



# The Decontamination of Surgical Instruments in the NHS in England Update report "A Step Change"

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# Executive summary

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The “Comprehensive Report: A review of the decontamination of surgical instruments in the NHS in England” published in December 2001 provided background information relating to the development and implementation of the Decontamination Programme aimed at improving the quality of surgical instrument reprocessing across the healthcare sectors in England. This report provides an update on progress towards compliance with current best practice guidance and shows, from analysis of data collected from the various stages of the decontamination assessment programme, that between November 2001 and August 2003 a significant “step change” occurred with respect to improvements across all aspects of the decontamination life-cycle.

Effective decontamination of surgical instruments is critical in the management of Healthcare Associated Infection and patient safety. It is essential that practices and processes applied to the reprocessing of surgical instruments are of the highest quality, reflecting modern-day standards.

To establish the level of compliance with existing best practice guidance, a series of assessments of decontamination facilities was undertaken between September 1999 and August 2003 with the aim of:

- reviewing working practices;
- assessing the condition of facilities and equipment; and
- agreeing local action plans to improve standards where necessary.

The information collected during these visits determined the focus for future work and ensured that investment was targeted at the areas of greatest need. During 2002/3, immediate investment was used to:

- replace over 400 major pieces of decontamination equipment;
- purchase additional surgical instruments and tracking systems; and
- upgrade existing central facilities as well as build new ones.

Further support was given to the NHS in the form of expert advice, and this, together with the investment, saw the implementation of local medium- and long-term plans to ensure that acceptable standards in decontamination were being applied to service provision.

To enable continuous improvement and access to services of the highest standard, a “National Decontamination Strategy for Modernising the Provision of Decontamination Services” was launched in July 2003. The strategy is available at [http://www.decontamination.nhsestates.gov.uk/national\\_strategy/index.asp](http://www.decontamination.nhsestates.gov.uk/national_strategy/index.asp).

In addition, a number of ongoing initiatives have been established to provide support to the NHS:

- Modernisation of all NHS Estates’ guidance relating to decontamination including;
  - the revision of existing guidance and the creation of new best practice guidance for the purchase and use of equipment;
  - surgical instrument tracking and management systems;
  - revised design guidance for upgrading and building new decontamination facilities.
- The development of a National Training Scheme that will see over 13,000 staff trained in the principles of decontamination during the next two years.
- The application of a national registration scheme for organisations to demonstrate compliance with the requisite standards. NHS Estates are working with the Healthcare Commission to develop a system to ensure that continuous and sustained improvements are being made.
- The establishment of the Engineering and Science Advisory Committee on the Decontamination of Surgical Instruments including Prion Removal (ESAC-PR), facilitating the application of new research-based decontamination technologies into the hospital setting.

A Failure Mode and Effect Analysis (FMEA) was applied to the datasets collected from the various stages of the decontamination assessments. The results clearly showed that a step change in the compliance with decontamination standards had taken place over a two-year period. This improvement is testimony to all of the hard work and efforts of the wider decontamination community and the enthusiasm and commitment of the staff involved.

Whilst recognising that these developments represent a major improvement, further work is needed to ensure that a sustainable service is provided based on a mixed economy of local and new joint venture decontamination facilities.

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# 1 Introduction – background to the decontamination programme

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In September 1999, following concerns surrounding the theoretical transmission of vCJD, the Department of Health (DH) commissioned a snapshot survey of the decontamination of surgical instruments in a range of NHS hospitals, private and voluntary organisations and general medical and dental practices in England. This was the first of its kind for over 40 years. The survey was to investigate the application of decontamination standards. The survey found instances where decontamination processes fell short of current standards and in some cases, practice was poor. It identified that substantial improvements could be achieved by ensuring effective management of decontamination services, and improvements to staff training and development. However, many of the buildings and equipment used in Sterile Services Departments (SSDs) needed refurbishment or replacement. Analysis of the findings of this initial

survey (contained in the Snapshot Survey report ‘Decontamination Review’) highlighted the need for a comprehensive review of decontamination services across the whole of the NHS.

In October 2000, the National Decontamination Programme was launched and a national review was carried out until November 2001. The main objective was to assist the NHS in England in complying with extant guidance, whilst developing a modern and sustainable service for the future. Recognising that financial support was also required to achieve the required standard, the Government announced in January 2001 that it had allocated £200 million to improve the standard of decontamination in the NHS in England. A two-phase approach was adopted to modernise services.

## 2 Review programme – Phase 1

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Since the initial Snapshot Survey in 1999, a series of reviews have taken place. They consisted of a series of assessment visits to identify the level of support required to provide acceptable decontamination services in all hospitals. Following the initial Snapshot Survey, the comprehensive review included visits to all trusts with SSDs. Second visits were made to some trusts to assist them in developing action plans to raise standards with the effect of making immediate improvements where these were necessary. The results of the initial reviews showed that 109 of the 249 hospital SSDs did not meet acceptable standards. However, by working with trusts to implement urgent action plans, standards were raised, so that by December 2001 all acute hospitals in England had access to decontamination services of an acceptable standard, with the results being published in the Comprehensive Report. Visits continued, initially as a form of quality control, but latterly as a means of providing continuous support to the NHS. Visiting assessors assisted trusts in developing action plans to improve standards and practices further, ensuring that realistic goals were established and achieved within agreed timescales. The further visits etc carried out since December 2001 are depicted in the chronological diagram (Appendix 2).

