National Decontamination Programme

Theatre Support Pack
Introduction

This support pack was produced by the Department of Health (DH) in collaboration with the Association for Perioperative Practice (AfPP) and the Institute of Decontamination Sciences (IDSc). It aims to provide clinical teams with clear and concise advice on the processes underpinning the transfer of instrument decontamination services as part of the National Decontamination Programme (NDP). The pack may also be of interest to other users of sterile instruments.

Relocation of services from a hospital site can be a cause of concern to clinical teams but, if properly planned, managed and supported, there is every reason to believe this can be a successful way forward in providing effective and safe decontamination services. It is hoped that the information contained in this pack will support clinical teams in identifying and addressing necessary changes in practice and aid the formulation and implementation of local operating procedures.

This pack cannot replace careful planning of service transition and the need for appropriate support from all levels of NHS management to ensure that patient safety remains paramount, the move to off-site services is as seamless as possible and that disruption to normal business is minimised.

Further information on some of the topics covered here can be found in resources published by the NDP, AfPP and IDSc. Links for these bodies can be found on the last page of this pack.

Any words in **bold** have a description in the glossary (Appendix 2).
Background

Decontamination is a combination of processes including cleaning, inspection, and sterilization. Reusable surgical devices, including instruments, require decontamination throughout their life-cycle.

In 2001, the DH completed the first ever comprehensive national survey of decontamination services for surgical instruments in the NHS in England. The results of this survey showed that a number of these services did not meet acceptable standards. The survey followed advice from the Spongiform Encephalopathy Advisory Committee (SEAC) that a key factor in reducing the theoretical risk of person-to-person transmission of variant Creutzfeldt-Jakob Disease (vCJD) is a high standard of decontamination of surgical instruments. It was the Committee's opinion that:

"Effective cleaning and decontamination of surgical instruments is the most important measure to reduce the risk of possible transmission of vCJD, via the use of surgical instruments"

(p21, SEAC Annual Report 2004)
The review highlighted various common deficiencies that needed to be addressed. Key amongst them were:

- Poor levels of staff training, particularly amongst staff undertaking ‘local’ reprocessing in wards and departments
- Poor environmental conditions in many areas
- Lack of evidence that appropriate protocols and procedures were in place and in use
- Old, unsatisfactory and in some cases un-validated equipment (particularly washer-disinfectors) in use

The advice of the DH was that all reprocessing of surgical instruments should be undertaken away from the clinical environment where possible, and preferably in Sterile Services Departments. The DH developed a strategy to counter these deficiencies and this included instigating a long-term procurement strategy – the NDP. The first Trusts started to receive their services from providers secured as part of the NDP in 2007 and to date there are four operational facilities in West Yorkshire, Birmingham and Manchester.

The DH issued a “Code of Practice for the Prevention and Control of Healthcare Associated Infection” in 2006. This code of practice requires the NHS to meet minimum acceptable decontamination standards. Trusts have been assessed on compliance with the Code as part of their annual assessment by the Healthcare Commission since April 2007.

Those Trusts transferring services as part of the NDP have chosen to take the outsourcing route to ensure patient safety and the requirements of the code of practice are met and this offered the most robust effective route for their situation. For example, in some cases, an in-house solution may be unsuitable due to the cost or time required to invest in the plant, equipment, staff and service development.

The procurement of an outsourced service as part of the NDP is managed as a project and uses a recognised system of project management called PRINCE2. It is recommended that the process of services transfer is managed in a similar manner. Further information on PRINCE2 can be found on the Office of Government Commerce Website, details of which are given at the back of this pack.

An overview of the procurement process is given in Appendix 1.
Contractual Arrangements and Key Personnel

The contract between the Customer and the Service Provider (SP) is called the Decontamination Services Agreement or DSA. The overall contract is managed by a Joint Management Board (JMB) consisting of representatives of the SP, the Trusts (including a senior clinical lead) and the Customer Manager. The DSA will specify the order in which the participating Trusts will transfer into the SP facilities.

