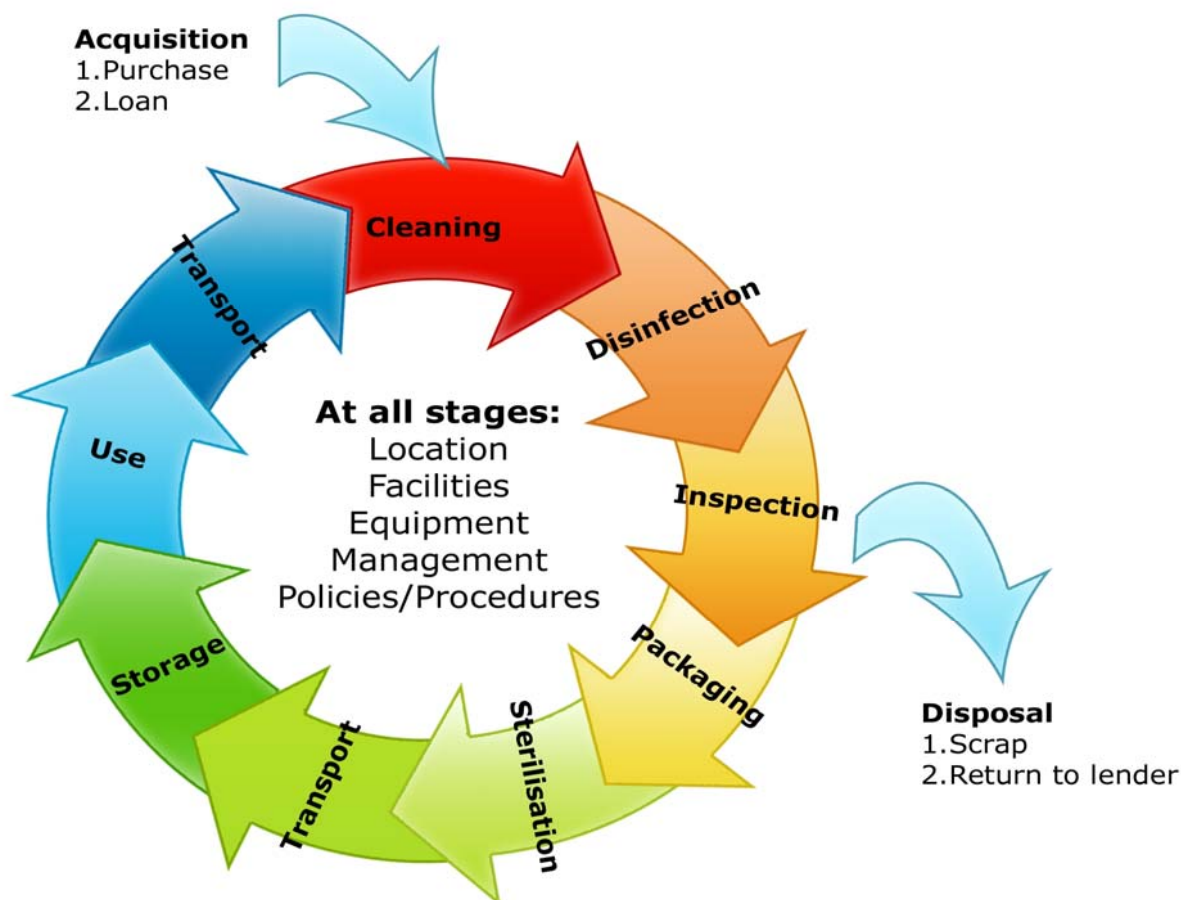


## PART 6: AUDIT TOOL

# Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices



## Reader Information

<b>Directorate:</b>	Health Service Executive (HSE)
<b>Title:</b>	HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices
<b>Document Purpose:</b>	Standards & Recommended Practices—Part 6
<b>Author:</b>	Steering Committee for Decontamination of Reusable Invasive Medical Devices
<b>Publication Date:</b>	August 2007
<b>Target Audience:</b>	All staff in the public health service who work in Central Decontamination Units, Endoscopy Units, Dental Services and other relevant staff with responsibility for decontamination of reusable invasive medical devices
<b>Description:</b>	The Code of Practice is a guide to the standards of practice required in the decontamination of reusable invasive medical devices in Central Decontamination Units, Endoscopy Units and Dental Services, based on current legal requirements and professional best practice
<b>Superseded Docs:</b>	NA
<b>Review Date:</b>	August 2008
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**Part 6**