There have been four main stages to the first phase review programme. Following this, the latest Operational Review stage re-assessed those sites visited during the initial Snapshot Survey. This was to determine the extent of progress made over the last four years and to identify the extent of any future support required. The programme of visits was adapted over time to reflect the changing priorities of the decontamination initiative and the way in which the NHS is organised. A database was created to capture the information collected during the visits, and subsequently analysed to measure the outcome of the programme. A sample of the findings from these visits will be discussed in more detail later.

Stage 1 visits were successful in providing information to allow prioritised investment to be made and to raise standards to acceptable levels. However, not all existing facilities were capable of being upgraded to meet the desired standards, and therefore new buildings need to be constructed in order to achieve a sustainable service for the future.

### 3 The development of the National Strategy – Phase 2

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Phase 2 was initiated to develop and take forward the programme towards a long-term solution for high-quality sustainable services. It builds on the work undertaken so far, namely the assessment visits and improvement programme and the immediate and intermediate funding phases; and puts in place local structures, corporate support, and delivery mechanisms to provide a sustainable improvement in decontamination services. This initial support provided trusts with expert advice and financial investment and has allowed immediate improvements in practices, upgrades to facilities and equipment replacement to take place.

The National Strategy has been developed to give impetus to a programme in which all local health economies in England have access to decontamination services that are both sustainable and conform to recognised standards. National seminars were held in July 2003, attended by over 550 delegates, to launch the strategy and to provide an update to the NHS on decontamination issues. It supports Departmental policy in rationalising and centralising services, concentrating decontamination services in purpose-built, well-maintained and managed units.

## 4 Investment programme

In January 2001, the Department of Health announced £200 million to improve decontamination services in England. An initial two-stage investment programme was developed. Stage 1, immediate investment, which is now complete, involved assessing and approving bids to the value of £96.5 million to support over 100 local schemes. A further £40.5 million has been allocated in support of strategic schemes, with an additional £29 million allocated for the further purchase of surgical instruments. The table below provides a breakdown of current expenditure, including central investment to support the implementation of improved decontamination services in primary care.

Figure 1

| Area of investment  | Immediate investment | Long-term solution for high-quality services |
|---------------------|----------------------|----------------------------------------------|
| Washer-disinfectors | £11.0m               |                                              |
| Sterilizers         | £5.5m                |                                              |
| Instruments         | £50.0m*              | £29.0m                                       |
| Facilities          | £30.0m               |                                              |
| Strategic schemes   |                      | £40.5m                                       |
| Primary care        |                      | £21.0m                                       |
| Dental schools      |                      | £6.0m                                        |
| Totals              | £96.5m               | £96.5m                                       |

**\* This will have triggered matching investment of £50m locally**

Data analysed from the comprehensive review in 2001 showed that 27% of sterilizers were more than 16 years old, with 22% between 11 and 15 years old. The investment in the purchase of new washer-disinfectors and sterilizers, and upgrades to the facilities, has begun to address the service deficiencies identified by the Snapshot Survey. These deficiencies were reinforced in the Health Service Circular 2000/032 'Decontamination of Surgical Instruments'.

The bar chart in Figure 2 shows how the percentage compliance with the highest standards of cleaning and sterilization have improved from the time of the

Snapshot Survey to the Operational Review in August 2003, from 9% to 68% and 58% to 93% respectively. This reflects the amount of investment in replacement decontamination equipment and a heightened awareness of test and maintenance requirements for this type of equipment.

Whilst this indicates that there have been significant improvements in the application of standards for cleaning and sterilization, there are still sites where further improvements are required to achieve a fully compliant status. No sites visited were undertaking decontamination below acceptable standards.

This improvement is reinforced by the graph in Figure 3, which shows compliance to the highest standards for washer-disinfectors and sterilizers across all stages of the decontamination programme review. Here the improvement in compliance across the range is from 41% to 77%. The text boxes describe other events from the decontamination programme which have contributed to improvements in compliance.

Significant investment has been allocated for upgrading decontamination facilities and purchasing additional surgical instruments and tracking systems to facilitate centralisation of instrument processing from clinical areas to SSDs. Investment was allocated towards the purchase of additional instrumentation on a "match funding" basis, where organisations were expected to match central investment with funding from their own capital budgets.

Stage 2, intermediate investment, supported larger strategic schemes which rationalised services between trusts. In line with the NHS Plan, investment has been prioritised to ensure that standards are maintained and continue to improve whilst value for money is achieved.

In support of trusts who wish to implement the National Strategy and who have formed multi-trust partnerships, financial support is being offered to project-manage schemes and to purchase additional surgical instruments, where this is necessary to facilitate off-site decontamination.

