPA accredited and should support the infection control service via processing, data provision, surveillance and specialist testing.

There should be access to and provision for timely specialist microbiology support, including the interpretation of results either on-site, or via reference laboratories

There should be a written procedure for the reporting of results on each test.

The ICT should have appropriate access to laboratory results via an effective computer system.

Microbiology services should be available on a 24-hour basis.

Examples of verification:

- Microbiology laboratory policy
- Standard operating procedures
- Policy on funding infection outbreaks

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 9

Surveillance of infection is carried out using defined methods in accordance with agreed objectives and priorities, which have been specified in the annual infection control programme.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

There should be agreed objectives and priorities for targeted surveillance of infection, developed by the ICT and endorsed by the ICC.

Methods of surveillance should be defined and in place. There should be continuous "alert organism" and "alert condition" surveillance covering the whole organisation to prevent and rapidly detect outbreaks of infection.

Confidentiality for patients and staff should be maintained at all times.

Results of the analysis of surveillance with interpretation and recommendations should be reported to the ICC, clinicians, nurses and others who need to know regularly. Any appropriate action should agreed with the ICT.

Examples of verification:

- Surveillance policy

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CRITERION 10

A comprehensive infection control report is produced by the Infection Control Team on an annual basis, reviewed by the Risk Management Committee/Group and presented to the board.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

The annual infection control report should contain, as a minimum, information on the following:

- ❑ Progress of the infection control programme.
- ❑ A review of reported adverse incidents, including reports by external agencies e.g., environmental health departments.
- ❑ Any recommendations made on measures taken to prevent recurrence of incidents.
- ❑ Surveillance data.
- ❑ Education and training undertaken.
- ❑ Results of audit.

The report should be submitted to the Risk Management Committee/Group for review. The Risk Management Committee/ Group, should present the report to the board via the appropriate channel bringing to the board's attention any significant risks or other issues.

Examples of verification:

- ➢ Documented infection control report
- ➢ Minutes of Risk Management Committee/Group

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 11

The Infection Control Committee and Infection Control Team have access to up-to-date legislation and guidance relevant to infection control.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the Scottish Executive.

As a minimum, the ICC and ICT should have access to the key references listed on the front page of this standard.

Examples of verification:

- Library
- CD-ROMs
- Internet access

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 12

Education in infection control is provided to all health care staff, including those employed in support services where appropriate.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

All staff, including those employed by support services, where appropriate, should receive training in prevention and control of infection.

Infection control should be included in induction programmes for new staff, including support service staff.

There should be a programme of ongoing education for existing staff, including update of policies, feedback of audit results and the action needed to correct deficiencies.

All medical staff should receive training in infection control and antimicrobial prescribing as part of their continuing professional development (CPD).

Records should be kept of attendance of all staff on infection control education programmes.

Examples of verification:

- Documented training programme(s)
- Training logs/records

RESPONSE

	YES	NO	N/A
COMPLIANT?			

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CRITERION 13 – not yet developed

As a key component of clinical governance core indicators capable of evaluating the efficacy and usefulness of the infection control service need to be developed nationally.

INFORMATION

Key Source:

Guidance:

Examples of verification:

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 14

The system in place for control of infection is monitored and reviewed by management and the board in order to make improvements to the system.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

It is the responsibility of the Chief Executive and the board to monitor and review all aspects of the infection control system, including:

- ❑ Accountability arrangements
- ❑ Processes, including risk management arrangements
- ❑ Capability
- ❑ Outcomes
- ❑ Internal audit findings

The Infection Control Committee will review the detailed issues surrounding infection control. Risk Management Committee/Group will play a significant role in monitoring and reviewing all aspects of the system as a basis for establishing significant information that should be presented to, and dealt with by the board. The Clinical Governance Committee may also play a significant role in monitoring and reviewing control of infection as it impacts on the quality of clinical service provision. The Audit Committee should review internal audit findings.

Examples of verification:

- ➢ Internal audit report(s)
- ➢ Audit Committee minutes
- ➢ Infection Control Committee minutes
- ➢ Risk Management Committee minutes
- ➢ Clinical Governance Committee minutes

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CRITERION 15

The Infection Control Committee and Infection Control Team, supported by Internal Audit carries out periodic audits to provide assurances to the board, that a system of infection control which conforms to this standard is in place.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

The ICC and ICT, supported by internal auditors should periodically verify that a suitable and effective system of internal control exists with respect to infection control. The level of independent audit should be based on risk, which will be determined principally by reference to assurances given by the ICC and ICT.

Reports from audits should be presented for consideration to the relevant Trust committee with responsibility for internal audit. They should submit an annual assurance statement on audit findings for consideration and approval by the Trust Board.

The Trust Board should include the assurance statement in its annual report.

Examples of verification:

- Internal Audit report(s)
- Internal Audit statement to Chief Executive
- Audit Committee minutes
- Risk Management Committee/Group minutes
- Clinical Governance Committee minutes

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 16

A clear handwashing policy and mechanism to ensure effective implementation and sustainable process control is in place.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

The Chief Executive is responsible for ensuring that there are effective arrangements to support and promote good levels of hand hygiene by healthcare workers. Compliance with handwashing policy should form part of the systematic risk review by Trusts.

The policy should include the undernoted principles of good practice related to hand hygiene, developed by "The epic Project: Developing National Evidence-based Guidelines for Preventing Healthcare Associated Infections" commissioned by the Department of Health (England).

- ❑ Hand decontamination immediately before and after ever episode of direct patient contact/care or any activity that potentially results in hand contamination.
- ❑ Use of liquid soap and water for hands visibly soiled or potentially contaminated with dirt or organic material.
- ❑ Use of alcohol-based hand rub or handwashing with liquid soap and water to decontaminate hands between different patients or between different caring activities on same patient.
- ❑ Removal of all wrist and ideally hand jewellery at the beginning of each clinical shift before regular hand decontamination begins.
- ❑ Covering all cuts and abrasions with a waterproof dressing.
- ❑ Effective hand-washing technique including:
  - wetting hands under tepid running water before applying liquid soap or antimicrobial preparation;
  - hand wash solution must come into contact with all surfaces of hands;
  - vigorous rubbing of hands for minimum of 10-15 seconds with particular attention to tips of fingers, thumbs and between fingers;
  - thorough rinsing;
  - drying with good quality paper towels.
- ❑ Effective alcohol handrub technique:
  - use only on hands free of dirt and organic material;
  - handrub solution must come into contact with all surfaces of hands;
  - vigorous rubbing of hands, with particular attention to tips of fingers, thumbs and between fingers, until the solution evaporates and hands are dry.
- ❑ Application of an emollient hand cream regularly to protect skin from drying effects of regular hand decontamination.
- ❑ Access to occupational health advice in the event of skin irritation caused by a particular soap, antimicrobial hand wash or alcohol product.

Induction and appraisal programmes for all staff should include the topic of hand washing.

Examples of verification:

- ➢ Hand washing policy document
- ➢ Documented training programme
- ➢ Training logs/records
- ➢ Hand washing facilities audits
- ➢ Hand washing practice audits
- ➢ Hand washing posters, leaflets etc.
- ➢ Hand washing promotional events

RESPONSE

	YES	NO	N/A
COMPLIANT?			

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RECORD OF COMPLIANCE WITH CRITERIA

1. With reference to the completed criterion worksheets tick the Y, N and N/A boxes as appropriate.
2. For **non-compliant** and **non-applicable** responses give summary of reasons from details noted in individual criterion comments sections.

		Compliance Status			Reasons why non-compliant or non-applicable
C	**CATEGORY**	**Yes**	**No**	**N/A**	
1	Accountability arrangements				
2	Infection Control Committee				
3	Infection Control Team				
4	Planning and development				
5	Infection control programme				
6	Policies, procedures and guidance				
7	Policies procedures and guidance				
8	Microbiological services				
9	Surveillance				
10	Infection control report				
11	Legislation and guidance				
12	Education				
13	Key indicators			✓	National indicators still to be developed
14	Monitoring and review				
15	Internal audit				
16	Hand washing				

INSTRUCTIONS FOR ACTION PLANNING

1. Identify the criterion number to which the action relates. Enter the action number and a brief description of the action.
2. Identify a simple priority for the action. This could be high, medium or low, or could relate to timescale for implementation, e.g. immediate action; action within 1 month; etc.
3. Identify any costs associated with the action. Where appropriate, identify both non-recurring (e.g. capital) and recurring (e.g. revenue) costs.
4. Identify the due date for the action and enter the date when the action is complete (Date Comp).

PAGE ___ OF ___

CRIT No.	ACT No.	DESCRIPTION	PRIORITY	RESPONSIBILITY	COST(£)		DUE DATE	DATE COMP
					Recurring	Non-recurring		

DECONTAMINATION OF RE-USABLE MEDICAL DEVICES

STANDARD

There is a system in place that ensures as far as reasonably practicable that all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are adequately managed.

OVERVIEW

This standard was originally produced by the Controls Assurance Team, NHS Executive (England). It has been reviewed and adapted for Scotland.

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

a) is intended by the manufacturer to be used for human beings for the purpose of:

   i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
   iii. investigation, replacement or modification of anatomy or of a physiological process;
   iv. control of conception.

b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means.

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

The decontamination of re-usable medical devices is the combination of processes, which if not correctly undertaken, individually or collectively, may increase the likelihood of micro-organisms being transferred to patients or staff.

The re-usable medical device life cycle comprises the following processes - acquisition, cleaning, disinfection, inspection, packaging, sterilisation, transportation, and storage before use. This cycle is used to render a re-usable item safe for further use.

In this standard, the term *reusable medical device* applies to all such devices whether owned by the organisation, rented, on loan or acquired by any other means.