*Part 6*  
*Audit Tool*

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## Introduction

# 1 Introduction

## 1.1 Standards for decontamination of reusable invasive medical devices

During 2007, standards for decontamination of reusable invasive medical devices (hereafter referred to in this document as RIMD) were developed using a consistent methodology. A literature review was undertaken which included a search for all relevant guidance and evidence. Expert opinion was also sought for the standards. A national consultation process was undertaken and feedback, where appropriate, was incorporated into the final version of the standards. An e-audit tool (based on the 'Safety and Health Audit Tool for the Healthcare Sector) was then developed to assist in the monitoring of the standards for decontamination of RIMD in the Health Service Executive.

## 1.2 Audit

Audit is a function of all developing and progressive organisations. The outcome from an audit can facilitate an organisation to be knowledgeable about its areas of non-conformance and to identify and implement corrective action where necessary.

## 1.3 Audit Tool

This audit tool in this document relates to the principles of the decontamination process and includes: organisational structure and accountability, suitability of decontamination facilities and management and key personnel. The audit tool can be used to provide objective data on conformance with the standards within the Health Service Executive (HSE). Year-on-year data can assist in monitoring the effectiveness of decontamination of RIMD programmes and assist in strategic planning to meet long term objectives in relation to decontamination of RIMD.

## 1.4 Levels of Audit

There are two levels of audit against the HSE Decontamination of RIMD Standards: self-assessment and external review.

Self assessment is a process whereby the healthcare facility measures its conformance against National Standards. Each healthcare facility will be asked to undertake a self-assessment exercise for its service against the standards. This will be completed annually and signed by the CEO/Manager.

External review uses the same National Standards to independently measure the healthcare facility through an on-site audit.

## **Guidelines for using the audit tool**

## **2 Guidelines for using the audit tool**

### **2.1 Decontamination of RIMD audit tool**

The audit tool is intended for use by the decontamination coordinator, decontamination unit managers, staff with a demonstrated interest in decontamination of RIMD and trained audit personnel.

### **2.2 Planning the audit programme**

It is envisaged that the quality and risk committee (or appropriate committee) will plan and prioritise the use of the audit tool based on a review of specific policies, on the results of a previous audit or in response to specific clinical incidents.

### **2.3 Time required**

The time required to complete a specific audit will vary according to the tool, the size of the healthcare facility, the type of procedures audited and the experience of the auditor.

### **2.4 Conformance**

A conformance categorisation has been incorporated into the scoring system to provide a clear indication of conformance. The allocation of conformance levels is based on the scores obtained, which will be automatically allocated within the database. For the purpose of these audits the categories will be allocated as follows: minimal conformance 75% or less, partial conformance 76-84% and conforming 85% or above.

### **2.5 Feedback of information and report findings**

It is advised that the auditor should verbally report any areas of concern and of good practice to the decontamination unit manager in charge of the area being audited prior to leaving. A written report should also be developed by the auditor and should be given to the relevant decontamination unit manager for action. The report should clearly identify areas requiring action. The decontamination unit manager is responsible for developing an action plan to address the issues identified within a given timescale.

The audit team may decide to reaudit the department if there are concerns or a minimal conformance rating is observed. A system of feedback to the quality and risk committee (or appropriate committee) on the action taken by wards/departments should be in place. This may involve feedback meetings or the return of completed action plans to the quality and risk committee (or appropriate committee).

## Guidelines for using the audit tool

### 2.6 Scoring

Fifteen standards for audit of decontamination of RIMD are described in the following sections. Each standard is stated and followed by questions based on the standard criteria. Below is an explanation of the abbreviation used under each criterion.