Figure 2 Aspect of decontamination: cleaning and sterilization

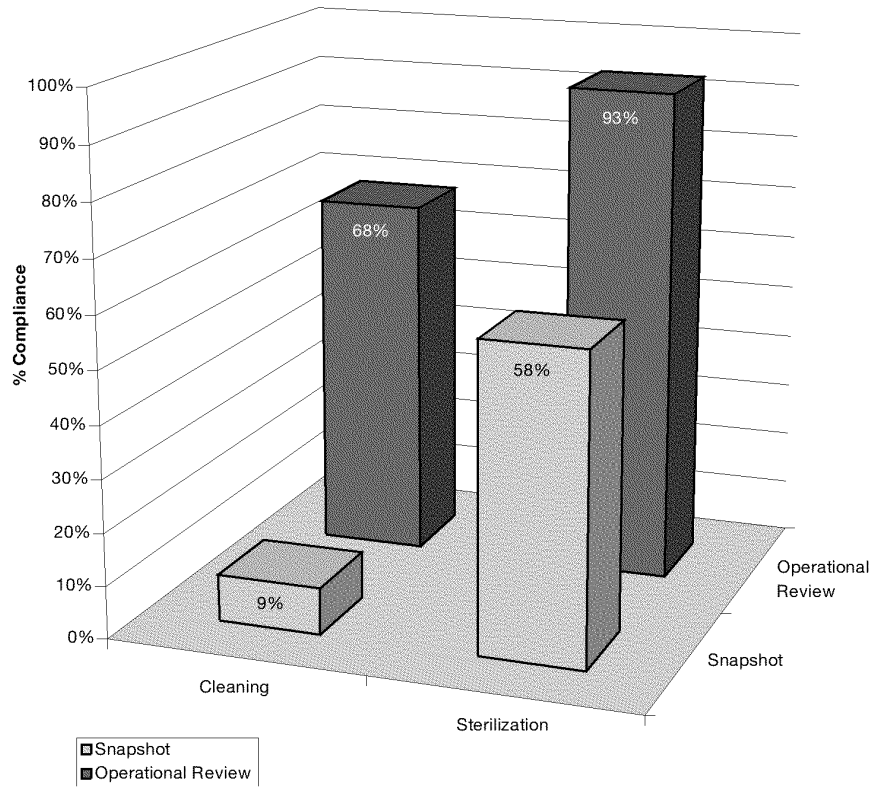
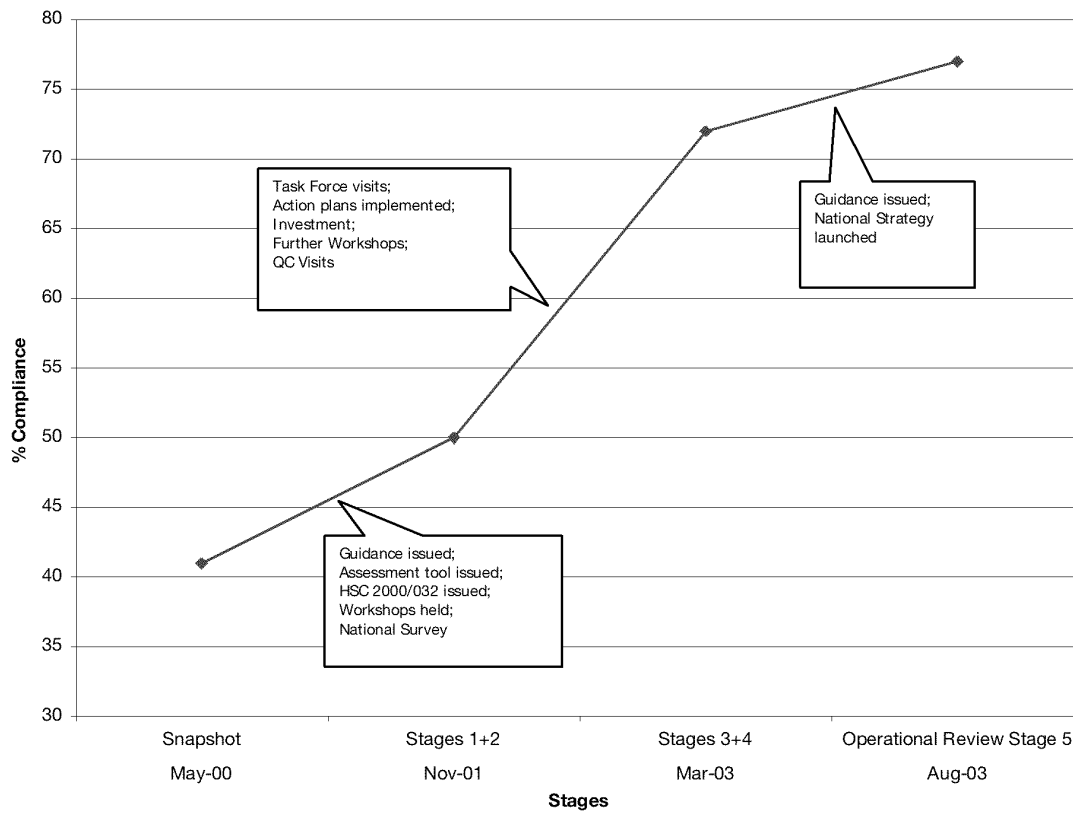


Figure 3 Aspects of decontamination: equipment compliance



## 5 Case studies

To illustrate the effects of the investment programme, two case studies are described below.

### MID YORKSHIRE HOSPITALS NHS TRUST

The merger of Pinderfields and Pontefract Trusts in April 1997 created a single trust operating from two major and three satellite hospital sites. This merger created the opportunity to undertake a thorough strategic review of decontamination provision throughout the new trust in order to increase efficiency, optimise value for money and remove duplication of services.

The Trust provided decontamination services from three Sterile Services Departments at two different hospitals. All three departments had outdated non-compliant decontamination equipment, poor facilities and a lack of spare capacity. A review of the facilities and service provision resulted in the Trust developing a business case to centralise all decontamination services at the Pinderfields Hospital in a purpose-built department.



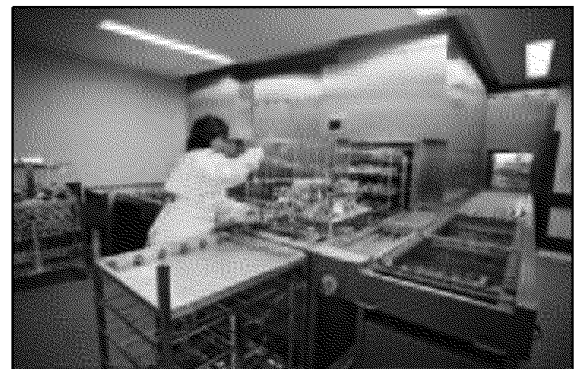
Old Wash Room (above); Old Packing Room (below)



The Trust's business case for immediate investment funding was based on a study of local needs taking into account community and Primary Care Trust requirements for the area. £2,276,415 was allocated to the Trust in support of their business case. Over £1 million was spent on new decontamination equipment, with £300,000 invested in the purchase of additional instrumentation.