Re-Usable Medical Device Life Cycle

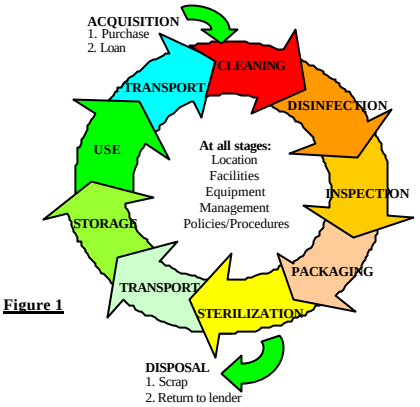

Figure 1

The decontamination process is required to make medical devices:

- Safe for staff members to handle
- Safe for use on the patient

This standard focuses on high and intermediate risk items. The MAC Manual description has been used for the purpose of this standard.

<u>High risk</u>
These items penetrate skin or mucous membrane, enter the vascular system or sterile spaces.

<u>Intermediate risk</u>
These items come into contact with intact mucous membranes or maybe contaminated with particularly virulent or readily transmissible organisms. They require high-level disinfection to remove vegetative bacteria.

<u>Low risk</u>
These items either contact only intact skin or do not come into contact with the patient.

Whilst this standard focuses on the high and intermediate risk devices, it is equally applicable to the lower risk devices, which are frequently decontaminated locally in a clinical unit.

The key references, contained within this standard, demonstrate the wide range of legislation and guidance applicable to the decontamination cycle in order to effectively achieve its objectives. These include, but are not limited to:

- The Health & Safety at Work etc. Act and its regulations, which require employers to assess the risks to their employees.
- The Control of Substances Hazardous to Health Regulations, which provide a framework of actions designed to control the risk from a range of hazardous substances including biological agents.
- EU Council Directive 93/42/EEC concerning medical devices.
- EU Council Directive 99/34/EEC (the Product Liability Directive), which states that a product is defective 'if the safety of the product is not such as persons are generally entitled to expect'. SHTM 2030 suggests that it is likely that civil action could be taken against a hospital for supplying, for example, "disinfected" products that were not in fact disinfected and caused the infection of a patient.

The guidance given in Scottish Health Technical Memoranda (SHTM), Medical Devices Agency (MDA) Device Bulletins (DB) and the CD-ROM issued with MEL(1999)79, has been designed to ensure that the hazards are minimised and that decontamination procedures comply with legislative requirements and good practice.

KEY REFERENCES

1. Health and Safety at Work etc Act (1974).
2. The Management of Health & Safety at Work Regulations 1992.
3. The Control of Substances Hazardous to Health Regulations 1999 (COSHH).
4. Scottish Hospital Planning Note 13 (SHPN 13) 13 Sterile Services Department.
5. Scottish Health Planning Note (SHPN) 13 Sterile Services Department, NHS in Scotland, Edinburgh (1994) HMSO.
6. SHTM 2010. Sterilization.
7. SHTM 2030. Washer-disinfectors.
8. SHTM 2031. Clean steam for sterilization.
9. The Reporting of Injuries, Disease and Dangerous Occurrences 1995 (RIDDOR)
10. NHS MEL(1999)65 Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the risk of transmission.
11. NHS MEL(1999)79 NHS In Scotland Infection Control: Decontamination of Medical Devices. (accompanying CD ROM on Decontamination Guidance).
12. MDA DB 9605 (1996) The Purchase, Operation and Maintenance of Bench Top Sterilisers.
13. MDA DB 9607 (1996) Decontamination of Endoscopes.
14. NHS MEL(1998)47 Advisory Committee on Dangerous Pathogens (ACDP) / Spongiform Encephalopathy Advisory Committee (SEAC),Guidance "Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection.
15. Institute of Sterile Services Management (2000) Standards and Practice. ISSM.
16. MDA DB 2000 (O5) Guidance on the Purchase, Operation and Maintenance of Vacuum Benchtop Steam Sterilisers.
17. MDA DB 9804. The Validation and Periodic Testing of Benchtop Vacuum Steam Sterilisers.
18. MDA DB 2000 (04) Single-use Medical Devices : Implications and Consequences of Re-Use.
19. Sterilisation, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health Medical Devices Agency (MAC Manual).
20. AS/NZS 4360 :1999. Risk Management.
21. NHS MEL(1999)86 Clinical Negligence and Other Risks (Non-clinical) Indemnity Scheme (CNORIS).
22. The Scottish Office Department of Health Advisory Group on Infection (1998) Scottish Infection Manual: Guidance on core standards for the control of infection in hospitals, health care premises and at the community interface.
23. NHS MEL(1993)7 and NHS MEL(1993)86. Hospital Laundry Arrangements for Used and Infected Linen.
24. MDA DB 9801 Medical Device and Equipment Management for Hospital and Community Based Organisations.
25. BS 7320: 1990. Specification for sharps containers.
26. SHTM 2025 Ventilation in healthcare premises.
27. SHTM 2040 The control of legionellae in healthcare premises - a code of practice (1999).
28. Safety Action Notice: Reporting of Adverse Incidents in NHSScotland, SAN(SC)01/01 22JAN2001.

29. EN 980. Graphical Symbols for Medical Devices.
30. Medical Device Directive 93/42/EEC.
31. EN 554 Sterilisation of Medical Devices - Validation and routine control of sterilisation by moist heat.
32. EN 724: 1995 Guidance on the application of BS EN 29001 and BS EN 46001 and of BS EN 29002 and BS EN 46002.
33. EN 46002 Quality systems - Medical Devices - Particular requirements for the application of EN 29002.
34. MDA DB 2000 (02) Medical Devices and Equipment Management and Maintenance Provision.
35. NHS HDL(2001)10 Decontamination of Medical Devices.
36. Statutory Instrument 2000. No 128. The Pressure Systems Safety Regulations 2000 (PSSR).
37. BS55295 Parts 0/1 Environmental Cleanliness in Enclosed Spaces.
38. European Standard EN554 (1994).
39. BS/EN 866 Part 2.
40. NHS HDL(2001)10 Decontamination of Medical Devices.
41. Scottish Executive Working Group Report, Decontamination of Surgical Instruments and Other Medical Devices (2001).
42. Audit Commission (1996) Goods for your health: Improving Supplies Management in NHS Trusts.
43. Sterile Supplies Policy Advisory Group (SSPAG) Decontamination and Disinfection of Equipment (1993) NHS in Scotland Management Executive.

CRITERION 1

Board level responsibility for decontamination of re-usable medical devices is clearly defined and there are clear lines of accountability for decontamination matters throughout the organisation, leading to the board.

INFORMATION

Source: Scottish Executive Health Department

Guidance:

The Chief Executive is responsible for ensuring that there are effective arrangements for the decontamination of medical devices. Arrangements should include a senior manager (i.e., either a member of the Trust Board or directly accountable to a member of the Trust Board) who is designated as having overall responsibility for risk assessment and management processes relating to decontamination of medical devices. He/she will be responsible for receiving and ensuring the circulation of relevant advice and working with SEHD, the Clinical Standards Board for Scotland and other agencies on improving practice – NHS HDL(2001)10.

Clear lines of accountability, for all parts of the decontamination cycle should be established defining the relationships between users and the Risk Management, Clinical Governance, and Infection Control Committees and the Infection Control Team.

An annual report on the efficacy of the decontamination process should be submitted to the Risk Management Committee/Group for review. This committee/group should present the report to the Board.

The scope of responsibility should also consider contractors and professional liability where the organisation either buys in or sells services to other organisations.

Examples of verification:

- Accountability arrangements chart including end users.
- Job plan of designated individual.
- List of senior management contacts for out of hours support.
- Board and committee minutes including action and audit plans.
- Annual report on the quality or efficacy of the decontamination process.
- Appropriate wording in contractual agreements which clearly specifies responsibilities, if an external supplier is used.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 2

Decontamination issues are considered prior to the purchase of re-usable medical devices and decontamination equipment.

INFORMATION

Source: MDA DB9801, MDA DB2000(02) MDA DB9605, MAC Manual, SHTM 2010, SHTM 2030, SHTM 2031, European Standard EN554 (1994), Audit Commission, MDA DB2000(05)

Guidance:

Organisations should have a specialist group to consider and advise on the full implications of procurement and disposal of medical devices and non-medical equipment, where appropriate. Representatives should include:

- ❑ Medical physics.
- ❑ Electro-medical equipment (EME) / Electronic & biomedical equipment (EBME).
- ❑ Risk management.
- ❑ Infection control team.
- ❑ Sterile services department.
- ❑ Estates.
- ❑ Procurement /purchasing.
- ❑ Medical and Nursing Directors.

The group should oversee a wide range of purchasing issues including, where appropriate:

- ❑ Technical specifications*.
- ❑ Ensuring that the medical device manufacturer's decontamination instructions are compatible with the decontamination equipment available and policies in place*.
- ❑ Regulatory compliance information*.
- ❑ Device/equipment evaluation reports.
- ❑ User experience and preferences.
- ❑ Comparing costs and features of alternative devices.
- ❑ Standardising on a single model where possible.
- ❑ Training and maintenance implications.
- ❑ Organisational/departmental policy.
- ❑ Safety Action and Hazard notices issued by Scottish Healthcare Supplies (SHS).

Where appropriate advice on should be sought from the Authorised Person, [AP(S)] and Microbiologist (sterilisers). There should be minimum reliance on a purchase questionnaire.

* A number of documents provide information on the technical requirements that should be addressed prior to purchase of specific items of equipment.

- SHTM 2010 provides details of information to be obtained from manufacturers prior to purchasing new sterilisers, and similarly SHTM 2030 for washer disinfectors.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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INFORMATION continued……

- The MAC Manual provides generic advice on the decontamination information that users should expect to receive from manufacturers of CE marked re-usable devices.
- MDA DB9605 and MDA DB2000(05) provide advice on the purchase of benchtop sterilisers.

Examples of verification:

- A composition and terms of reference document.
- Group minutes and action plans.
- Purchase considerations include a risk and impact analysis.
- Cost life cycle details with defined disposal dates.

COMMENTS continued……

CRITERION 3

All surgical instrument sets are tracked through each decontamination process from acquisition to disposal.