The key parts of the DSA affecting clinical activity are Schedule 21, which covers the processes and key dates of transferring services (including the Customer Task List, some of which is relevant to clinical teams and referenced in Appendix 3) and Schedule 6 which provides details of the services to be provided e.g. turnaround times and delivery and collection points. Both completed Schedules will be available from the Customer Manager.

One of the lessons learned is that there is merit in having an experienced theatre practitioner seconded to the SP for a period before and immediately following transition to enhance communication and problem-solving and to be a key contact point. All current and future collaborations will be required to adopt this model.

The period between the contract being signed and the service being transferred (Pre-Transition) is a key time for theatres as the DSA will require certain actions to have been completed before the move takes place (key actions and timeframes for completion are detailed in Appendix 3). All members of the team including perioperative staff and surgical teams, should expect to be involved in this stage of the process as it will directly affect the way they work. Each individual site will need to put a mechanism (Local mobilization team) in place to ensure that the detailed planning of the transfer of services is carried out.

It is important that this involves appropriate members of the clinical team and a recognised Theatre Lead (an outline role for the Theatre Lead, following advice of the AfPP is in Appendix 4). Those involved in preparing clinical teams for decontamination services transfer, including the Theatre Lead, will require protected time for this work.

One pre-transition activity that the lessons learned from early transfers has shown to be of vital importance to the successful transfer of services is to ensure the timely completion, agreement and sign-off of tray content lists. The Theatre Lead should coordinate this work, which will be both detailed and time-consuming.
It is essential during the pre-transition stage that all members of the clinical team who are to be involved with the new pattern of service delivery are given access to and time for training provided by the Trust and the SP in new systems and procedures.

Because of the importance of transition as a key milestone in achieving safe and effective decontamination services, the DH provides national support given by Clinical, Human Resource and Technical Advisors, who can be accessed through the Customer Manager. Their role is to support the local teams with advice and recommendations, in addition to disseminating lessons learned from other projects in the NDP.

An Instrument Review Committee (IRC) will be established consisting of key clinical staff, including the users of sterile product, Customer Managers and representatives from the SP. The role of the IRC is to provide operational management of issues concerning instrument usage.

Both the Customers and SP operate under a quality regime known as the Performance Mechanism. This monitors problems during service delivery and ensures that the SP and the Customer take all relevant steps to ensure that deviations from planned performance are addressed and appropriate remedial actions implemented. Users are expected to report non-conformities as part of the Performance Mechanism. The performance mechanism, however, does not replace any local requirements for reporting defects and risks.

During Pre-Transition, the SP will issue a Service Handbook. The Theatre Lead working as part of the project should be a key member of the team liaising with the SP as to what should be contained in the handbook. The handbook is a ‘how to’ manual for the new service and will include a step-by-step guide on topics such as:

- What the turnaround times are
- How to order a fast-track item and costs attached
- How to manage loan equipment
- How to dispatch and receive instrument trays and supplementaries
- The arrangements for changing the contents of sets or adding new instruments
- How to report a non-conformance
- Delivery modes and times
- Reasons for instrument rejection (possibly using photographs)
• An example of the labelling system
• Arrangements for quarantining instruments
• Arrangements for instrument repairs
• Contact details for routine and emergency situations

It is important to note that individual Trusts retain ownership of their own instruments. This ensures traceability and minimises the risk of instrument migration.

The DSA requires the SP to make appropriate arrangements with Customers to ensure an effective response to any major incident, so that they can handle any increased demand for sterile product.

The SP is also required to ensure that they have plans in place to ensure business continuity and that the service will continue to supply its users in case of disruption to their facilities. This requirement will form a key part of the contract between the SP and the Customer.

For the purposes of the DSA, instrument trays and supplementaries are divided into 14 tray categories (Appendix 5) according to the number of instruments in the tray; each category attracts a different reprocessing cost. There will also be a premium for the fast-track service and any requests for low temperature sterilization. All the costs are agreed at Financial Close.