In line with the National Strategy for long-term sustainable decontamination services, Mid Yorkshire NHS Trust has rationalised its sterilization services into one technically compliant new facility. The resulting increased capacity has allowed centralisation of decontamination services, minimising the extent of local decontamination practices and procedures.

Since the original bid for funding, the Trust has merged with Dewsbury Healthcare NHS Trust. In addition to taking on reprocessing for Dewsbury, the new decontamination facility at Pinderfields Hospital may in the future develop further collaborative partnerships with neighbouring Trusts.



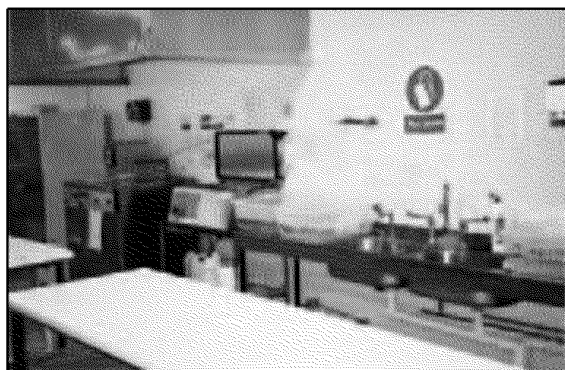
New Wash Room (above); New Packing Room (below)



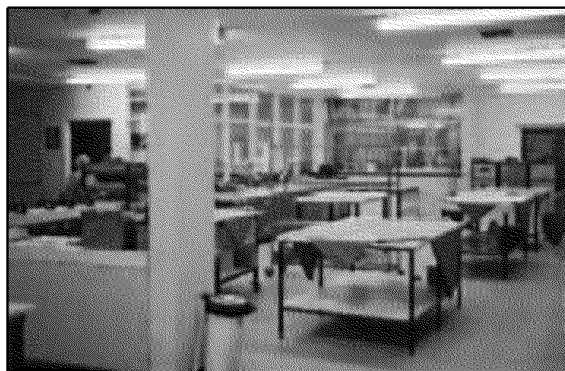
## DARLINGTON MEMORIAL HOSPITAL

County Durham and Darlington Acute NHS Trust comprises Bishop Auckland Hospital and Darlington Memorial Hospital. In early 2000, the Trust rationalised the provision of decontamination services by closing its Sterile Services Department at the Bishop Auckland General Hospital, and transferring its decontamination service to an upgraded unit at Darlington Memorial Hospital.

At the time of NHS Estates' first decontamination visit to the hospital in June 2001, the department was registered to the ISO 9002 quality system standard. However, the open-plan design of the department prevented it from complying with the environmental requirements for segregation of processes to allow registration to the higher standards required by the Medical Devices Directive. Much of the equipment was outdated and in need of replacement. The Trust developed a business case for immediate investment to undertake a major refurbishment of the Darlington SSD, which would enable centralisation of local decontamination from clinical areas.



*Old Wash Room (above); Old Packing Room (below)*

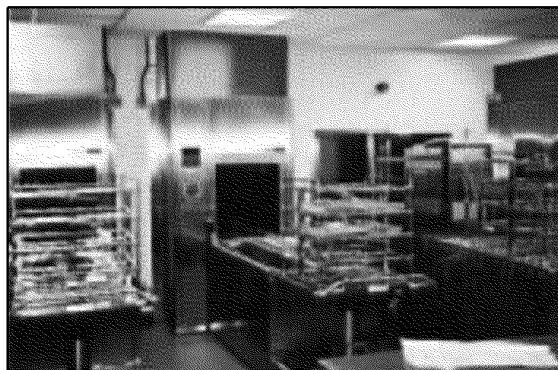


The investment allocation of £1,897,183 allowed the Trust to purchase three washer-disinfectors and four sterilizers, and to undertake a major refurbishment programme of the facilities and manufacturing environment of the unit.

The refurbishment programme, which began in August 2002 and was completed in April 2003, was undertaken in a phased manner, which allowed the department to continue working and ensure minimal disruption to services. The installation of three new pass-through washer-disinfectors and four new pass-through sterilizers contributed towards improving the flow of work between clean and dirty processing. This also enabled the replacement of the old tray system with more modern baskets, which can be used for both the washing and the sterilization of instrument sets. Further improvements were made by combining a laundry folding area with an old storage facility to provide a new washroom, and old management offices were moved to create dedicated changing facilities. A staff training room has also been added to the facility.

In support of centralisation of local decontamination, over £1 million has been spent on the purchase of additional surgical instruments. This allocation was made on a matched funding basis, and £500,000 was allocated centrally with an equal amount contributed by the Trust. A tray tracking system has also been introduced to allow instrument sets to be traced through the decontamination processes (that is, washing and sterilization) and to the patient upon whom they have been used.

A significant amount of instrument reprocessing has been transferred from clinical areas into the Sterile Services Department, and consequently nine bench-



*New Wash Room (above); New Packing Room (below)*



top sterilizers have been decommissioned. The newly-refurbished unit has been constructed with spare capacity to allow for service expansion and additional work to be absorbed, with the Trust continuing to work towards transferring all local reprocessing work from clinical areas into the central unit.