- I = Interview
- O = Observation
- D = Documentation
  
- Y = Yes
- P = Partial
- N = No

#### Instructions on the completion of a standard worksheet

In order to effectively audit decontamination of RIMD it is necessary that all standards are audited as part of the audit process. The auditor can repeat a full audit of all standards at regular intervals in order to measure the level of improvement in the effectiveness of decontamination of RIMD.

There are fifteen standards in this audit tool and for each standard there is a worksheet, which details a list of questions to be answered. There is specific information to be completed in the worksheet and this is explained below:

#### Step 1:

For each question the auditor can use an “X” to indicate the appropriate answer, which is “Yes”, “Partial” or “No”. In this example we will assume the answer is “No”

	I		Y	P	N														
I	<input type="checkbox"/>	<b>Is the department designed to allow segregation of ‘dirty’ and ‘clean’ activities?</b>  <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				X
Yes	No		Partial	A	B	C	Total score												
Score 10	Score 0			Score 8	Score 5	Score 2													
O	<input type="checkbox"/>																		
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

**Guidelines for using the audit tool**

**Step 2**

For each question the auditor can use an “X” to indicate the method of verification used in trying to get an answer to the question. The auditor may have interviewed ( I ) an employee, observed ( O ) a particular work practice or reviewed a particular document ( D ). The auditor may have used all three methods. For this example the auditor observed the layout of the department and used an “X” to indicate this on the worksheet.

	<b>I</b>							<b>Y</b>	<b>P</b>	<b>N</b>										
<b>I</b>	<input type="checkbox"/>	<b>Is the department designed to allow segregation of ‘dirty’ and ‘clean’ activities?</b>									<b>X</b>									
<b>O</b>	<input checked="" type="checkbox"/>		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2					
Yes	No		Partial	A	B		C	Total score												
Score 10	Score 0	Score 8		Score 5	Score 2															
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																		

**Step 3**

The auditor can then detail some supporting evidence or comments to explain the reason for the relevant answer. In this example the answer to the question was “No” because clean and dirty activities take place in the same areas in the department.

**Step 7**

	<b>I</b>							<b>Y</b>	<b>P</b>	<b>N</b>										
<b>I</b>	<input type="checkbox"/>	<b>Is the department designed to allow segregation of ‘dirty’ and ‘clean’ activities?</b>									<b>X</b>									
<b>O</b>	<input checked="" type="checkbox"/>		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2					
Yes	No		Partial	A	B		C	Total score												
Score 10	Score 0	Score 8		Score 5	Score 2															
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  <b>There is no segregation of activities in the department. Clean and dirty activities take place in the same areas.</b>  Risk Category_____																		



## Guidelines for using the audit tool

### Step 4

The auditor can use an “X” to indicate the appropriate answer for each question, which will be “Yes”, “Partial” or “No”.

#### The different scoring options are as set out below:

If the auditor selects “Yes” as his/her answer to the question, then the auditor uses an “X” to select “Yes” in the score table and enters a total score of “10” in the score table. An answer of “Yes” means there is full evidence of conformance and this is allocated a score of 10.

YES X
Score 10

If the auditor selects “No” as his/her answer to the question, then the auditor uses an “X” to select “No” in the score table and enters a total score of “0” in the score table. An answer of “No” means there is no evidence of conformance and this will be allocated a score of “0”.

NO X
Score 0

If the auditor selects “Partial” as his/her answer to the question, then the auditor must choose from one of three options. A, B and C. The categories have the following meaning:

- A: Evidence of significant level of conformance
- B: Evidence of a reasonable level of conformance
- C: Very little evidence of conformance

The auditor uses an “X” to select the appropriate option A, B or C.

A	B	C
Score 8	Score 5	Score 2

## Guidelines for using the audit tool

### Step 5

The auditor should check that he/she has entered the appropriate total score in the score table for each question.