Finally, each acute trust participating in the NDP is allocated additional funding for instruments by the DH, as well as further sums for loan sets and to ensure satisfactory arrangements for receipt and distribution. Further advice on how to spend the instrument money is available from the NDP.
Pre-Transition Audits

The NDP has developed three audits, to be carried out during pre-transition. It is also recommended that at Financial Close an early benchmarking audit in these work streams is also completed to identify and prioritise any deficiencies in current service provision that will need addressing during pre-transition.

Members of the NDP or local stakeholders using the national audit templates available from the Customer Manager can complete the benchmarking audits.

The Clinical Audit

The aim of the clinical audit is to ensure that the Customer’s in-house theatre systems are reviewed and, where necessary aligned with best practice and the needs of the outsourced decontamination service. The scope of the audit is restricted to the point at which the instrumentation enters the sterile storeroom within the theatre suite to the point at which it leaves the dirty instrument area for return to the SP.

The Technical Audit

This is an independent assessment of readiness to transfer the decontamination services. It is undertaken by independent experts from the decontamination industry chosen by the Customer, based on a list supplied by the NDP. The audit looks at areas such as assimilation of tray checklists on the SP tracking system, logistics, arrangements for loan items and tagging of instrument sets.

Both the HR and Technical audits are normally undertaken 4-6 weeks before transfer for each hospital.

The Human Resources (HR) Audit

The HR audit reviews the staffing numbers and working hours to ensure there are sufficient skilled staff available to meet the planned service requirements. The audit also ensures that systems are in place to provide the terms and conditions, pensions, travel solutions and training that the SP promised during negotiations.
Medical Devices Directive Compliance and Implications for Clinical Practice

The SP is required to operate within the framework of the Medical Devices Directive 93/42/EEC or MDD. MDD compliance is required of organisations that provide a decontamination service to third parties such as NHS Trusts. The SP will be audited to the MDD requirements by an independent organisation known as a Notified Body. The Notified Body audit will ensure quality standards are met and a copy of the audit report can be issued to the JMB if requested.

Some theatre practices may have to change because of MDD requirements. These changes will vary from site to site and may be implemented during pre-transition or on service transfer. Changes may include alternative tray wrapping methods, the need to reprocess instruments in accordance with the manufacturer’s guidelines and maintaining accurate tray checklists.

Part of MDD compliance involves the SP maintaining quality through a Quality Management System (QMS) which requires regular auditing. It is essential that theatre and SP teams work closely together; for example any changes to tray content or layout will require documentation and agreement. Equally, any complaint or non-conformance will need to be documented in accordance with QMS requirements.

The main points which clinical teams who are working with an MDD compliant facility need to note are:

- Instruments should be reprocessed only in accordance with the manufacturer’s written guidance. The SP will be required to keep manufacturers’ guidance in a technical file for reference.

- **Single use** items will not be reprocessed by the SP.

- Equipment designated “limited use”, such as laryngeal masks, some diathermy leads and forceps will only be reprocessed up to their maximum uses. When transferring equipment to the SP it is essential that accurate records of usage are also transferred.

- Only items intended and marketed by the manufacturer as medical devices can be reprocessed if manufactured after 1993.
• Tray checklists will be version controlled.

• Any packaging (of whatever type) will have to meet the necessary quality standards (e.g. BS EN ISO 11607).

• Any non-conformance observed by clinical teams will have to be reported to the SP.

• All new instruments should be purchased in a controlled, documented manner. Those responsible for purchasing must ensure that the manufacturer’s reprocessing instructions are available and that the instrument, where possible, can be appropriately reprocessed within the facilities provided by the SP.

There will be a suite of **Standard Operating Procedures** (SOPs) for procedures such as handling high risk instrumentation and instrument loans. Clinical teams must be involved in formulating these procedures - which they will then be expected to follow.

Further information on matters relating to MDD compliance is available from the Medicines and Healthcare Products Regulatory Agency (website address on last page).
Good Theatre Instrument Management Guide

Service transfer offers a good opportunity to review how the instrument stock in theatres or hospital sites is managed. There can be millions of pounds worth of instrumentation in a theatre suite and it should be viewed as a key asset in ensuring patient safety and the effective operation of theatre lists.

The following offers some practical advice to clinical teams in managing their instrument stock and maintaining the integrity of the sterile tray/set or what may be referred to as 'product'.