The Trust Chief Executive, Mr John Saxby, said, "We are extremely grateful for the advice and support provided by NHS Estates and consequently with the progress we have been able to make in improving our decontamination services. These improvements represent a major contribution towards infection control within the Trust and improving the patient experience."

## 6 Review programme findings

### METHOD

Statistical analysis has been undertaken to compare the different stages of the review process to determine the effects of the programme over a four-year period between 1999 and 2003.

These stages were:

- Snapshot Survey
- Stage 1 – Central Nervous System/Posterior Ophthalmology (CNS/PO)
- Stage 2 – Comprehensive Review
- QC Visits – Initial Quality Control Programme (18 hospitals)
- Stage 3 – Quality Control
- Stage 4 – Extended Quality Control
- Stage 5 – Operational Review.

Each of the assessment stages identified above focused on the application and adherence to recognised best practice guidance in decontamination. All information from the five stages of the review programme has been stored in a dedicated database. Information from initial stages of the reviews was used to target investment, identifying the trusts who needed to replace equipment, upgrade facilities etc and to create local action plans, which informed future improvement work. As the initiative developed and compliance to certain key areas improved, it was possible to re-focus at each stage of the assessments and target specific areas for

improvement. A comparison of questions between all stages of the review process was made which identified those which were common throughout, and which covered all aspects of the decontamination life-cycle.

After the initial reviews, a systematic evaluation of information was undertaken to identify any major risk issues. This allowed NHS Estates to target specific deficiencies, ensuring that efforts were directed towards the reduction in risk associated with decontamination practices, for example validation of sterilizers and washer-disinfectors.

In addition to a mathematical analysis of the data, a risk analysis has been undertaken to assess the elements of the life-cycle using a “Failure Mode Effect Analysis” (FMEA). Using this method, it has been possible to identify the key elements of the decontamination life-cycle which present the greatest risk.

### ANALYSIS

A sample of 19 trusts covering 29 hospital SSDs was selected for specific analysis as being representative of national trends for comparison between the Snapshot Survey and the Operational Review.

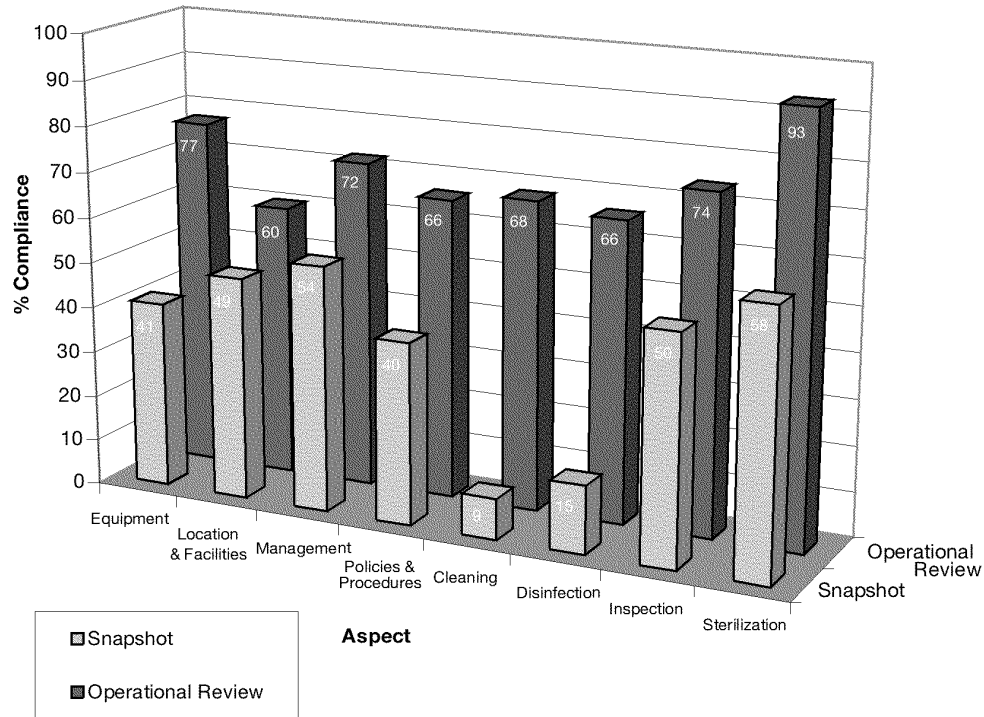
The table below (Figure 4) shows the results of the analysis, which are given as levels of compliance for all major aspects of the decontamination life-cycle across the merged survey stages. These levels of compliance are determined by analysis of the responses of groups of survey questions. Without exception, all aspects show an improvement in compliance between the beginning and the final stage review.

Figure 4 Aggregated data showing compliance for merged review stages

| Stage                      | Equipment    | Location & Facilities | Management    | Policies & Procedures | Cleaning |
|----------------------------|--------------|-----------------------|---------------|-----------------------|----------|
| Snapshot                   | 41%          | 49%                   | 54%           | 40%                   | 9%       |
| Stages 1 + 2               | 50%          | 51%                   | 59%           | 48%                   | 37%      |
| Stages 3 + 4               | 72%          | 57%                   | 66%           | 54%                   | 51%      |
| Operational Review Stage 5 | 77%          | 60%                   | 72%           | 66%                   | 68%      |
| Stage                      | Disinfection | Inspection            | Sterilization | Average               | Median   |
| Snapshot                   | 15%          | 50%                   | 58%           | 42%                   | 45%      |
| Stages 1 + 2               | 37%          | 53%                   | 64%           | 47%                   | 49%      |
| Stages 3 + 4               | 55%          | 65%                   | 83%           | 63%                   | 61%      |
| Operational Review Stage 5 | 66%          | 74%                   | 93%           | 72%                   | 70%      |

The chart below (Figure 5) compares the level of compliance between the Snapshot Survey and the Operational Review stages of the programme.