INFORMATION

Source: Scottish Executive Health Department, MAC Manual, SHTM 2010, SHTM 2031, Medical Devices Directive 93/42/EEC, ISSM 2000.

Guidance:

It is important that systems are in place to allow surgical sets of instruments to be tracked through decontamination processes in order to ensure that all aspects of the process, from acquisition to disposal, have been carried out effectively.

Examples of verification:

- Review of documentation
- Physical verification

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 4

The use of all surgical instrument sets on individual patients can be traced to the appropriate patient.

INFORMATION

Source: Scottish Executive Health Department, MAC Manual, SHTM 2010, SHTM 2031, Medical Devices Directive 93/42/EEC, ISSM 2000.

Guidance:

Systems should be implemented to enable the identification of patients on whom instrument sets have been used. This is important so that relevant patients can be identified in the event of exposure to a potential risk, and is relevant to both the primary and secondary care sectors. This requirement for traceability of instrument sets is in addition to the measures for identification and tracing of flexible endoscopes set out in MEL(1999)65.

Examples of verification:

- Review of documentation
- Physical verification

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 5

All contaminated re-usable medical devices are handled, collected and transported to the decontamination area in a manner that avoids the risk of contamination to patients, staff and any area of the healthcare facility.

INFORMATION

Source: Institute of Sterile Services Management, BS 7320, MEL(1993)7 & 86, MAC Manual.

Guidance:

The incorrect handling, collection, and transportation of medical devices may negate any decontamination process they are subjected to, and also present a risk to patients and staff.

The Institute of Sterile Service Management recommends the following:

- ❑ Personnel should be trained to handle, collect and transport contaminated medical devices/ equipment and should wear protective clothing in accordance with local safety policies and procedures.
- ❑ Persons aware of the potential infection hazards should separate reusable devices from clinical waste at the point of use.
- ❑ Sharps should be removed and placed into approved containers conforming to BS 7320 at the point of use.
- ❑ Re-usable textiles should be placed in appropriate soiled linen bags and returned to the laundry service (MEL(1993)7 & 86).
- ❑ Contaminated liquids should be placed into leak proof containers for disposal unless facilities exist for the user to empty them into a clinical sluice.
- ❑ Contaminated medical devices should be confined and contained in closed leak-proof plastic bags or containers to avoid spills, the generation of aerosols or contact with staff and environmental surfaces. They should be transported as soon as possible after use to the decontamination area; the contents of the containers should be labelled to facilitate processing.
- ❑ Used equipment should be bagged and transported to the decontamination area in enclosed containers where necessary.
- ❑ Contaminated medical devices and equipment must be kept separate from clean medical devices/equipment during transportation. This is achieved by using separate containers to provide physical barriers between clean and dirty items.
- ❑ Contaminated medical devices / equipment shall only enter the department through the decontamination area.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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INFORMATION continued……

Examples of verification:

- Documented policies and procedures.
- Risk Assessments.
- Control of Infection monitoring and audit reports.
- Training Records.
- Transport and traceability records.
- Instruction for the use of devices or equipment.
- Device/equipment and use schedules e.g. are there enough devices to meet the requirements of the operating session list – particularly endoscopes.

COMMENTS continued……

CRITERION 6

Cleaning, disinfection, storage and use of flexible or rigid endoscopes is undertaken in accordance with MDA DB 9607, SHTM 2030 and current legislative requirements.

INFORMATION

Source: Scottish Executive Health Department, COSHH, MDA DB 9607, SHTM 2030.

Guidance:

Guidance on all aspects of decontamination of endoscopes is provided in MDA DB 9607. Annexes 1 & 2 provide suggested protocols. Where possible the disinfection of flexible endoscopes should be carried out using automated endoscope reprocessors.

If a local policy decision is that the disinfectant contact time be different from the SEHD guidelines, an automated cleaning process shall be used and the contact time shall not be less than the minimum specified by the disinfectant manufacturer.

Endoscopes should be stored (e.g., over the weekend) suspended vertically in a ventilated storage cabinet to allow circulation of air. They should not be stored in a wet condition because they are likely to become contaminated and in particular may develop biofilms within the internal channels, which are very difficult to remove.

Safe use of glutaraldehyde

- The use of glutaraldehyde is covered by the Control of Substances Hazardous to Health Regulations (COSHH). The Health and Safety Executive has set a Maximum Exposure Limit of 0.05ppm. Although details given below relate to glutaraldehyde, the principles should be followed for the use of any chemical disinfectant. The COSHH regulations require that a risk assessment be carried out.
- Failure to comply with COSHH constitutes an offence and renders the employer liable under the Health & Safety at Work etc Act 1974.

Control Measures for Use of Glutaraldehyde

Exposure to glutaraldehyde can be reduced if alternative processes such as moist heat sterilisation of autoclavable accessories are used.

Safe working practices should be adopted which include the following:

- Disinfection should be carried out away from other staff and members of the general public in a dedicated room with a sink, running water and a suitable vapour extraction system.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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- ❑ Nitrile gloves, impermeable plastic aprons, eye protection and respiratory protective equipment should be used when mixing glutaraldehyde or dealing with spillages.
- ❑ The levels of atmospheric glutaraldehyde should be monitored, at a frequency determined by local policy, to indicate the effectiveness of control measures. A competent person designated by management only should carry out atmospheric monitoring and records and reviews kept of the results.
- ❑ Staff who may be exposed to glutaraldehyde should receive regular health surveillance. If surveillance demonstrates the occurrence of occupational dermatitis or asthma, further exposure must be avoided. Staff should be encouraged to report any health problems to their line manager.
- ❑ All staff who may be exposed to glutaraldehyde must be informed of the risks involved and trained in the use of the control measures.
- ❑ Safe working procedures should be available in written form and distributed to all staff involved. The procedures should include instructions for the use of control measures and spillage procedures.
- ❑ Staff should not be authorised to use glutaraldehyde until they have completed training (MDA 9607).

Examples of verification:

- ➢ Documented procedure for the cleaning, disinfection and sterilisation of endoscopes and re-usable accessories.
- ➢ Documented disinfectant, concentration, contact time, maximum number of uses, shelf life or made-up disinfectant and method of safe disposal.
- ➢ Type of disinfectant utilised.
- ➢ Evidence of Risk assessment undertaken to meet COSHH requirements.
- ➢ Physical verification of facilities.
- ➢ Appropriate protective equipment available.
- ➢ Evidence of regular atmospheric monitoring.
- ➢ Records of health surveillance.
- ➢ Training logs and the content of programmes for staff exposed to glutaraldehyde.
- ➢ Documented procedures, which staff are aware of, which related to the use of control measures and spillage procedures.

COMMENTS continued……..

CRITERION 7

All other re-usable medical devices are decontaminated in accordance with legislative and good practice requirements.

INFORMATION

Source: MEL(1999)65, MEL(199)79, SHTM 2010, SHTM 2030, SHTM 2031, ISSM, MDA DB9605, MDA DB9804, MAC Manual, MDA DB2000(04, MDA DB2000(05), BS55295 Parts 0/1 Environmental Cleanliness in Enclosed Spaces, MDD 93/42/EEC Annex V.

Guidance:

Decontamination is the combination of processes, including cleaning, disinfection and/or sterilisation, used to render a re-usable medical device safe for a further episode of use. In order to decontaminate medical devices effectively, all organic debris (e.g. blood, tissue and other body fluids) must be removed from the item prior to disinfection and/or sterilisation. Effective cleaning of medical devices prior to disinfection or sterilisation is of the utmost importance in reducing the risk of transmission of infectious agents. Medical devices intended for single-use only should not be re-processed for re-use.

Policies should exist as a point of reference, and should be available for all personnel involved in any aspect of decontamination.

- ❑ All stages of the decontamination process should be clearly defined, documented and controlled.
- ❑ There should be a regular review of all procedures and any changes documented.
- ❑ Processing data should be retained.

Devices should be cleaned in accordance with manufacturer instructions. Cleaning can be separated into mechanical processes, using an automated washer-disinfector or ultrasonic and manual processes.

Automated mechanical cleaning provides an efficient, reproducible process whose effectiveness can be verified. It is more consistent and more easily controlled, than manual methods.

<u>Automated washer-disinfectors</u>

- ❑ Mechanical washer-disinfectors should be specified, in accordance with BS 2745 and commissioned and monitored in accordance with SHTM2030, “Washer-disinfectors”, which provides the necessary guidance.
- ❑ Sterile water is recommended for the final rinsing of all types of endoscope to be used for invasive procedures.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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INFORMATION continued……

Manual cleaning

Non-abrasive implements should be used to prevent damage. Devices with lumens or small holes should be cleaned with designated cleaning brushes of appropriate diameter where manual cleaning is unavoidable.

Particular attention should be paid to the following:

- Where manual cleaning is carried out, it should be undertaken in an appropriate area, which is separate to the sink provided for hand washing and segregated from the patient area.
- Staff are to be trained in manual washing techniques.
- Staff are to be immunised against hepatitis B.
- Appropriate personal protective equipment is to be issued.
- There are to be procedures for monitoring the adequacy of cleaning and rinsing.
- Manual washing procedures are to be recorded.
- Detergents are to be used in accordance with Material Safety Data Sheets (MSDS).

Unless the item to be sterilised is known to be damaged by the application of heat or moisture, then moist heat sterilisation using steam under pressure should always be used in preference to other methods since it is more reliable and can be monitored effectively.

Sterilisers

Particular attention should be paid to the following areas:

- Validation and management of sterilisation equipment using SHTM 2010.
- Monitoring of the steam supply of porous load sterilisers using SHTM 2031.
- Frequent periodic review of the effectiveness of benchtop steam sterilisers against relevant guidance to be undertaken.
- Ensuring benchtop sterilisers are fitted with independent process monitoring or recording equipment.
- Ensuring ethylene oxide steriliser installations meet HBN 13 Supplement 1.