Advice on how clinical teams should handle loan items.

These are the IDSc and AfPP’s recommendations for managing loan items.

1. Ensure that scheduling of routine surgery recognises the appropriate procedures for managing the use of loan equipment.

2. As soon as a request for equipment is made to the loan company, inform the SP with full delivery details and the date and time of the proposed surgery.

3. In normal circumstances, equipment must be ordered to arrive at the hospital site, a minimum of 72 hours ahead of use, to enable thorough checking by the surgical team. This will allow adequate time for the loan company to provide training to both theatre and SP staff.

4. Agreed costs for loan equipment should include sufficient time to allow for initial checking and decontamination prior to use.

5. Check that requests for loan items include the provision of:
   a. tray lists
   b. delivery note
   c. manufacturer’s decontamination instructions
   d. completed decontamination certificate

6. Ensure loan company understands where and how the items should be delivered in accordance with local policy.

7. On receipt, the user should ensure that all instruments are checked against tray checklist and that, where implants are provided, the required range is available.
8. After checking, loan items should be sent to SP for processing ensuring items are accompanied by the reprocessing instructions and the tray checklist.

9. The SP will process loan items both before and after use in accordance with the manufacturer’s instructions. If this information is missing or, if the manufacturer’s instructions cannot be followed, the SP must contact the user immediately.

10. Check that indemnity forms have been completed and that responsibilities for the loaned items have been clearly identified and documented.

11. After use, instruments must be checked by the user before they are returned to the SP.

12. The SP will reprocess the loaned items and return to the user for onward transportation to the owner. The SP will include a decontamination certificate.

13. Loaned items must be tracked through the whole episode of care including reprocessing and use. This tracking should include reference to the use of the loan item in the appropriate part of the patient’s clinical record.

**Instrument tray weight**

The Health and Safety Executive offers guidelines on minimising the risk of moving heavy objects such as instrument trays (“Getting to Grips with Manual Handling”, INDG143 (rev2), 2004). The guideline weight for an object carried using extended arms is 7kg for a female and 10kg for a male. Best practice would suggest that these weights form a basis for local teams to discuss the issue and reduce the number of trays above 10kg as far as possible. It is growing increasingly common to see instrument trays weighed, and their weights displayed on the external tray label to inform the handler.

From a decontamination perspective, heavy trays are at increased risk of tray wrap tears as well as being difficult to move.

The placing of instrument trays on shelving within the storage area must be in accordance with manual handling regulations, with an appropriate risk assessment to identify and reduce the risk of injury to staff when moving and handling them. Heavier trays should be easily accessible and not placed on top of lighter ones, as
this could result in damage to instruments.
As part of the NICE guidance covering high-risk surgery (NICE IPG196, November 2006, available for download from the NICE website), there is a requirement for supplementary instruments to be kept with their parent sets. This must be borne in mind when reviewing the contents of high-risk instrument trays.

**Naming of surgical instruments**

Clinical teams are strongly advised to work with the SP to review tray checklists in a timely manner during early pre-transition and agree a standardised approach in naming instruments.

Non-standardised approaches can lead to the same instrument being named differently within neighbouring theatres. This could be a risk to patient safety and is best avoided. An example of naming inconsistency is given below:

- Mayo Scissors
- Scissors – Mayo – 5 1/2 inch
- HEAVY SCISSORS 14CM

An example of a standardised approach would be

<table>
<thead>
<tr>
<th>Type</th>
<th>Keyword</th>
<th>Use</th>
<th>Dimension</th>
<th>Extra Information</th>
<th>Manufacturers Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scissors</td>
<td>Mayo</td>
<td></td>
<td>14cm</td>
<td>Curved</td>
<td>1246785-12</td>
</tr>
<tr>
<td>Reamer</td>
<td>Acetabular</td>
<td></td>
<td>50cm</td>
<td>Colour coded red</td>
<td></td>
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<tr>
<td>Handle</td>
<td>BP</td>
<td></td>
<td></td>
<td>No 4</td>
<td></td>
</tr>
<tr>
<td>Scalpel</td>
<td>Harmonic</td>
<td></td>
<td></td>
<td>Blade</td>
<td></td>
</tr>
<tr>
<td>Forceps</td>
<td>Brooks</td>
<td>Biopsy</td>
<td>27cm</td>
<td>Aka Miss Lawson's Forcep</td>
<td></td>
</tr>
</tbody>
</table>
Introducing splitting of elements in a name leads to far greater consistency and control.