Yes	No	Partial	A	B	C	Total score
Score 10	Score 0		Score 8	Score 5	Score 2	X

### Step 6

The auditor should calculate the criterion score as a percentage. This is explained by a worked example below:

Number of Questions in Standard:	13
Maximum Standard Score ( MS )	
(Total Number of Questions x Maximum Score (10)):	130 (13 x 10)
Actual Standard Score ( AS ) (Sum of the total scores for each question)	100

**Note:** In this example the actual score used was 100, however the actual score will vary depending on the scores allocated to each question.

Standard Score as a percentage =  $AS/MS \times 100/1$

In this example Standard Score as a percentage =  $100/130 \times 100/1 = 76.92\%$

Note: Where a question in a standard is not applicable, it will not be given a score.

*Example:*

*In the above case; if there were only 12 questions applicable then the maximum criterion score (MS) would be 120 (12 x 10).*

## Guidelines for using the audit tool

The auditor repeats Step 1-6 for each question in the standard worksheet.

### Step 8

When a standard has been fully audited, the auditor can detail a summary of the results in the standard report form. This information can be taken from the worksheet or the auditor may use his/her own notes taken during the audit. This report form should be completed for each standard. An example of what information can be included in this report form is detailed below.

### Step 9

<b>Standard 2: Organisational structure and accountability</b>
Individual responsibility for decontamination of RIMD is clearly defined throughout the organization and there are clear lines of accountability leading up to the most Senior Manager or Director.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<p><b>Conformance in the area</b> <i>Managers are aware of responsibilities</i></p> <p><b>Non-conformance in the area</b></p>
<b>Standard Score: 100/130 76.92%</b>

## Guidelines for using the audit tool

The areas of non-conformance in each standard report form should be transferred to a Quality Improvement Action Plan. An example of a blank Quality Improvement Action Plan is detailed in section 5 of this document. Below is an example of the type of information that would be documented in this quality improvement action plan by the auditor.

<i>Standard</i>	<i>Area of Non Conformance</i>	<i>Corrective Action</i>	<i>Responsible Person</i>	<i>Time-frame</i>	<i>Review</i>
1	<i>No segregation of clean and dirty activities in the department</i>	<i>Discuss with decontamination unit manager. Identify any resources required.</i>	<i>CEO/Manager</i>	<i>Oct 2007</i>	<i>Feb 2008</i>

The auditor may have a number of areas of non-conformance for each standard. The Quality Improvement Action Plan should be agreed in consultation with the senior management committee (or appropriate committee). The action plan is used to summarise the main findings of the audit and it is used as a tool for continuous improvement.

**Note:** The auditor may use the Auditors Notes section in section 7 of this document to compile further relevant information.

## Guidelines for using the audit tool

### STANDARD SCORING SUMMARY SHEET

Step 10:

The auditor should detail the scoring for each standard in a Standard Scoring Summary Sheet. A completed Standard Scoring Summary sheet is detailed below and a blank Standard Scoring Summary sheet is detailed in section 6 of this document.

Standard	Actual Standard Score (AS)	Maximum Standard Score (MS) Total Number of Question x Maximum Score (10)	Standard Score as a percentage (AS/MS x 100/1)
1	70	80	87.5
2	90	130	69.2
3	240	340	70.6
4	400	510	78.4
5	110	130	84.6
6	90	110	81.8
7	50	100	50
8	60	80	75
9	100	170	58.8
10	120	150	80
11	90	140	64.3
12	15	30	50
13	90	110	81.8
14	100	120	83.3
15	15	30	50
<b>Overall Audit Score</b>	<b>1,640</b>	<b>2,230</b>	<b>73.5</b>

## Guidelines for using the audit tool

### Step 11:

Using the example above the auditor needs to calculate the Overall Audit Score.

### Overall

**Audit Score** = Sum of all actual standard scores (AS)/Sum of all maximum standard  
Scores (MS) x 100/1

**Overall Audit Score** = 1640/2230 x 100/1 = 73.54%

This Overall Audit Score can be used to benchmark performance from year to year and the individual standard score allows the auditor to identify areas where most attention is needed.