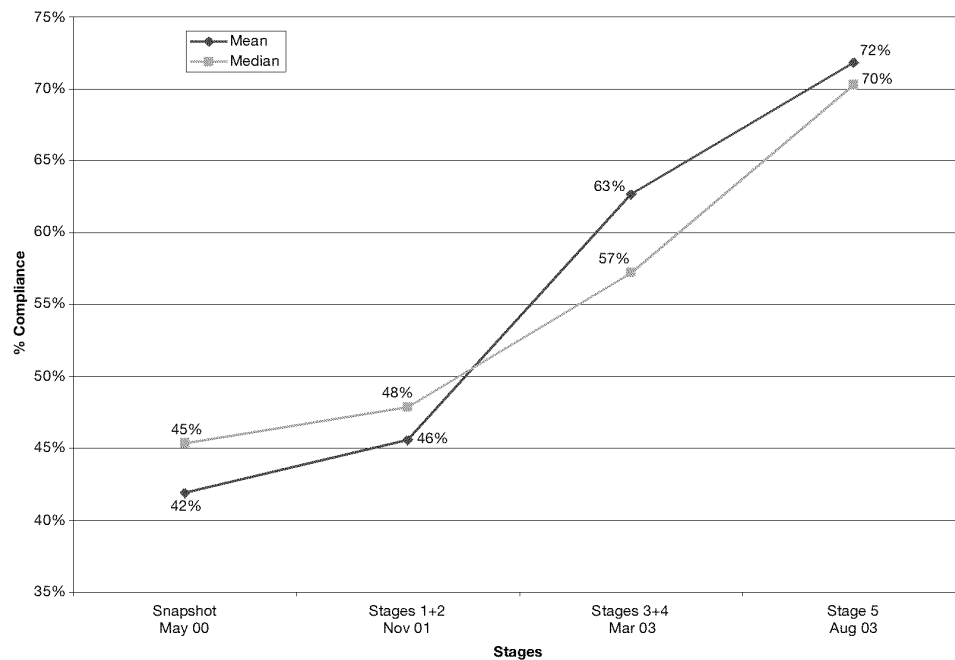
Figure 5 Aspects of decontamination: Snapshot vs Operational Review



The graph below (Figure 6) shows the aggregated data mean and median values, and illustrates the improvements across the four amalgamated stages of the review process. This clearly shows the “step

change” in improvement that occurs from stages 1 and 2 onwards, and shows a continued and sustained improvement up to and including the most recent Operational Review (Stage 5).

Figure 6 Overall decontamination compliance across stages



This improvement can be correlated to key events related to the National Decontamination Programme. For example, between stages 1 and 2 and 3 and 4 demonstrating the greatest rise in compliance, national training seminars were held, investment in the service from the £200 million funding was being allocated, and local action plans from the visit programmes were being implemented.

The link between compliance values and overall findings is provided in the table below:

| Compliance value | Description            |
|------------------|------------------------|
| 0%–20%           | Poor                   |
| 21%–40%          | In need of improvement |
| 41%–60%          | Average                |
| 61%–80%          | Good                   |
| 81%–100%         | Very good              |

The chart (Figure 7) shows the changes in compliance of the 29 SSDs surveyed, between the Snapshot Survey and the Operational Review, for all chosen aspects of the decontamination life-cycle. The overall intention of this study was to show the trend in risk for decontamination across the NHS between the Snapshot and Operational Review exercises. Initial compliance in 1999 shows the majority of SSDs fell into the “in need of improvement” or “average” categories, whereas following the Operational Review there had been a

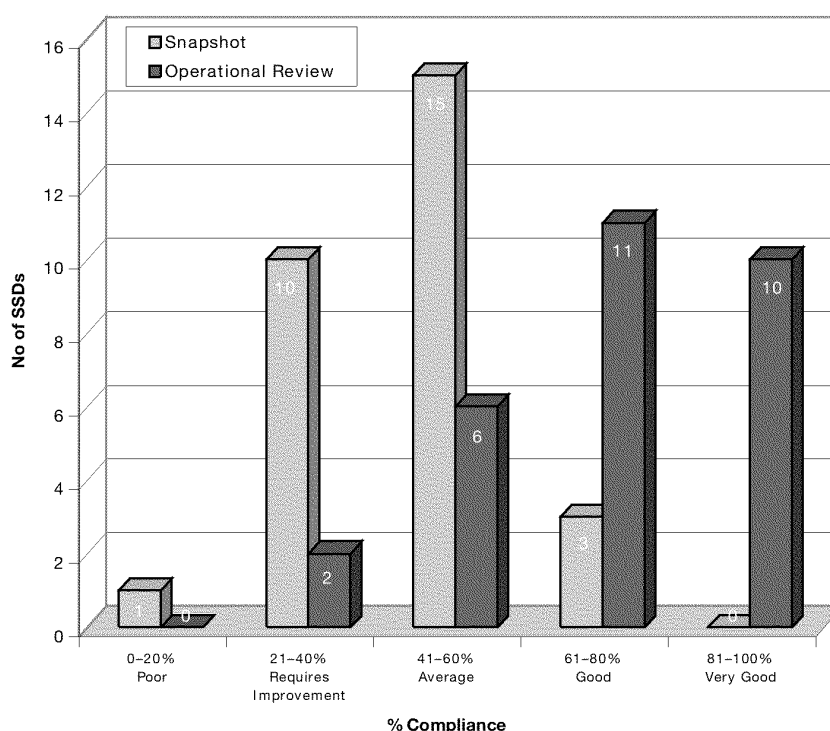
distinct shift in compliance towards the “good” and the “very good” categories. Of the ten SSDs shown in the “very good” category, eight of these fall in the range 80–90%, with the remaining two falling in the range 91–94%.