Other considerations for local agreement during the period prior to the transfer of tray checklists to the SP include:

1. The use of capital letters
2. Standardising the use of abbreviations e.g. cvd vs. curved
3. Standardising the use of fractions e.g. 0.25 vs. ¼
4. Standardising the use of singular vs plural e.g. forcep or forceps
5. Correct spelling
6. Exclude ‘non standard’ characters such as {}, &, etc
7. Remove unnecessary comments or extraneous information
8. Avoid using localised instrument names e.g. ‘Mr Tefler’s Forceps’
Pre and Post Procedural Checking of Instrument Trays and Supplementaries

To maintain service consistency and ensure turnaround times are achievable, it is imperative that clinical teams return used trays and supplementary items in the pre-agreed manner to the SP via the Customer’s designated delivery and collection points.

The AfPP recommends:

1. When sterile product arrives at the hospital site, the delivery should be checked against the delivery note for completeness. The condition of items should be checked to ensure that the packaging is fit for purpose (items failing this initial check should not be integrated into the theatre storage facility and should be returned to the SP following non conformance protocol).

2. Before opening sets within theatres, the outer container/wrap should be checked to ensure its integrity as well as the presence of valid labelling and external sterility indicators.

3. Once opened, the contents should be checked to ensure there is no residual moisture; internal sterilization monitors are present and valid; and there are no visual signs of contamination. Any non-conformances should be reported, following local policy.

4. The contents should be checked against the tray checklist and then signed by the circulator undertaking the check. Any discrepancies should be noted, documented on the checklist and reported as a non conformance. At the end of the case, a further check of the set should be undertaken and the checklist signed by the scrub practitioner.

5. Any broken/missing instruments or instruments requiring attention, such as sharpening, should also be documented on the checklist.

6. At the end of the procedure, all sharps, swabs or other clinical waste should be disposed of appropriately and the sets should be reassembled, ensuring that all instruments are placed back in the correct set.
7. Any supplementary items should be segregated and returned to the SP in line with local policy. All identifiers, such as barcode tags, should be retained with the instrument(s) to which they belong at all times. **Note** NICE Guidance IPG196 should be followed in the management of high-risk surgery supplementary items.

8. Instrument sets should be returned wrapped in accordance with local policy and any additional wraps should be disposed of prior to return.

9. Undertake any post procedural user cleaning of instruments where recommended by the manufacturer or local policy – for example, flushing of phaco-emulsification hand pieces.

10. Local hospital procedures for instrument traceability requirements should be completed e.g. place tray label in patient notes.

11. Used supplementary items and sets should be packaged appropriately with supporting documentation e.g. a signed tray checklist – and placed in designated transport containers for collection by the service provider.

12. Transport trolleys should be loaded so as to ensure the safety of staff and ease of unloading.
Key Tips for Successful Transition

A Practitioner’s View

Jan Rayner, Specialist Perioperative Practitioner from Chapel Allerton Orthopaedic Centre, Leeds Teaching Hospitals NHS Trust, was involved in services transfer to an offsite centre during early 2008. Here she gives her recommendations for a successful transfer of decontamination services.

Allow sufficient time to prepare for the transfer. Don’t underestimate how long it will take. We had 1000 trays and it took about 20 working days to complete the tagging process. We had to do this over a number of weekends as we were unable to reduce lists to free up the kit to be tagged.

Put ‘transition to SP’ as a regular item on theatre team meeting agenda.

Invite both the Customer Manager and SP to theatre meetings.

Ensure tray checklists are correct and ensure theatre specialities are provided with a master copy of the sheets, ensuring it matches what is owned. This will require clinical teams taking time out from routine working.