Benchtop Steam Sterilisers

MDA DB 9605 and SHTM 2010 provide detailed guidance on the use and testing of benchtop sterilisers. In particular, organisations should ensure that the following are **not** sterilised using a traditional benchtop steriliser:

- Single use devices.
- Devices in any form of wrapping (including pouches).
- Equipment with lumens or cavities.
- Porous loads.

Benchtop sterilisers should only be used to sterilise loads for immediate use.

Benchtop Vacuum Steam Sterilisers

MDA DB 9804 provides detailed guidance on the testing of vacuum benchtop steam sterilisers.

COMMENTS continued……

INFORMATION continued……

Examples of verification:

- Physical verification that single use devices are not being re-used.
- Policy defining all stages of the decontamination process, that is readily available to staff.

Benchtop Sterilisers

- Documented reviews of all small electrically heated benchtop sterilisers for effectiveness and suitability for use.

Porous Load Sterilisers

- Documented evidence of monitoring of the steam supply for porous load sterilisers.
- Documented evidence that porous load sterilisers are assessed against process monitoring requirements.

COMMENTS continued……

CRITERION 8

Decontamination equipment is subject to validation, calibration, monitoring and maintenance by appropriately qualified persons.

INFORMATION

Source: HBN 13, Supplement 1, SHTM 2010, SHTM 2030, SHTM 2031, MDA 9605, MDA DB 9804, MDA DB2000(05), BS3970 Part 4, EN1422 Ethylene Oxide Sterilisers (Specifications).

Guidance:

Planned maintenance is an essential part of the decontamination process. Equipment (washer-disinfectors, sterilisers etc.) to be used in validated processes requires planned preventative maintenance and periodic calibration and testing to ensure it remains in the same condition as when validated. Validated processes require monitoring of critical variables of each cycle and this should be independent of any monitoring used to control the decontamination equipment. Processes that require validation should only be carried out using automated equipment to ensure reproducibility.

Failure to maintain the equipment and its systems gives rise to the potential for inadequate decontamination.

SHTM 2010, SHTM 2030, MDA 9605, MDA DB 9804 and MDA 2000 (05) define the minimum standards required to ensure safe operation of the disinfection process.

The key areas are:

Washer-disinfectors
The control protocols described in SHTM 2030 provide the means for ensuring that a washer-disinfector is fit for its intended purpose and is subject to a planned programme of:

- ❑ Tests ensuring that standards of performance and safety are met.
- ❑ Tests to monitor performance.
- ❑ Planned preventative maintenance.

The protocols also ensure that the equipment is operated in accordance with an agreed procedure by staff trained in its use and that the user is designated to exercise certain responsibilities of inspection.

Benchtop Sterilisers
MDA 9605. MDA DB 9804, MDA DB2000(05) and SHTM 2010 provide testing and maintenance requirements for benchtop sterilisers. In particular:

- ❑ The user is responsible for daily testing.
- ❑ Weekly tests and safety checks should be undertaken.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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INFORMATION continued……

- Planned preventative maintenance should be carried out as per the steriliser manufacturer's instructions and HTM 2010.
- The Test Person (Sterilisers) should conduct quarterly and annual tests.
- The records of the above tests should be kept in a logbook (see MDA DB 9605 and DB2000(05)).

Ethylene Oxide Sterilisers

Where ethylene oxide sterilisers are in use, the following is required, as defined in HBN 13 supplement 1.

- The steriliser should be specified, installed, commissioned and processes validated following the guidance in HTM 2010 or other recognised sterilization standards.
- The use of a microbiological system for routine monitoring of the process.
- Since ethylene oxide is toxic and leaves residues, the aeration and degassing during quarantine of the product must be included as part of the validation process.

The guidance in SHTM 2010 should also be followed.

Washer-disinfectors [SHTM 2030]

The washer-disinfector should be validated in accordance with the guidance in HTM2030 and it is strongly recommended that in all cases the User receives professional advice from a microbiologist or an AP(S).

The Pressure Systems Safety Regulations (PSSR)

The PSSR apply to any vessel that contains steam at any pressure. It applies to most, if not all, benchtop steam sterilisers and to other equipment in which steam is generated e.g. some washer-disinfectors. These regulations require a Competent Person (Pressure Vessels) who is not the User (see criteria 14), to be designated to exercise certain responsibilities. These include verifying the suitability of the written scheme of examination and performing the examination in accordance with the written scheme.

Examples of verification:

- Schedules and documentation for installation checks, validation tests and periodic tests.
- Plant history file and a steriliser process log.
- Log of daily and weekly testing for benchtop sterilisers.
- Testing and maintenance is carried out by individuals with the appropriate skills / training (see SHTM 2010 or SHTM 2030).
- Protocol for test failures.
- ICT monitoring and reports given to ICC.

COMMENTS continued……

CRITERION 9

Ethylene oxide sterilisers are operated and used in accordance with legislative and good practice requirements.

INFORMATION

Source: HBN 13, Supplement 1, COSHH,

Guidance:

Ethylene oxide is hazardous. It is toxic, flammable and a wide range of mixtures with air are explosive. It is also classified as a human carcinogen and therefore needs to be handled safely, with necessary precautions taken.

HBN 13, supplement 1 provides details of the requirements for the installation of ethylene oxide sterilisers. This includes, but is not limited to, a number of operational safety requirements defined in paragraph 2.5, which should be present as well as fire precautions stated in paragraph 3.5.

The operational safety requirements specific to positive pressure sterilisers is also described in HBN13 Supplement 1.

Schedule 1 of the Control of Substances Hazardous to Health (COSHH) Regulations lists ethylene oxide as a substance, which is subject to maximum exposure limit for inhalation. These limits are reviewed annually and up-dated by amendments. These limits must be regarded as safe work exposures.

Examples of verification:

- Operational procedures.
- Prominent display of procedures for detailed processes.
- List of authorised persons and safeguards to prevent unauthorised access.
- Physical verification of environment.
- Availability of goggles and respirators for use in an emergency or maintenance.
- Physical verification against requirements in HBN 13, supplement 1.
- Environmental sampling and COSHH test results.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 10

All medical devices, decontamination equipment and surfaces are properly dealt with after use on patients known to have or who are in a risk category for transmissible spongiform encephalopathy agents.

INFORMATION

Source: NHS MEL(1998)47 Transmissible Spongiform Encephalopathy Agents. Safe Working and the Prevention of Infection (ACDP/SEAC), NHS MEL(1999)65 vCJD Minimizing the risk of Transmission.

Guidance:

"Transmissible Spongiform Encephalopathy Agents. Safe Working and the Prevention of Infection" provides guidance to employers on the precautions necessary to minimise the exposure of employees and others to TSE agents from work activities. NHS MEL(1999)65 updates the ACDP/SEAC guidance and states ' it is essential that all existing cleaning and sterilisation procedures operate to the highest standards'.

Detailed guidance can be found on all other aspects within the document "Transmissible Spongiform Encephalopathy Agents. Safe Working and the Prevention of Infection".

Examples of verification:

- Documented procedures.
- Local guidance which reflects national TSE requirements.
- COSHH assessments.
- Training logs.
- Availability and staff awareness of source documents.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 11

All decontamination equipment that does not meet the requirements of current standards and test methods is upgraded or replaced as soon as practicable in accordance with a planned replacement programme and within a set and recorded deadline.

INFORMATION

Source: NHS MEL(1999)79

Guidance:

NHS organizations should develop a programme to upgrade or replace as soon as practicable any decontamination equipment that does not meet the requirements of current standards or is unable to be validated in accordance with extant guidance.

Trusts may need to make significant capital expenditure to bring sterile services departments up to current standards. However, before committing to such expenditure a comprehensive review of services should be undertaken in order to determine the most economical means of providing the necessary service. Consideration of centralised or decentralised services should be part of this comprehensive review.

Examples of verification:

- Risk assessment of decontamination processing.
- Action plan to mitigate identified risks.
- Work plans to mitigate any residual risks.
- ICT monitoring, audit and action reports.
- Decontamination equipment validation results.
- Organisation's Development and Operational Strategy.
- Estates Strategy.
- Documented planned replacement programme.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 12

All medical devices that cannot be easily cleaned are identified and, where practicable, and in a planned programme, replaced with versions that are easier to clean.

INFORMATION

Source: NHS MEL(1999)79, SHHD/DGM(1987)66, MAC Manual

Guidance:

Decontamination equipment will work less effectively on instruments that are difficult to clean and/or in poor condition. Consideration should, therefore, also be given to the condition of medical devices in use. Devices that cannot easily be cleaned should be identified and, where practicable and within a planned programme, replaced with versions that are easier to clean.

For certain complex medical devices, it may be necessary to disassemble the device in accordance with the manufacturer's instructions in order to ensure that all of the surfaces are exposed to the washing process. It is also important that load carriers are loaded into the automated washer-disinfectors so that the maximum cleaning efficacy can be achieved.

Examples of verification:

- Risk assessment of instrument decontamination processing.
- Action plan to mitigate identified risks.
- Work plans to mitigate any residual risks.
- ICT monitoring, audit and action reports.
- Decontamination validation results.
- Organisation's Operational Strategy.
- Documented planned replacement programme.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 13

Every location in which the decontamination of re-usable medical devices is carried out is properly designed, maintained and controlled.

INFORMATION

Source: EN 724, BS 5295 parts 1 to 4, MEL(1999)65 & 79, SHPN 13, SHTM 2025, , SHTM 2030, SHTM 2040, Health & Safety at Work etc Act 1974, COSHH, Institute of Sterile Services Management, Medical Devices Directive (93/42/EEC).

Guidance:

Any area in which the decontamination process takes place should meet the conditions defined in the source documents, including:

- ❑ Being physically separated from all other work areas.
- ❑ Being accessible from a service corridor.
- ❑ Being mechanically ventilated. (HTM 2025/ 2040).
- ❑ Having temperatures being controlled between 18-22°C and relative humidity between 35-60%.
- ❑ Having walls and other surfaces finished with flush junctions, be smooth, non-linting, water resistant and able to withstand frequent cleaning.
- ❑ Having floors sealed with a washable non-slip finish.
- ❑ Having adequate lighting available to permit good working practices.
- ❑ Hand washing and gowning facilities being located in or near to the decontamination area (Institute of Sterile Service Management).