Whilst these comparisons show a marked improvement over the four-year period, it should be noted that the data analysis has been limited to a range of key questions, related to the decontamination life-cycle, and which are common to all stages of the review process. SSDs that fall into the highest compliance category may still require improvement in order to demonstrate compliance to the standards in the Medical Devices Directive.

## RISK ANALYSIS

In order to determine which activities and elements of the life-cycle should form the basis of any on-site assessments, each stage of the decontamination life-cycle was individually assessed for risk using a Failure Mode Effect Analysis (FMEA) approach. FMEA is a formal methodology for identifying potential failure modes and their associated hazards, and it can be applied to the engineering design of a product or process. In this case, it has been applied to the processes associated with the production of a sterile surgical instrument.

Figure 7 Histogram showing overall compliance of 29 SSDs surveyed in the Snapshot and Operational Review



The key product characteristic against which the processes were assessed for risk was sterility.<sup>†</sup> A risk was perceived to be any aspect of the process which could have a detrimental effect on the attainment and maintenance of sterility under normal circumstances.

Hazards were identified for each stage of the life-cycle and these were in turn assessed for potential causes. The risk was calculated by scoring the potential severity of the outcome of each hazard and assessing this against the likelihood of its occurrence.

A number of hazards had several potential causes, and these were scored separately for each one in order to determine which aspects of the process should be targeted as a priority.

When the likelihood of occurrence was taken into account, the stages of the life-cycle which presented the most significant risks were shown to be as follows:

- Cleaning
- Disinfection
- Inspection
- Sterilization.

These elements therefore formed the focus of subsequent assessments by NHS Estates.

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<sup>†</sup> Sterility in this context is as defined by EN 556 (that is, a SAL of 10<sup>-6</sup>)

## 7 Future work – maintaining the momentum

### GUIDANCE

Understanding the guidance applicable to decontamination is a prerequisite for maintaining competency among staff. Evidence suggested that although guidance had been issued to the NHS it was not reaching the personnel who needed to apply it. To address this issue, NHS Estates has regularly reviewed the technical guidance available to the NHS and has consolidated up-to-date versions on CD-Rom and put these on the NHS Estates website, the latest having been issued at national seminars in July 2003. Approximately 3000 copies of the four editions have been distributed throughout the NHS.

NHS Estates has also developed self-assessment tools for both the acute and primary healthcare sectors to assist organisations in continuously monitoring the application of standards for decontamination.

New guidance written by NHS Estates includes:

- ‘A Guide to Decontamination of Re-usable Surgical Instruments’, a handy A5-sized handbook containing information on the basic principles of decontamination;
- ‘Primary Care Audit Matrix’ (PAM), a self-assessment tool for checking compliance with decontamination standards within primary care;
- Model Engineering Specification C30, which is used to specify the purchase of washer-disinfectors used for decontamination;
- Health Building Note 13 – ‘Sterile services departments’;
- Model Engineering Specification C32, ‘Automated endoscope reproprocessors’.

### NATIONAL TRAINING SCHEME

The national surveys have shown that improving staff training can significantly contribute to the overall improvement in decontamination practices. To address this, a number of national workshops and seminars were held, with approximately 1500 representatives from the acute and primary healthcare sectors receiving training in aspects of decontamination.

During the summer of 2003, NHS Estates chaired a multidisciplinary group with representatives from major professional organisations including the Institute of Sterile Services Management, the Infection Control Nurses Association and the National Association of Theatre Nurses to identify a national training provider through an official procurement process throughout the European community.

Following consultation with the National Health Service University, a National Training Scheme was developed. In September 2003, a training provider was appointed to develop and deliver a blended learning solution to NHS staff commencing in autumn 2004. Central funding was identified to develop and administer the training, which will ensure the availability of training for all those directly involved in decontamination, as well as those requiring an appreciation of the basic principles. This blended e-learning package aims to provide some 13,000 staff over the next two years with best-practice advice and guidance related to the decontamination of surgical instruments. The training package is currently being finalised but has already seen some 1500 staff sign up as registered users, with over 3500 hours of e-learning being undertaken.

### NATIONAL REGISTRATION SCHEME

Approximately 50% of SSDs currently employ a quality system against which their production standards and practices are audited, and some SSDs comply with the Medical Devices Directive. Notified Bodies, who in turn are overseen by the Medicines and Healthcare Products Regulatory Agency (MHRA) for auditing compliance to the Directive, currently monitor these departments. NHS Estates is working with the Healthcare Commission to ensure that momentum is maintained and standards continually improved where necessary.

### RESEARCH AND DEVELOPMENT – DECONTAMINATION OF SURGICAL INSTRUMENTS WITH SPECIAL REFERENCE TO PRIONS

Some Transmissible Spongiform Encephalopathy (TSE) strains, including variant Creutzfeldt-Jakob Disease (vCJD), are relatively resistant to inactivation by conventional decontamination techniques. Many physical and chemical methods used to inactivate

conventional micro-organisms or pathogens show little effect on the infectious agent Prions.

In June 1999, DH commissioned a working group to determine what research was needed to advise the Department on new or modified technologies that could be introduced to ensure that re-usable surgical instruments were free of material containing infectious Prions. Consequently, the first meeting of the Working Group on Research into the Decontamination of Surgical Instruments was held in January 2000 under the Chairmanship of Professor Don Jeffries, when a range of research projects was commissioned. Today, the work of this group is maintained through meetings held every six months, to which all of the research contributors are invited.