Ensure any instrument marking tape or tape used to label trays is fit for purpose. We had problems with it flicking in trays leading to tray rejects where instrument marking tape had not been replaced over time and it had become brittle. (Note - the AfPP and IDSc do not recommend the use of tape in marking instrument trays or individual instruments).

Ensure all staff within theatres are aware of the documentation required to run the service, fast-track request forms, non-conformance forms, loan kit protocols, etc. Keep a duplicate copy of any sent forms in theatres.

Schedule operating lists according to operation type to facilitate the tagging of specific kit for example, joint replacement trays. Obviously, some will be generic, and lists must accommodate this. Try working with pre-assessment or the theatre bookings department to negotiate appropriate lists.

Suggest tagging all important or unique supplementary instrumentation, to enable traceability and minimizing the risk of it getting lost.
Ensure a SP representative is on site full time during transition.

Discuss with the SP how they will monitor the filters in the lids of any rigid containers. Who is counting, and how, as lids may not be necessarily placed back on the same base container.

Agree shelf life of sterilization, and discuss reprocessing of expired stock.

Agree fastrack times, emergency instruments, possibility of increasing levels of instrumentation available for department… purchase or loan.

Where scanning equipment is been used in theatres, ensure all the relevant staff are trained in the art of scanning the trays into and out of the department.

Consider having staged transfers for departments, and don’t proceed with another department/speciality transfer until current transfer process has been successfully achieved.

Try to ensure that the appropriate people are signing off the tray checklists, i.e., the people that work with the trays on a regular basis.

Loan problematic trays/instruments to the SP ahead of transfer, so that sample wrapped or containerised instrumentation can be assessed for damage or wetness prior to complete transition.

Attempt to replace ‘tired’ instruments – rusting or damaged – as SP may refuse to process them.
Appendix 1: Procurement Route for Sterile Services (Negotiated Procedure)

- Options Appraisal
  - Outline business case (OBC) approved
  - Project Team to establish project plan and agree to timetable
    - Place notice in OJEU (source Service Providers)
    - Receive expressions of interest issue PQQ / SQ
    - Project Team shortlists preferred Bidders (3) and notifies unsuccessful Bidders
    - Prepare ‘Invitation to Submit Final Offer’ (ISFO)
    - Project Team issue ISFO to preferred Bidders
      - Bidders prepare and submit final offer
      - Project Team evaluate and score final offers
      - Project Team carries out final clarification exercise
      - ‘Final Offer’ adjudication meeting
      - Project Team conducts and concludes contract with preferred Bidders
        - Trust board approval
          - Local Project Board meeting
            - Project Manager to send notification to all bidders of notification to award contract
          - Award of contract
            - 10 day stand still period
              - Contract starts
                - Debrief unsuccessful Bidder