Examples of verification:

- ➢ Physical verification of workflows.
- ➢ Documented procedures for control of personnel in the clean area.
- ➢ Risk assessment of existing facilities.
- ➢ Action plan to mitigate identified risks.
- ➢ Work plans to mitigate any residual risks.
- ➢ ICT monitoring, audit and action reports.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 14

A risk management process is applied to all aspects of decontamination of re-usable medical devices

INFORMATION

Source: AS/NZS 4360:1999, SHTM 2010, SHTM 2030, COSHH, CNORIS

Guidance:

Decontamination risks can be systematically identified using a number of approaches including:
- ❑ Review of incidents.
- ❑ Review of safety notices.
- ❑ Inspections / assessments.
- ❑ Review of audit reports.
- ❑ Workshops for all staff.

The COSHH regulations provide a framework of actions designed to control the risk from a range of hazardous substances including biological agents. Schedule 9 of the COSHH regulations specifically refers to biological agents that include TSE agents.

SHTM 2010 & 2030 draws attention to the hazards which are implicit in the practice of decontamination.

The following risk management elements should be in place:
- ❑ All identified risks should be documented as part of a risk register and systematically assessed and prioritised.
- ❑ Risk treatment plans should be developed and implemented in order of priority and alongside other risk treatments which are necessary to deal with the wider risks faced by the organisation, where appropriate, in order to minimise risk.
- ❑ Risks and the effectiveness of implemented risk treatments should be monitored and reviewed frequently.
- ❑ Senior management and the board should be informed of any significant risks and associated risk management plans.
- ❑ All relevant staff, including those on a fixed contract and other relevant stakeholders should receive information on systems in place to minimise risk to the decontamination process.
- ❑ Where appropriate, staff training should be undertaken.

Examples of verification:

- ➢ Risk register
- ➢ Risk management plans
- ➢ Staff training / information log
- ➢ Correspondence with stakeholders
- ➢ ICT monitoring and reports to ICC

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 15

SSD facilities meet the requirements for the segregation of clean and dirty activities set out in SHPN 13 and ISSM 2000.

INFORMATION

Source: EN 724, SHPN 13, ISSM 2000

Guidance:

To achieve the required standard there must be segregation of soiled returns and clean supply (see SHPN 13 for advice).

There will be separate areas for the following:

- ❑ Reception, sorting and decontamination of reusable medical devices and equipment.
- ❑ Inspection and function testing of decontaminated devices / equipment.
- ❑ Preparation and assembly of packs.
- ❑ Pre-sterilisation holding.
- ❑ Sterilisation.
- ❑ Processed goods storage.
- ❑ Distribution of processed items.
- ❑ Raw materials preparation and storage.
- ❑ Administration and training.
- ❑ Staff changing and rest areas.

All personnel entering and leaving the clean production area must do so through a dedicated entrance / exit and wear appropriate clothing whilst in the area.

All persons requiring entry to the clean production area should:

- ❑ Enter through the dedicated gowning area.
- ❑ Wear head cover and dedicated footwear.
- ❑ Thoroughly wash and dry hands and don a clean, non linting gown.
- ❑ Clean hands prior to entering.
- ❑ Exit through the gowning area where clean room clothing will be removed and discarded into an appropriate facility. The use of clean room clothing outside of the clean area contributes to the risk of contamination and should be prohibited.

SHPN 13 refers to the design of new SSD facilities. Its standards should be compared with those in existing departments as part of the risk assessment and management process. Adoption of the design standards as a principle is encouraged, and action plans to bring existing facilities up to this standard should be part of the organisation's risk reduction plan.

Examples of verification:

- ➢ Physical verification of workflows.
- ➢ Documented procedures for control of personnel in the clean production area.
- ➢ Risk assessment of existing facilities detailing areas at risk from lack of segregation.
- ➢ Action plan to mitigate identified risks.
- ➢ Work plans to mitigate any residual risks.
- ➢ ICT monitoring, audit and action reports.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 16

Appropriately qualified key personnel are in place in accordance with SHTM 2010 and SHTM 2030.

INFORMATION

Source: SHTM 2010 – Sterilisation, SHTM 2030 – Washer disinfectors, HASWA, COSHH.

Guidance:

Key persons and responsibilities (defined in detail in SHTM 2010 and SHTM 2030) are as follows:

- ❑ The Chief Executive is ultimately accountable for the operation of the premises and the decontamination process.
- ❑ The User, as defined in SHTM 2010 and SHTM 2030 is the person designated by management to be responsible for particular elements of the decontamination process. In a hospital the user could be the sterile service manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager. In primary care he /she could be a GP, practice manager, dentist or other health professional.
- ❑ The Competent Person (pressure vessels) is defined as a person or organisation designated by management to exercise certain legal responsibilities (SHTM 2010).
- ❑ The Authorised Person (sterilisers) [AP (S)], and the AP(Washer-disinfectors) [AP(WD)], are defined in SHTM 2010 and 2030, as a person designated by management to provide independent auditing, and advice on decontamination, together with reviews and witness documentation on validation of processes.
- ❑ The Test Person (sterilisers), [TP(S)], is designated by management to carry out validation and periodic testing of sterilisers and similarly the TP(WD) for washer-disinfectors (see SHTM 2010 and SHTM 2030 Washer-disinfectors.
- ❑ The Maintenance Person (sterilisers,) MP(S), and the Maintenance Person (washer-disinfectors) MP(WD), are designated by management to carry out maintenance and, with the appropriate length of experience, periodic testing on sterilisers and washers-disinfectors (see SHTM 2010and SHTM 2030).
- ❑ The Microbiologist (steriliser) is designated by management to be responsible for advising the user on microbiological aspects of decontamination.
- ❑ The Infection Control Doctor is defined as the person designated by management to be responsible for advising the user on all aspects of infection control.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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INFORMATION continued……

- The Independent Advisor is defined in SHTM2030 as a person who may or may not be registered as an AP(S), but can demonstrate to the satisfaction of management previous training and experience appropriate to carry out the designated tasks in respect of WDs as the AP(S) would carry out in respect of sterilisers. AP(S) is a suitable person to carry out the functions of an independent advisor.

Examples of verification:

- Documented named individuals.
- Job descriptions and individuals aware of their responsibilities.
- Evidence of current relevant training/qualifications to fulfil the role.
- Contract with AP (S).

COMMENTS continued……

CRITERION 17

All staff involved in decontamination processes have access to up-to-date legislation and guidance.

INFORMATION

Source: Scottish Executive Health Department, Medical Device Directive 93/42/EEC, ISSM2000, MAC Manual, SHTM 2010, SHTM 2030.

Guidance:

Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the Scottish Executive Health Department.

As a minimum, staff should have access to the key references listed on the front of this standard. All sterile services departments should have accurate and updated documented systems.

There are many sources of information on European and national legislation and decontamination guidance. The CD-ROM issued on decontamination provides information on the main requirements including:

- ❑ Scottish Health technical memoranda (SHTM).
- ❑ Scottish hospital planning (SHPN).
- ❑ Device bulletins.
- ❑ Generic guidance on decontamination.
- ❑ Other guidance including that on transmissible spongiform encephalopathy agents.
- ❑ Quality standards and recommended practices for sterile service departments.

Scottish Executive Health Department guidance can also be accessed on the internet on the Scottish Health on the web (SHOW) website (http://www.show.scot.nhs.uk). Advice and guidance documents are listed on the MDA homepage (http://www.medical-devices.gov.uk). The Health and Safety Executive's website (http://www.hse.gov.uk) contains up-to-date information on legislation and guidance. Full text copies of legislation can be downloaded from (http://www.hmso.gov.uk) which contains information on UK official documents.

Wherever possible, the Controls Assurance website and CD-ROM contains electronic copies of relevant legislation and guidance.

Examples of verification:

- ➢ Staff are aware of, and have access to relevant legislation and guidance.
- ➢ Department procedures comply with legislation and good practice.
- ➢ SSD has an up-to-date library of regulations and standards.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

(If non-compliant or non-applicable - document reasons)

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CRITERION 18

Education and training in relevant aspects of decontamination practice is provided to relevant healthcare staff, including those working in a clinical environment.

INFORMATION

Source: SHTM 2010, SHTM 2030, EN 980, ISSM 2000, MAC Manual, MDA DB 9605, MDA DB 9804, MDA DB 2000(05) DB9607.

Guidance:

Personnel at all levels should have a general knowledge of the principles, design and function of decontamination equipment. They should be trained in those types and models with which they are concerned.

Training should include:

- ❑ Departmental policies, procedures and standard.
- ❑ Infection control.
- ❑ Quality issues in the department.
- ❑ Health and Safety at Work etc Act.
- ❑ COSHH regulations.
- ❑ Accident / incident reporting.
- ❑ Health and Safety issues including chemical and environmental hazards.
- ❑ Lifting and handling techniques.
- ❑ Safe operation of equipment.
- ❑ Personal hygiene and dress codes.
- ❑ Communications within the organisation.
- ❑ Fire hazards and regulations.
- ❑ Awareness of SHTMs and MDA Bulletins and their implementation.

The Institute of Sterile Services Management (ISSM 2000) suggests that SSD personnel should be trained to the following minimum standard:

- ❑ Departmental managers should be members of the Institute of Sterile Services Management.
- ❑ Supervisory staff should be trained to VQ level 3, or equivalent in supervisory management; additionally, supervisors should be accredited by the ISSM technical training programme for this grade.
- ❑ Technicians should be trained to VQ level 3 or equivalent ISSM technician training programme leading to accreditation of skills.
- ❑ Decontamination issues should be included in induction programmes and ongoing education for existing staff, including update of policies, feedback of audit results and the action needed to correct deficiencies.