A summary sheet with Standard and Overall Audit Score could be attached to the Quality Improvement Action Plan as a full Audit Report.

## Risk level categories

### 3 Risk level categories

A response is categorised as non-conforming if it does not meet the criteria identified in the HSE Standards for decontamination of RIMD. An indication of the seriousness of the non-conformance is given by a risk category that is attached to each non-conformance statement. The categorisation of risk should provide some assistance in prioritising remedial actions.

On the right hand side of each statement is a risk level categorisation. These are organised as shown in Table 1.

**Table 1: Definition of risk levels used in non-conformance statements**

Level	Category	Description
1	Observation	This category includes reported facts which, although not necessarily non-conformances, should be considered when any remedial action is planned.
2	Low Risk	The reported fact(s) indicate a minor hazard with a low likelihood of the hazard occurring.
3	Medium Risk	The reported fact(s) indicate either a minor hazard with a significant likelihood of the hazard occurring or a significant hazard with a low likelihood of the hazard occurring.
4	High Risk	The reported fact(s) indicate a significant hazard with a significant likelihood of the hazard occurring.

## **Standards for decontamination of reusable invasive medical devices**

### **4 Standards for Decontamination of RIMD**

#### **Standard 1: Communication and consultation**

Appropriate and effective mechanisms shall be in place for communication and consultation on matters relating to decontamination of reusable invasive medical devices (hereafter referred to in this document as RIMD), with key stakeholders within and outside the organisation.

#### **Standard 2: Organisational structure and accountability**

Responsibility for procurement, storage, transport, use and decontamination of RIMD shall be clearly defined and there shall be clear lines of accountability for decontamination matters throughout the organization.

#### **Standard 3: Suitability of decontamination facilities**

Decontamination facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination of clean and disinfected RIMD. For guidance see PD CEN ISO/TR 14969:2005. Additional detailed guidance is available in Health Building Note 13 (Sterile Service Departments)/Health Building Note 36 (Dental Facilities) and Health Building Note 52 (Endoscopy Units).

#### **Standard 4: Decontamination equipment**

All decontamination equipment that does not meet the requirements of current standards shall be identified and upgraded or replaced in accordance with a planned replacement programme.

All new decontamination equipment shall be procured in conformance with extant harmonized standards.

All decontamination equipment shall be validated, maintained, periodically tested and monitored to current standards.

#### **Standard 5: Procurement of reusable invasive medical devices**

Decontamination issues shall be considered prior to the acquisition of RIMD.



## **Standards for decontamination of reusable invasive medical devices**

### **Standard 6: Decontamination process**

RIMD e.g. surgical instruments, powered devices, rigid and flexible endoscopes, etc. shall be decontaminated in accordance with the recommendations of the manufacturers validated instructions for decontamination (Ref. EN ISO 17664:2004) current legislation and quality system standards.

### **Standard 7: Management and key personnel**

Appropriately qualified key personnel shall be in place to ensure that the decontamination service is provided effectively and efficiently.

### **Standard 8: Education and training**

Education and Training in relevant aspects of decontamination practice shall be provided to all new, temporary and existing staff members.

### **Standard 9: Quality management system**

Central decontamination units shall operate a quality management system in accordance with EN ISO 13485.

Endoscope and local decontamination units shall operate a quality system in accordance with the key operational elements of EN ISO 13485.

### **Standard 10: Risk management system**

The organisation shall have a risk management system in place to identify the hazards associated with the decontamination process, to estimate and evaluate the risks, control the risks and monitor the effectiveness of the control.

### **Standard 11: Health and safety**

Decontamination shall be carried out in a manner that minimizes the risk to patients and staff from contamination on used devices and process chemicals.

### **Standard 12: Complaints management**

All complaints and comments shall be properly managed and shall be systematically recorded and analysed to identify trends and other performance information.