- Estimated No’s of Bidders (“3-2-1”)
  - 10 - 12 Bidders
  - 3 Bidders
  - 1 Supplier
### Appendix 2: Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Bedding In Period</td>
<td>the time period immediately after services transfer during which performance penalties are relaxed</td>
</tr>
<tr>
<td>Collaboration</td>
<td>the group of Trusts that have contractually joined to procure decontamination services</td>
</tr>
<tr>
<td>Customer</td>
<td>a Trust which is part of the decontamination service collaboration</td>
</tr>
<tr>
<td>Customer Manager</td>
<td>the NHS employee who manages the contract on behalf of all the Trusts in the collaboration</td>
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<tr>
<td>Decontamination Services Agreement (DSA)</td>
<td>the legal contract between the Trust and the Services Provider</td>
</tr>
<tr>
<td>DSA Schedules</td>
<td>the 31 appendices to the contract, which are populated with local information</td>
</tr>
<tr>
<td>Fastrack</td>
<td>the priority reprocessing service offered by the outsourced service</td>
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<tr>
<td>Financial Close</td>
<td>the date when the contract is signed by each NHS Trust and the Services Provider</td>
</tr>
<tr>
<td>Instrument Review Committee (IRC)</td>
<td>the operational group looking at best use of instrumentation. It is made up of both Trust and Services Provider personnel</td>
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<tr>
<td>Joint Management Board (JMB)</td>
<td>the executive group managing the contract and made up of Trust and Services Provider personnel</td>
</tr>
<tr>
<td>Local Mobilization Team</td>
<td>the group of people responsible for preparing for the transfer of decontamination services for a particular site or hospital</td>
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<tr>
<td>National Decontamination Programme</td>
<td>the Department of Health project aimed at improving standards in decontamination in England</td>
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<tr>
<td>Non-conformance</td>
<td>a failure to conform to the expected standard</td>
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<tr>
<td>Notified Body</td>
<td>the independent body responsible for auditing the Services Provider against the requirements of MDD 93/42/EEC</td>
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<tr>
<td>Performance Mechanism</td>
<td>the penalty regime of the contract</td>
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### Appendix 2: Glossary (cont.)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Pre-Transition</td>
<td>the time between contract signing and the transfer of services</td>
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<tr>
<td>PRINCE2</td>
<td>PRojects IN Controlled Environments and is the method of project management used by the UK Government</td>
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<tr>
<td>Quality Management System (QMS)</td>
<td>the Services Provider’s documented regime for maintaining consistent service quality</td>
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<tr>
<td>Schedule 21</td>
<td>the appendix in the contract that covers the issue of transition</td>
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<tr>
<td>Schedule 6</td>
<td>the appendix in the contract setting out the expected service delivery outcomes of the contract. Also known as the “Output Specification”</td>
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<tr>
<td>Services Provider (SP)</td>
<td>the organisation which is contracted to supply the decontamination services</td>
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<tr>
<td>Single Use Device</td>
<td>a medical device that is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on a different patient</td>
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<tr>
<td>Standard Operating Procedure (SOP)</td>
<td>a document outlining work instructions for a particular task</td>
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<tr>
<td>Steady State</td>
<td>the time when the bedding in period is complete and the performance criteria are met</td>
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<tr>
<td>Theatre Lead</td>
<td>the named theatre person tasked with leading on the services transfer</td>
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<tr>
<td>Transition</td>
<td>the time period when the reprocessing of instruments transfers to the new decontamination service</td>
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<tr>
<td>Tray Categories</td>
<td>the grouping given to instrument trays and supplementaries according to the number of instruments in the set. Each category attracts a different cost in the contract</td>
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<tr>
<td>Tray Checklist</td>
<td>the list of instruments for a particular instrument set</td>
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<tr>
<td>Turnaround Time</td>
<td>the period from when an item is made available for reprocessing, to the time when it logged back into the Receipt and Distribution Point</td>
</tr>
<tr>
<td>User</td>
<td>Trust staff who use surgical instruments as part of their job</td>
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Appendix 3: Clinical Team Task List

This list highlights the tasks which require clinical input from the ‘Customer Task List’ in Schedule 21. The timings listed are contractual obligations on the Customer and failure to meet them may result in remedial action.

Tasks that should be completed at financial close

- Collate non-conformities of current decontamination service.
- Detail current deficiencies in the hospital’s tray stock as tray shortage or missing instruments.
- Check instruments and trays for superfluous tape and marking methods.
- Ensure the proposed date of service transfer does not clash with increased service demand such as waiting list initiatives.
- Place orders for additional instrumentation from DH money to ensure this instrumentation is in place for transition.
- Ensure an up to date risk register is in place for theatres.
- List all service changes such as loss of textile provision, removal of hollowware etc.
- Issue first generation of tray checklists to the SP.
- Any trays that are incomplete due to missing instruments or any that deviate from the tray checklist should be identified to the SP.
- Issue schedule of all customer instrument user locations to the SP.
- Create list of trays with missing instruments, etc and replace where possible.
- Record current fastrack demand.