In particular, the following issues should be addressed in the training of clinical staff:

- ❑ The correct and safe method of washing instruments manually
- ❑ The use of benchtop sterilisers

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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INFORMATION continued……..

- The use of automated washer-disinfectors.
- The use of ultrasonic baths.
- Graphical symbols described in EN 980.

Records should be kept of attendance of all staff who receive training.

Examples of verification:

- Correspondence with stakeholders.
- Documented training programmes.
- Reports to ICC.
- Risk register.
- Risk management plans.
- Staff training / information log.
- Training logs / records.

COMMENTS Continued ……..

CRITERION 19– not yet developed

As a key component of clinical governance core indicators capable of evaluating the efficacy of decontamination provision need to be developed nationally**.**

INFORMATION

Source:

Guidance:

Examples of verification:

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 20

The system in place for decontamination is monitored and reviewed by management and the board in order to make improvements.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

INFORMATION

Source: Scottish Executive Health Department

Guidance:

It is the responsibility of the Chief Executive, the designated senior manager and the board to monitor and review all aspects of decontamination, including:

- ❑ Accountability arrangements.
- ❑ Process, including risk management arrangements.
- ❑ Capability.
- ❑ Outcomes.
- ❑ Internal audit findings.
- ❑ External audit / inspection findings where appropriate.

The designated senior manager will review the detailed issues surrounding decontamination and report/inform the infection control committee.

The Risk Management Committee/Group will play a significant role in monitoring and reviewing all aspects of the system as a basis for establishing significant information that should be presented to, and dealt with by the board.

The Clinical Governance Committee may also play a significant role in monitoring and reviewing decontamination issues as it impacts on the quality of clinical service provision. The Audit Committee should review internal audit findings.

Examples of verification:

- ➢ Internal audit report(s).
- ➢ Audit committee minutes.
- ➢ Infection Control Committee minutes.
- ➢ Risk Management Committee minutes.
- ➢ Clinical Governance Committee minutes.
- ➢ Audit plans, reports and risk mitigation plans.
- ➢ Record of incidents and untoward events together with action taken to mitigate potential risk.

COMMENTS
(If non-compliant or non-applicable - document reasons)

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CRITERION 21

The senior manager with responsibility for decontamination in conjunction with relevant specialists, in consultation with the Infection Control Committee and with the support of internal audit, carries out periodic audits to provide assurances to the board that the decontamination of re-usable medical devices conforms to the requirements of this standard.

INFORMATION

Source: Scottish Office Health Department

Guidance:

Relevant specialists with the support of internal audit, should periodically verify that a system of internal controls exists with respect to decontamination. The level of independent audit should be carried out based on risk, which will be determined principally by reference to assurances given by the senior manager with responsibility for decontamination.

Reports should be presented to the Audit Committee and copied to the Risk Management Committee/Group and other relevant sub-committees (e.g., Clinical Governance Committee).

Examples of verification:

- Audit committee minutes.
- Infection Control Committee minutes.
- Risk Management Committee/Group minutes.
- Clinical Governance Committee minutes.
- Audit plans, reports and risk mitigation plans.
- Record of incidents and untoward events together with action taken to mitigate potential risk.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS
(If non-compliant or non-applicable - document reasons)

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RECORD OF COMPLIANCE WITH CRITERIA

1. With reference to the completed criterion worksheets tick the Y, N and N/A boxes as appropriate.
2. For **non-compliant** and **non-applicable** responses give summary of reasons from details noted in individual criterion comments sections.

		Compliance Status			Reasons why non-compliant or non-applicable
C	**CATEGORY**	**Yes**	**No**	**N/A**	
1	Accountability arrangements				
2	Device/equipment purchase				
3	Surgical instrument traceability				
4	Surgical instrument traceability				
5	Handling, collection and transportation				
6	Endoscopes				
7	Other re-usable devices				
8	Validation, maintenance, etc.				
9	Ethylene oxide sterilisers				
10	Procedures relating to CJD				
11	Replacement of decontamination equipment				
12	Replacement of medical devices				
13	Facilities				
14	Risk management				
15	SSD facilities				
16	Key personnel				
17	Legislation and guidance				
18	Education and training				
19	Key indicators			✓	**National indicators still to be developed**
20	Management system for decontamination				
21	Internal audit				

INSTRUCTIONS FOR ACTION PLANNING

1. Identify the criterion number to which the action relates. Enter the action number and a brief description of the action.
2. Identify a simple priority for the action. This could be high, medium or low, or could relate to timescale for implementation, e.g. immediate action; action within 1 month; etc.
3. Identify any costs associated with the action. Where appropriate, identify both non-recurring (e.g. capital) and recurring (e.g. revenue) costs.
4. Identify the due date for the action and enter the date when the action is complete (Date Comp).

PAGE ___ OF ___

CRIT No.	ACT No.	DESCRIPTION	PRIORITY	RESPONSIBILITY	COST(£)		DUE DATE	DATE COMP
					Recurring	Non-recurring		

CLEANING SERVICES

STANDARD

Healthcare Facilities are managed so as to provide safe, efficient, effective and clean physical environments of care.

OVERVIEW

This standard is based on existing Scottish or United Kingdom statutory, mandatory and best or good practice requirements. Where the "key source" of a criterion is the Scottish Infection Manual, NHS MEL, HDL or CMO letter or "Our National Plan: A plan for Action a plan for health", this is cited as "Scottish Executive Health Department".

The hospital environment must be visibly clean, free from dirt and dust, and acceptable to patients, staff and visitors. Good hospital cleaning and hygiene is an important part of an effective risk management programme and any strategy for the prevention and control of infection. There are also Health and Safety and legal requirements to be met.

There is a large body of clinical evidence, derived from case reports and outbreak investigations, which identifies links between poor environmental hygiene and the transmission of micro-organisms causing hospital acquired infection. The need for attention to cleanliness and hygiene in all their manifestations is at the heart of existing guidance

The 1998 House of Lords Science and Technology Select Committee Report "Resistance to Antibiotics and other Antimicrobial Agents" recommended that "...hospital services should put infection control and basic hygiene where they belong, at the heart of good management and clinical practice, and should redirect resources accordingly". NHS MEL(1999)39 set out action for NHSScotland in response to the report. The letter asked NHS Trusts, LHCCs and Health Boards to "improve infection control services and systems where necessary" and "review and improve as needed, the use of routine hygiene procedures".

Patients rightly expect that their stay in hospital will be as safe and comfortable as possible. High standards of cleanliness are particularly important. This was acknowledged in "Our National Health: A plan for action, a plan for change", a key theme of which was the introduction of national standards. Also, NHS Trusts are expected to have acted on the recommendations of the Accounts Commission report "A Clean Bill of Health".

It is evident, therefore, that a commitment to improving cleanliness in hospitals through setting and monitoring clear national standards, delivered at a local level, is essential.

The importance of hygiene in hospitals in the pre-antibiotic era was well established. Now, possibly more than ever, the importance of hygiene in hospitals needs to be re-affirmed and a service reinstated which matches the demands of modern healthcare.

The physical environment is an important factor in the patient care experience. An effective and well-run clean physical environment will help ensure that patients, staff and visitors are safe and comfortable. It is, therefore, essential that organisations publicly state the standards of cleanliness they aim to achieve.

KEY REFERENCES

1. AS/NZS 4360: 1999 Risk Management.
2. Auditor General (2000) *A clean bill of health?* Audit Scotland.
3. Health and Safety at Work etc. Act 1974.
4. The Control of Substances Hazardous to Health Regulations 1999 (COSHH).
5. The Reporting of Injuries, Disease and Dangerous Occurrences 1995 (RIDDOR).
6. House of Lords Select Committee on Science and Technology Report (1998) *Resistance to Antibiotics and Other Antimicrobial Agents*, The Stationery Office.
7. Infection Control Nurses' Association & Association of Domestic Management (2000) *Standards for environmental cleanliness in hospitals.*
8. Institute of Chartered Accountants in England & Wales (1999) *Internal Control: Guidance for Directors on the Combined Code of Practice of Practice on Good Corporate Governance* (The Turnbull Report).
9. Management of Health and Safety at Work Regulations (1999).
10. Scottish Health Management Efficiency Group (1987) *Domestic Services – Part* 1.

11. Scottish Office Department of Health Advisory Group on Infection (1998*) Scottish Infection Manual: Guidance on core standards for the control of infection in hospitals, health care premises and at the community interface.*
12. Standing Medical Advisory Committee Sub-Committee on Antimicrobial Resistance (1998) *The Path of Least Resistance*, Department of Health.
13. NHSScotland, (2000) *Our National Plan: A plan for action, a plan for change,* Scottish Executive.
14. NHS MEL(1998)32 – Management of Support Services in the NHS in Scotland: Quality and Value.
15. NHS MEL(1998)63 – Priorities and Planning Guidance for the NHS in Scotland 1999-20002.
16. NHS MEL(1998)75 – Clinical Governance
17. NHS MEL(1999)39 – Resistance to Antibiotics and other Antimicrobial Agents.
18. NHS MEL(1999)86, Clinical Negligence and Other Risks (Non-clinical) Indemnity Scheme (CNORIS).
19. NHS HDL(2001)10 Decontamination of Medical Devices.

CRITERION 1

Responsibility for cleanliness in healthcare premises is clearly defined at Board level and there are clear lines of accountability throughout the organisation, leading to the board.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

INFORMATION

Key Source: Scottish Executive Health Department, "A clean bill of health?"

Guidance:

Ultimately, the Board and the Chief Executive are responsible for ensuring a safe, effective and clean physical environment of care, in health care facilities.

Every NHS Trust must designate a senior manager (i.e., either a member of the Trust Board or directly accountable to a member of the Trust Board), to have overall responsibility for risk assessment and management processes relating to cleaning services. He/she will be responsible for receiving and ensuring the circulation of relevant advice on these matters and working with SEHD, the Clinical Standards Board for Scotland and other agencies on improving practice (NHS HDL(2001)10).