## **Standards for decontamination of reusable invasive medical devices**

### **Standard 13: Audit and monitoring**

Audits shall be carried out to ensure that the procedures for decontamination of RIMD conform to the required standard, that the processes undertaken conform to the procedures and to identify opportunities for improvement.

### **Standard 14: Key performance indicators**

Key performance indicators that are capable of showing improvements in the efficacy of the decontamination process shall be used. The usefulness of the indicators shall be reviewed regularly.

### **Standard 15: Procedures relating to transmissible spongiform encephalopathies (TSEs)**

The organisation shall have processes in place to minimize the exposure of patients and employees to TSE agents.

## Communication and consultation

### Standard 1: Communication and Consultation

Appropriate and effective mechanisms shall be in place for communication and consultation on matters relating to decontamination of reusable invasive medical devices (hereafter referred to in this document as RIMD), with key stakeholders within and outside the organisation.

	1.3.1		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p><b>Has the organisation developed a set of shared values, behavioural guidelines and quality principles in support of the Health Service Executive Code of Practice for Decontamination of RIMD that are reflected in job descriptions and vision statements?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	

	1.3.2		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p><b>Have Healthcare Workers been given an opportunity to provide feedback on these values, guidelines and quality principles?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	

	1.3.3		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p><b>Are these values, guidelines and quality principles reflected in each departments business plans?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	

**Communication and consultation**

	1.3.4		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Are regular reviews undertaken to ensure that business plans are translated into action?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	1.3.5		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Has the organisation developed and implemented a practical methodology for sharing best practice both internally and with key stakeholders in relation to decontamination of RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	1.3.6		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Has the organisation informed their staff and patients about the Health Service Executive Code of Practice for Decontamination of RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Communication and consultation**

	<b>1.3.7</b>		<b>Y</b>	<b>P</b>	<b>N</b>																
<b>I</b>	<input type="checkbox"/>	<p>Are educational materials provided (in relation to decontamination of RIMD) using a variety of different media as required?</p>																			
						<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
								Yes	No	Partial		A	B	C	Total score						
Score 10	Score 0	Score 8	Score 5	Score 2																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

	<b>1.3.8</b>		<b>Y</b>	<b>P</b>	<b>N</b>																
<b>I</b>	<input type="checkbox"/>	<p>Are staff and key stakeholders encouraged to use feedback procedures to the organisation for any concerns they have in relation to decontamination of RIMD?</p>																			
						<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
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Score 10	Score 0	Score 8	Score 5	Score 2																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

	<b>1.3.9</b>		<b>Y</b>	<b>P</b>	<b>N</b>																
<b>I</b>	<input type="checkbox"/>	<p>Does the decontamination unit and the clinical units which it supplies have a service level agreement?</p>																			
						<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
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Score 10	Score 0	Score 8	Score 5	Score 2																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

**Communication and consultation**

	<b>1.3.10</b>		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Does the decontamination unit have in place a formal system for recording and analysing customer complaints?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
		Risk Category_____								

	<b>1.3.11</b>		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Does the decontamination unit have in place a programme to reduce customer complaints?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
		Risk Category_____								

## Communication and consultation—Standard Report Form

### Standard 1 Report Form

<b>Standard 1: Communication and consultation</b>
Appropriate and effective mechanisms shall be in place for communication and consultation on matters relating to decontamination of reusable invasive medical devices, with key stakeholders within and outside the organisation.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

**Communication and consultation**

	<b>1.3.10</b>		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Does the decontamination unit have in place a formal system for recording and analysing customer complaints?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
Risk Category_____										

	<b>1.3.11</b>		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Does the decontamination unit have in place a programme to reduce customer complaints?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
Risk Category_____										



## Organisational structure and accountability

### Standard 2: Organisational structure and accountability

Responsibility for procurement, storage, transport, use and decontamination of RIMD shall be clearly defined and there shall be clear lines of accountability for decontamination matters throughout the organization.