Tasks that should be completed for halfway during Pre-Transition

- Confirm with SP the identification methods to be used for tracking Supplementary instruments through the process.
- Agree the minimum range and number of instruments held by the SP for instrument replacement.
- Notify the SP of all current service deficiencies such as wet packs and torn tray-wrap, difficult to dry items, frequently rejected items and damaged baskets/trays.
- Confirm how and when items will be logged in and out of the collection and delivery points, clearly identifying responsibilities and expectations of both parties.
Appendix 3: Clinical Team Task List

Tasks that should be completed at transition – 3 months

- Ensure tagging of trays and supplementaries will be completed ahead of transition.
- Ensure maintenance and servicing of instrumentation is up to date and undertaken in line with manufacturers’ recommendations.
- Ensure arrangements are in place for top up of implants where transferring to theatre teams.
- Notify loan companies of change in decontamination arrangements.
- Clinical teams should ensure arrangements are in place for changes to service delivery such as removal of hollowware from trays or new pre-sterile items.

Tasks that should be completed at transition – 1 month

- Ensure additional instrumentation will be in place for transition.
- Agree condition of instruments with the SP.
- Ensure any consumables such as drapes or gowns previously ordered by the Sterile Services Department will be in supply at time of transition.
- Ensure instrument repair protocols are understood by each theatre team.
- Agree and sign off tray checklists.
Appendix 4: Theatre Lead Roles and Responsibilities

It is essential that each Trust or hospital site identifies a Theatre Lead to be recruited or seconded to the project and that this person has sufficient departmental experience to work as part of the project.

Ideally, the Theatre Lead should be identified in advance of Financial Close.

This individual(s) should

1. Have identified time for project work away from clinical duties.
2. Ideally have previous project experience and/or have a project management qualification – for example PRINCE2 Practitioner.
3. Represent theatre requirements in their organisation.
4. Identify key issues for theatres in the move to the new service.
5. Audit the implementation of lessons learned.
6. Active participation in project meetings.
7. Ensure sufficient instruments are available to the organisation when the service transfers.
8. Ensure pre-transition documentation is compiled and completed.
9. Assist in the planning and execution of transition.
10. Ensure theatre practices are robust.
11. Ensure the availability of clinical teams for training.
12. Prepare the clinical teams for the clinical and technical audits.
13. Ensure the contractual obligations of clinical teams are met (Appendix 3).
14. Act as point of contact for clinical teams.
15. Share theatre needs with the SP.
16. Have an understanding of the DSA so as to ensure smooth transfer of services.
## Appendix 5: Tray Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>a Supplementary single/double wrapped (Peel Pouched) with less than 5 instruments</td>
</tr>
<tr>
<td>Category 2</td>
<td>a Supplementary single/double wrapped (Peel Pouched) with more than 5 instruments</td>
</tr>
<tr>
<td>Category 3</td>
<td>Not used by the National Team but may be used locally</td>
</tr>
<tr>
<td>Category 4</td>
<td>power tools and endoscopes requiring manual washing. (Note that category 4 includes only those instruments requiring manual washing, the remainder of the instruments contained in the tray are to be allocated to the relevant tray category by quantity)</td>
</tr>
<tr>
<td>Category 5</td>
<td>ward/department type trays</td>
</tr>
<tr>
<td>Category 6</td>
<td>Instrument Trays with up to 10 instruments</td>
</tr>
<tr>
<td>Category 7</td>
<td>Instrument Trays with 11 to 20 instruments</td>
</tr>
<tr>
<td>Category 8</td>
<td>Instrument Trays with 21 to 30 instruments</td>
</tr>
<tr>
<td>Category 9</td>
<td>Instrument Trays with 31 to 40 instruments</td>
</tr>
<tr>
<td>Category 10</td>
<td>Instrument Trays with 41 to 50 instruments</td>
</tr>
<tr>
<td>Category 11</td>
<td>Instrument Trays with 51 to 60 instruments</td>
</tr>
<tr>
<td>Category 12</td>
<td>Instrument Trays with 61 to 70 instruments</td>
</tr>
<tr>
<td>Category 13</td>
<td>Instrument Trays with 71 instruments or more</td>
</tr>
<tr>
<td>Category 14</td>
<td>instruments not fitting into categories 1 to 13</td>
</tr>
</tbody>
</table>
Feedback

Comments and suggestions for inclusion in later versions are welcome and can be sent to emma.hall@dh.gsi.gov.uk

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Links

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