To demonstrate that there is Board-level commitment and organisational involvement in clean health care physical environments, the organisation should be able to produce a graphical table of organisation that describes how it is organised to provide a safe, clean, and effective physical environment. Such a depiction should visualise the lines of accountability from cleaning staff to line staff to management, and ultimately, to the Board.

Similarly, the important functions of each group represented in the table of organisation (e.g., clinicians, infection control, facilities staff, managers, etc.) should be able to be described in order to demonstrate that there are clear lines of accountability for the work required within cleaning services.

The scope of responsibility should also consider contractors and professional liability where the organisation either buys in or sells services to other organisations.

Examples of verification:

- Accountability arrangement charts.
- Board level responsibilities.
- Summary documents showing the current standard of physical environmental cleanliness, quality & efficacy, audit of cleaning standards, training, contractual arrangements, etc.
- Investigations of potential links between cleanliness of the physical environment and outbreaks of infection.

COMMENTS

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CRITERION 2

A suitably qualified person has been designated to manage the cleanliness of the health care facility.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

INFORMATION

Key Source: Standards for environmental cleanliness in hospitals, "A clean bill of health?"

Guidance:

The Healthcare Cleaning Services Manager is responsible for the second-largest group of staff in any NHS establishment.

For in-house cleaning, the organisation should appoint a healthcare cleaning services manager with appropriate qualifications and experience in all matters relating to cleaning, hygiene, contract management, cost control and budget management. This manager should liaise with the infection control team.

For outsourced cleaning services, it is essential that a director or senior manager oversees cleaning provision to ensure risks to the organisation, staff and, patients are minimised. In some organisations this is handled by the facilities director/manager.

Increasingly management of facets of health care facilities cleanliness requires access to a qualified person to meet mandatory requirements.

An organisation will need to satisfy itself that it can both meet its mandatory requirements and is receiving appropriate advice.

Examples of verification:

- Appointment of qualified healthcare cleaning services manager.
- A detailed personnel specification is recommended to reflect the calibre of person required, and make individuals aware of their responsibilities.
- A career structure in order to recruit and retain staff of an appropriate calibre.
- Evidence of current relevant training/qualifications to fulfil the role.

COMMENTS

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CRITERION 3

The organisation has a Board-approved policy and strategy for the management of cleaning services that meets the requirements of its business plan and service strategy.

INFORMATION

Key Sources: Scottish Executive Health Department, Standards for environmental cleanliness in hospitals, "A clean bill of health?"

Guidance:

Policies and procedures should be in place setting clear departmental objectives and standards, which should be published and readily available. They should be developed by internal review in conjunction with staff, patient groups and other customers.

The policies and procedures should set minimum frequencies, hygiene control mechanisms, audit requirements and control loops, complaint mechanisms, training, staff retention, etc. They will also include relationships with departmental staff, infection control teams, and patients.

The infection control team and domestic services managers should play an integral part in any contracting process.

Risk management is an essential part of the policy and procedures and should be used to determine the frequency and staffing of cleaning services in consultation with the infection control team. An example is where the frequency for cleaning patient areas is daily Monday to Friday but with no service at weekends. Or if due to shortage of staff a reduction of service needs to be considered, which service is prioritised. Formal methods of risk management are strongly recommended.

Examples of verification:

- Valid documented Board approved cleaning policy considering the issues above.
- Up-to-date documented cleaning strategy developed and agreed by the Board and other stakeholders.
- Documentation related to tendering process (e.g., Public Private Partnership).
- A current Service Level Agreement with acceptable timetables for audit, review and refinement.
- Reports to the Infection Control and Risk Management Groups, including investigation reports of outbreaks of infection relating to the environment.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

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CRITERION 4

An up-to-date operational cleaning policy exists and up-to-date operational procedures are in place.

INFORMATION

Key Source: Scottish Executive Health Department, "Clean Bill of Health?" Standards for Environmental Cleanliness.

Guidance:

An up-to-date operational cleaning policy and operational procedures will permit the development of an organisational service framework and business plan, which reflects clinical services strategy linked to the estate strategy, and its ongoing development. The operational policy and strategy is essential to ensure high quality clean health care facilities, which are provided with the right physical environmental cleanliness to facilitate the delivery of desired patient care services.

Domestic services providers and users should work collaboratively and co-operatively, recognising and respecting, their respective contributions to environmental cleanliness.

The policy and procedures provide clear guidance and direction to staff in carrying out specific tasks, some examples would be:

- Good housekeeping.
- Controlling the selection of cleaning products.
- Keeping on-site information about safe use of chemicals and products.
- Storage of cleaning equipment and consumables.
- Training.
- Placing of warning signs.
- Need for "spot cleaning" e.g., - management of blood spillage.
- Cleaning during construction work.
- Equipment and wall washing.
- Isolation room cleaning.
- Terminal cleaning of patient areas.
- Audit of cleaning standards.
- Investigations into potential links between cleanliness and outbreaks of infection.
- Infection control.
- Clinical waste handling and disposal.

In addition, the operational policy will provide guidance to staff in relation to minimum cleaning requirements where specific risks have been identified which can only be controlled by a strategy of timely checking and management, e.g., modifying cleaning frequencies due to staff shortages.

The cleaning priorities and standards for ward-based services should be agreed with the ward manager. These standards should be supervised and monitored jointly. The role of the ward sister in maintaining high standards of cleanliness is acknowledged in "Our National Plan: A plan for action, a plan for change".

Examples of verification:

- Documented policy and procedures.
- Audit reports.
- Cleaning product registers and information guides.
- Reports to the Infection Control Committee and Risk Management Group, including investigation reports of outbreaks of infection relating to the environment.
- Risk registers showing areas where there are high potential risks if cleaning frequencies are reduced.
- Minutes of multidisciplinary group meetings.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

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CRITERION 5

An annual review is undertaken to assess the capability of the Healthcare Cleaning Services Department or Contractor to meet the needs of the organisational and legislative requirements.

INFORMATION

Key Source: Scottish Executive Health Department, "Clean Bill of Health?".

Guidance:

An organisation requires up to date information on the ability of the healthcare cleaning services department or the cleaning contractor to achieve the levels of service specified and their ability to adapt to meet the changing needs of health care. In particular the adherence to statutory, mandatory, or good practice requirements especially in areas such as infection control and hygiene.

Risk can arise from a number of different areas, such as:

- ❑ Statutory non-compliance.
- ❑ Unsuitable, obsolete, or worn out equipment leading to failure of service.
- ❑ Poor investment plans leading to understaffing or inadequate training.
- ❑ Insufficient management or supervisory control.
- ❑ Insufficient participation in quality control.
- ❑ Insufficient identification of hazards which could contribute to "trips, slips or falls".
- ❑ Poor identification of hazardous materials e.g., chemical or cleaning agents.
- ❑ Inappropriate floor coverings e.g., non-slip in wet areas; non-reflective for partially sighted people; suitable carpet for use with walking aids.

The development and upkeep of a database containing all the relevant information will permit informed decision making.

Examples of verification:

- ➢ An annual audit with recommendations has been carried out and submitted to the Board.
- ➢ A gap analysis identifies the shortcomings, and the impact of time, cost, and risk is stated for each issue.
- ➢ Recommendations are prioritised and links to the organisations strategy identified.
- ➢ Database is in place and regularly updated.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

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CRITERION 6

The cleaning plan and associated risk is managed systematically, based on an agreed approach.

INFORMATION

Key Source: Scottish Executive Health Department**,** Standards for Environmental Cleanliness in Hospitals

Guidance:

There are three essential components:

- A complete inventory of the organisation's physical environment and cleaning inventory should be maintained.
- The inventory should be analysed and prioritised on the basis of its risks to the delivery of care, service, and statutory requirements.
- Based on priorities, a realistic cleaning plan is in place and complied with to ensure safe operation of the physical environment and the safety of people.

In order to manage the cleanliness of the physical environment, organisations first have to inventory all the tangible contents of that environment, which form part of the cleaning plan.

Without a complete and up-to-date register of the physical environments to be cleaned, their physical properties, and the types of use to which they are to be subjected, healthcare cleaning services managers or contract managers will be unable to assess and prioritise cleaning schedules, staffing, cleaning products, training, benchmarks, and other cleaning services issues.

Cleaning management is concerned with the whole operational cycle of health care facilities use. It is therefore essential to have a systematic, planned approach to the cleaning management of the physical environment.

Examples of verification:

- Cleaning plan in existence.
- Presence of a physical environment registers and inventory.
- Assessments and prioritisation of risks, cleaning schedules, staffing, cleaning products, training, etc.
- Cost indicators, reliability, quality, and performance data.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

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CRITERION 7

All cleaning management issues are evaluated, considered, and dealt with to achieve optimum customer satisfaction, utilisation and financial control.

INFORMATION

Key Source: Scottish Executive Health Department, "Clean Bill of Health?", Standards for Environmental Cleanliness in Hospitals **.**

Guidance:

In most NHS organisations, cleaning issues are managed through the Facilities function. With matters of physical environmental cleanliness in health care facilities there is increasing pressure to simultaneously meet patient desires and staff needs, while managing the space as a limited organisational resource. Organisations must demonstrate that their cleaning management and planning activities give due attention to achieving customer satisfaction within the context of financial and resource limitations.

The cleaning management of physical environment is highly conducive to measurement because it is quantifiable in terms of square metre, staffing, utilisation, and cost. Many NHSScotland organisations may choose to select this as a performance measurement target.

Patients, staff and visitors should be encouraged to report their perceptions of poor cleaning standards.

Examples of verification:

- Performance indicators demonstrating optimum utilisation, expenditure, and user satisfaction.
- Satisfaction surveys (patients/staff/visitors).
- Response to complaints.
- Documented expenditure analysis related to utilisation and cleaning.

Examples of targets and data collection are defined in " Standards for environmental cleanliness in hospitals".