2.3.1		Y	P	N													
I O D	<input type="checkbox"/>	<p><b>Is individual responsibility for decontamination of RIMD clearly defined throughout the organization and are there clear lines of accountability leading up to the most senior manager or director?</b></p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> <tr> <th>Score 10</th> <th>Score 0</th> <th>Score 8</th> <th>Score 5</th> <th>Score 2</th> <th></th> </tr> </thead> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

2.3.2		Y	P	N													
I O D	<input type="checkbox"/>	<p><b>Does the scope of responsibility also include the competence of contractors where the organisation buys in services and professional liability where the organisation sells services to other organisations?</b></p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> <tr> <th>Score 10</th> <th>Score 0</th> <th>Score 8</th> <th>Score 5</th> <th>Score 2</th> <th></th> </tr> </thead> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

2.3.3		Y	P	N													
I O D	<input type="checkbox"/>	<p><b>Is decontamination of RIMD a standard item on the agenda of the quality and risk management committee (or appropriate committee) in the organisation? Does the Decontamination Coordinator submit regular reports on management of decontamination to the committee?</b></p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> <tr> <th>Score 10</th> <th>Score 0</th> <th>Score 8</th> <th>Score 5</th> <th>Score 2</th> <th></th> </tr> </thead> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
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	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

**Organisational structure and accountability**

	2.3.4		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Is a twice yearly report on the conformity of the decontamination process within the organisation submitted to the Quality and Risk committee (or appropriate committee) for review. Does this committee, (which includes in its membership the CEO/Manager or CEO/Manager nominee), present the report to the Senior Management Team?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>																	

	2.3.5		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Has the organisation identified a Decontamination Co-ordinator? Do the duties of the co-ordinator encompass all aspects of the decontamination process which are not confined to any one aspect or decontamination function but encompass all decontamination processes wherever they occur within the organisation?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>																	

	2.3.6		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Does the Decontamination Coordinator have responsibility and authority for developing and monitoring policies, continuous quality improvement and/or strategies for decontamination of RIMD for approval by the Quality and Risk committee (or appropriate committee)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>																	

**Organisational structure and accountability**

	2.3.7		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p>Does the Decontamination Coordinator attend appropriate meetings/conferences local and national, relevant to decontamination of RIMD, which will increase their knowledge and improve their ability to undertake the role?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	
		Supporting Evidence/Comments																
		Risk Category_____																

	2.3.8		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p>Does the Decontamination Coordinator undertake the dissemination of all information, received from the National Hospitals Office and/or PCCC Directorates/relevant agencies relating to decontamination of RIMD within the organisation?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	
		Supporting Evidence/Comments																
		Risk Category_____																

	2.3.9		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p>Does the Decontamination Coordinator work with clinicians and decontamination unit managers to develop and improve the systematic approach to decontamination of RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	
		Supporting Evidence/Comments																
		Risk Category_____																

**Organisational structure and accountability**

	2.3.10		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is the Decontamination Coordinator responsible for ensuring that the audit activity for decontamination of RIMD, under the responsibility of each decontamination unit manager has been completed?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	2.3.11		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is the quality and risk committee (or appropriate committee) responsible for the implementation and monitoring of a decontamination of RIMD audit and monitoring programme in the organisation?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	2.3.12		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is each relevant member of staff made aware of their responsibility in relation to the decontamination process?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Organisational structure and accountability**

2.3.13		Y	P	N								
I O D	<input type="checkbox"/>	Does the organisation have a specific resource provision for decontamination of RIMD related at least in part to throughput?										
	<input type="checkbox"/>	Yes Score 10	No Score 0	Partial <table border="1"> <thead> <tr> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table>	A	B	C	Total score	Score 8	Score 5	Score 2	
	A	B	C	Total score								
Score 8	Score 5	Score 2										
<input type="checkbox"/>	Supporting Evidence/Comments											
		Risk Category_____										

## Organisational structure and accountability—Standard Report Form

### Standard 2 Report Form

<b>Standard 2: Organisational structure and accountability</b>
Responsibility for procurement, storage, transport, use and decontamination of RIMD shall be clearly defined and there shall be clear lines of accountability for decontamination matters throughout the organization.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

### Suitability of decontamination facilities

#### Standard 3: Suitability of decontamination facilities

Decontamination facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination of clean and disinfected RIMD. For guidance see PD CEN ISO/TR 14969:2005. Additional detailed guidance is available in Health Building Note 13 (Sterile Service Departments)/Health Building Note 36 (Dental Facilities) and Health Building Note 52 (Endoscopy Units).