The projects were intended to cover a wide range of relevant topics aimed at improving our ability to remove contamination through improved understanding and technologies. The key research areas include:

- studies on the contamination of surgical instruments (in particular stainless steel), including Prion proteins. These studies show that Prions can adhere to stainless steel and remain active in that form. Recently, additional work to examine the possibility of modifying the surface properties to aid removal of contaminating proteins has commenced;
- detection of Prion proteins by a range of techniques, some of which are both reasonably specific and could be developed for use in SSDs;
- investigations centred on the enhancement of essentially conventional decontamination techniques using hot alkali disinfection and modified steam sterilization are in progress, as are studies into their effectiveness;
- assessments of the harmful effects of conventional, modified and novel methods of decontamination on re-usable surgical instruments, including aspects such as instrument life, appearance and usability. These studies are likely to be extended to examine the effects upon the equipment used to carry out the decontamination, for example washer-disinfectors;
- development of new methods of decontamination based on novel technologies including treatment with cold plasmas, exposure to activated ozone and the use of Proteolytic enzymes which break down proteins.

The research is being carried out by a range of distinguished university and public-sector groups as well as by contributors selected from industry. The extent of the progress in many of these areas of research has prompted the need to consider the practical application of alternative techniques to be applied to existing decontamination services in the NHS.

#### **ENGINEERING AND SCIENCE ADVISORY COMMITTEE FOR THE DECONTAMINATION OF SURGICAL INSTRUMENTS INCLUDING PRION REMOVAL (ESAC-PR)**

The Department of Health has invested heavily in a number of decontamination research projects. In order to facilitate the introduction of new guidance and practices within the NHS, an Engineering and Science Advisory Committee has been established, chaired by NHS Estates' Chief Engineer. The new committee is constituted with the express intention of being of value at the interface between the disciplines of engineering and science, promoting necessary actions as identified by new knowledge or understanding. One of its prime functions is the transfer of knowledge from the laboratory bench to the hospital setting.

The committee's work relates entirely to the challenges to public health posed by both existing and new forms of infection, which may be capable of transmission through surgical instruments.

These challenges have been considered at meetings of the Working Group for Research on the Decontamination of Surgical Instruments and meetings of the new ESAC-PR committee itself. The committee structure will provide for efficient working, with a broad multidisciplinary membership drawn from DH, academic and industrial sources. The ESAC-PR will be composed of a principal group with a number of associated Working Parties, which will explore issues such as industry liaisons and training and education. The first meeting of ESAC-PR was held in January 2005.

#### **MODERNISING GUIDANCE GROUP**

NHS Estates is collaborating with a number of organisations, the Medical Royal Colleges, the Association of British Healthcare Industry, and other professional bodies to promote an exchange of information across all aspects of decontamination. The Agency has a major initiative to update all guidance documents relating to decontamination, with the first two, Health Building Note 13 – 'Sterile services department' and Model Engineering Specification C32 for Automated Endoscope Reprocessors, having just been re-issued.

Other guidance documents currently being revised and developed are:

- 'Specification for Surgical Instrument Management (Tracking and Traceability)';
- Model Engineering Specifications for Benchtop Sterilizers (C15) and Washer-Disinfectors (C31);
- a Specification for Validation and Maintenance Services for Decontamination Equipment.

## 8 Conclusion

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Since NHS Estates commenced its National Decontamination Programme in October 2000, a major step change has occurred in the standard of service delivery. Analysis of information collected showed that an initial mean level of compliance over all aspects of decontamination has risen from 45% to 70%, showing that considerable improvements have been achieved.

Whilst the decontamination initiative is in its fourth year, there are still trusts who have yet to complete the implementation of their local long-term action plans. We can therefore be confident that further improvements are imminent.

In order to achieve sustainable high-quality services for the future, it is important that the momentum of the Decontamination Programme be maintained. This can be achieved by continuing the implementation of the National Strategy, further investment support, modernising guidance and by maintaining awareness, through well-managed communications with all levels of staff within the NHS. The Department of Health will continue to facilitate support at trust level whilst the NHS continues to strive for excellence, contributing to controlling Healthcare Associated Infections and patient safety.

# Appendix 1 – References

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**Decontamination Programme Strategy: National Standards for Modernising the Provision of Decontamination Services**, NHS Estates, June 2003.

**Decontamination Review: report on a survey of current decontamination practices in healthcare premises in England**, NHS Estates, December 2001.

**A review of the decontamination of surgical instruments in the NHS in England**, NHS Estates, December 2001.

**Medical Devices Directive 93/42 EEC**, EU Council Directive, 1995.

**HSC 2000/032: Decontamination of Medical Devices**, Department of Health, 2000.

**The NHS Plan**, Cmnd. 4818-1, TSO, 2000.

**A guide to the decontamination of reusable surgical instruments**, NHS Estates, TSO, 2003-12-10.

**Model Engineering Specification C30: Washer-disinfectors for surgical instruments**, NHS Estates, 2001.

**Health Building Note 13: Sterile services department**, NHS Estates, 2004.

**Model Engineering Specification C32: Automated Endoscope Reprocessors for Flexible Endoscopes**, NHS Estates, 2004.

**Specification for Surgical Instrument Management (Tracking & Traceability)**, NHS Estates, currently in development.

**A Model Engineering Specification for Benchtop Sterilizers and Washer-Disinfectors**, NHS Estates, currently in development.

**A Specification for Validation and Maintenance Services for Decontamination Equipment**, NHS Estates, currently in development.

## Appendix 2 – Decontamination programme chronology