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

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CRITERION 8

A risk management process is applied to Healthcare Cleaning Services.

INFORMATION

Key Source: Scottish Executive Health Department, AS/NZS 4360: 1999, Turnbull Report,

Guidance:

The risks associated with the management of health care cleaning services can be systematically identified using a number of approaches including:

- ❑ Review of incidents.
- ❑ Review of control of infection audit.
- ❑ Inspections and assessments of services described in this standard.
- ❑ Review of audit reports.
- ❑ Workshops with staff.
- ❑ Consultation with users.

The following risk management elements should be in place:

- ❑ All identified risks should be documented as part of a "risk register" and systematically assessed and prioritised.
- ❑ Risk management plans should be developed, implemented, and prioritised alongside other risk management plans which are necessary to deal with the wider risks faced by the organisation, where appropriate, in order to minimise risk.
- ❑ Risk and the effectiveness of implemented risk management should be monitored and reviewed on a continuous basis.
- ❑ Senior management and the Board should be informed of any significant risks and associated risk management plans.
- ❑ All relevant staff, including those on fixed term contracts, and other relevant stakeholders should receive information on systems in place to minimise risks associated with using the assets described in this standard.
- ❑ Appropriate staff training should be undertaken.

Good records need to be maintained at all times.

Examples of verification:

- ➢ Risk register
- ➢ Risk management plans
- ➢ Audit reports and action plans
- ➢ Staff training/ information log
- ➢ Correspondence and meetings with stakeholders

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

COMMENTS

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CRITERION 9

The organisation has access to up-to-date legislation and guidance relating to Healthcare Cleaning Services.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the Scottish Executive Health Department.

As a minimum, those involved in the management of health care cleaning services should have access to the key references listed on the front page of this standard. There are many sources of information on legislation and cleaning guidance, including books and through subscriptions to specialist information providers.

The Health and Safety Executive's website (http://www.hse.gov.uk) contains up-to-date information on legislation and guidance. Full text copies of all legislation issued from 1 January 1997 can be downloaded from (http://www.official-documents.co.uk) which contains information on UK official documents.

Other Relevant Web Sites:
The Association of Domestic Management
http://www.adom.demon.co.uk/index.htm

Examples of verification:

- Library
- CD-ROMs
- Internet access

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 10

Relevant staff receive training and instruction on the safe operating and cleaning of healthcare facilities.

INFORMATION

Key Source: HSW Act 1974, Scottish Executive Health Department

Guidance:

Due to the diversity of needs in cleaning and operating health care facilities and the requirements of legislation, a structured training programme should be developed and implemented. This criterion covers training for both Healthcare Cleaning Services Managers and for frontline staff.

Some of the drivers of the training needs are:
- ❑ Legislative change
- ❑ Risk assessments
- ❑ New equipment
- ❑ New technology
- ❑ Infection control
- ❑ Approved codes of practice
- ❑ Refresher training

Clear records of all training should be maintained and a regular review of potential changes carried out. A prioritisation system for allocation of training should be implemented related to the key risks faced by the organisation.

Examples of verification:

- ➢ Training programme developed, reviewed and prioritised.
- ➢ Records of individuals' training.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 11

The competency and performance of healthcare facilities cleaning personnel to meet legislative requirements and perform regular duties is evaluated, and acceptable standards are achieved and maintained.

INFORMATION

Key Source: HSW Act 1974

Guidance:

An analysis of the skills and capability needed by the organisation to operate and clean facilities should be carried out and a competency program should be devised to achieve these obligations.

For the organisation to meet the basic requirements of the Health and Safety at Work Act it will be necessary to analyse what skills are required among healthcare cleaning services personnel to safely clean health care facilities. These skills may not necessarily exist in-house but the organisation will need to be able to access appropriate staff to discharge its responsibilities in meeting its service needs.

Examples of verification:

- Skills requirement matrix developed.
- Analysis of skills available within the organisation workforce.
- Arrangements in place to remedy gaps in capability.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 12

Key indicators capable of showing improvements in the management of healthcare facilities cleaning services and/or providing early warning of risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

INFORMATION

Key Source: Scottish Executive Health Department. "Clean Bill of Health?".

Guidance:

An essential component of managing cleaning of health care facilities is performance targets, against which the performance of the service can be monitored and measured. National performance specifications for domestic services will form part of a performance framework for NHSScotland (Our National Plan: A plan for action, a plan for change).

Appropriate performance targets that will measure over time:

- Improvement in the quality of cleaning.
- Improvement in productivity.
- Changes in the revenue cost of cleaning services.
- Improvement in the cleaning frequencies.
- Adherence to contract specification.
- Reduction in staff turnover.

Achieving these targets will not only involve healthcare cleaning service managers and the Board but also require understanding and support from the whole organisation. One approach is to have publicly declared targets and report to all staff within the organisation through:

- In-house newsletters.
- Management cascade briefing meetings.
- Advertisements.
- Staff suggestion schemes.

Commitment of all staff to this process is crucial.

Examples of verification:

- Performance indicators agreed with the Board.
- Targets set and agreed.
- Contract performance and review.
- Monitoring in progress.
- Regular updates to all staff.
- NHSScotland Performance Management framework.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 13

The organisation benchmarks itself against other organisations.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

Meaningful performance indicators are extremely desirable in facilitating improvement and reducing risk. All cleaning departments should be engaged in development and use of key indicators for their own internal performance, but they should also maximise the value of such measures by comparing themselves against like organisations, whether those are other NHS Trusts or others who measure similar processes. These are often referred to as internal and external "statistical" benchmarking.

The term "benchmarking" is often misconstrued as the activity of measurement, when it is actually much more involved than that. Measuring performance is merely the first step in benchmarking. Actual "process" benchmarking involves using the insights provided by meaningful data to identify and partner with "high-performing" organisations or departments with whom there would be mutual benefit derived from collaboration.

Statistical benchmarking is extremely important as a filter for identifying best practice opportunities in healthcare. But the hands-on work of process benchmarking is where organisations will experience the value from a great deal of measurement activity.

Examples of verification:

- Documented analysis of key parameters that could form the basis of benchmarking.
- Documented identification of suitable comparable organisations who excel in cleaning management .
- Documented identification of the key areas to be compared and benchmarked.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 14

The system in place for managing Healthcare Facilities and cleaning services, including risk management arrangements, is monitored and reviewed by management and the board in order to make improvements to the system.

INFORMATION

Key Source: Scottish Executive Health Department,

Guidance:

If management of cleaning services is to be successful, it is essential that a quality control system exist to monitor and review the effectiveness of the service. Adoption of such a system in an organisation implies a pro-active approach concerned with setting standards and continual improvement of service. Development of a system requires the input of a wide range of stakeholders such as, Trusts, patient representative groups, local authorities and others.

Whilst the key requirement is to meet the service needs of the organisation, the impact of external drivers must also be included when considering quality if the system is to achieve maximum benefit. Organisations will need to ensure that they have in place effective processes to evaluate the relative risks, costs and benefits of these impacts.

A quality control/monitoring and review system would include a number of elements:

- ❑ Statement of a quality policy.
- ❑ Outline of objectives and responsibilities.
- ❑ Development of a quality structure including documentation, records and audit.
- ❑ Design and specification of service delivery.
- ❑ System for review, adjustment and corrective action.
- ❑ System for customer assessment.

Examples of verification:

- ➢ Records of meetings with stakeholders.
- ➢ Quality initiatives agreed and commenced.
- ➢ Quality system in place.
- ➢ Objectives set and communicated to stakeholders.

RESPONSE

	YES	NO	N/A
COMPLIANT?	☐	☐	☐

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CRITERION 15

Relevant technical specialists, supported by internal audit carry out periodic audits to provide assurance to the board that a system of managing healthcare facilities cleaning services is in place that conforms to the requirements of this standard.

INFORMATION

Key Source: Scottish Executive Health Department

Guidance:

The managers of cleaning services, together with users and supported by internal audit, should periodically verify that a system of internal control exists with respect of the management of their contract/services. The level of independent audit carried out should be based on risk assessment.

Reports from audits should be presented for consideration to the relevant Trust committee with responsibility for internal audit. They should submit an annual assurance statement on audit findings for consideration and approval by the Trust Board.

Examples of verification:

- Internal Audit report(s).
- Internal Audit statement to Chief Executive.
- Audit Committee minutes.
- Risk Management Committee/Group minutes.
- Infection Control Committee minutes.

RESPONSE

	YES	NO	N/A
COMPLIANT?			

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RECORD OF COMPLIANCE WITH CRITERIA

1. With reference to the completed criterion worksheets tick the Y, N and N/A boxes as appropriate.
2. For **non-compliant** and **non-applicable** responses give summary of reasons from details noted in individual criterion comments sections.

		Compliance Status			Reasons why non-compliant or non-applicable
C	**CATEGORY**	**Yes**	**No**	**N/A**	
1	Accountability arrangements				
2	Cleaning services management				
3	Policy and strategy				
4	Operational policy and procedures				
5	Annual requirement review				
6	Cleaning plans				
7	Clean healthcare environment management				
8	Risk management				
9	Legislation and guidance				
10	Training and instruction				
11	Competency evaluation				
12	Key indicators				
13	Benchmarking				
14	Monitoring and review				
15	Internal audit				

INSTRUCTIONS FOR ACTION PLANNING

1. Identify the criterion number to which the action relates. Enter the action number and a brief description of the action.
2. Identify a simple priority for the action. This could be high, medium or low, or could relate to timescale for implementation, e.g. immediate action; action within 1 month; etc.
3. Identify any costs associated with the action. Where appropriate, identify both non-recurring (e.g. capital) and recurring (e.g. revenue) costs.
4. Identify the due date for the action and enter the date when the action is complete (Date Comp).

PAGE ___ OF ___

CRIT No.	ACT No.	DESCRIPTION	PRIORITY	RESPONSIBILITY	COST(£)		DUE DATE	DATE COMP
					Recurring	Non-recurring		