	3.3.1		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p><b>Is the department designed so that it is physically separated from all other work areas?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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<b>O</b>	<input type="checkbox"/>																	
	<input type="checkbox"/>	Supporting Evidence/Comments																
<b>D</b>	<input type="checkbox"/>	Risk Category_____																

	3.3.2		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p><b>Is the department designed to allow segregation of 'dirty' and 'clean' activities?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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<b>O</b>	<input type="checkbox"/>																	
	<input type="checkbox"/>	Supporting Evidence/Comments																
<b>D</b>	<input type="checkbox"/>	Risk Category_____																

	3.3.3		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p><b>Is the department designed to facilitate a unidirectional work flow from the 'dirty' area to the 'clean' area?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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<b>O</b>	<input type="checkbox"/>																	
	<input type="checkbox"/>	Supporting Evidence/Comments																
<b>D</b>	<input type="checkbox"/>	Risk Category_____																

**Suitability of decontamination facilities**

	3.3.4		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Is the department <i>not used</i> for any other purpose?</b>							
		Yes	No	Partial	A		B	C	Total score
		Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
	<input type="checkbox"/>	Risk Category _____							

	3.3.5		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Is the department <i>not used</i> as a thoroughfare?</b>							
		Yes	No	Partial	A		B	C	Total score
		Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
	<input type="checkbox"/>	Risk Category _____							

	3.3.6		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Is the department <i>not part</i> of any patient treatment area?</b>							
		Yes	No	Partial	A		B	C	Total score
		Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
	<input type="checkbox"/>	Risk Category _____							



**Suitability of decontamination facilities**

	3.3.7		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Are all rooms in the department mechanically ventilated and controlled to provide a comfortable working environment? (typically temperatures shall be controlled between 18-22 degrees Celsius and relative humidity shall be controlled within the range 35-60%)</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.8		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is the environment in which clean non-sterile RIMD are inspected, assembled and packed controlled as a clean room to ISO 14644-1: 1999 Class 7 or 8?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.9		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is the clean area microbiologically monitored to demonstrate consistently low levels of microbial contamination. (Reference EN ISO 14698: 2003)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Suitability of decontamination facilities**

	3.3.10		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Are safe storage facilities provided for process chemicals used in decontamination?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

	3.3.11		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Are storage facilities for bulk items provided external to the clean room and the wash room?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

	3.3.12		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Are storage facilities provided for sterile product prior to despatch?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

**Suitability of decontamination facilities**

	<b>3.3.13</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
I	<input type="checkbox"/>	<p><b>Is the shelving in storage facilities manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging?</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No		Partial	A	B	C	Total score												
Score 10	Score 0			Score 8	Score 5	Score 2													
O	<input type="checkbox"/>																		
D	<input type="checkbox"/>																		

	<b>3.3.14</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
I	<input type="checkbox"/>	<p><b>Is required personal protective equipment easily accessible in each of the work areas?</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No		Partial	A	B	C	Total score												
Score 10	Score 0			Score 8	Score 5	Score 2													
O	<input type="checkbox"/>																		
D	<input type="checkbox"/>																		

	<b>3.3.15</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
I	<input type="checkbox"/>	<p><b>Is entry to the decontamination unit restricted to authorised personnel only?</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No		Partial	A	B	C	Total score												
Score 10	Score 0			Score 8	Score 5	Score 2													
O	<input type="checkbox"/>																		
D	<input type="checkbox"/>																		

**Suitability of decontamination facilities**

	3.3.16		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Is there a changing area for donning work wear which includes shower facilities, toilet facilities and lockers in proximity to the decontamination area?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category _____							

	3.3.17		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Is access to the wash room and to the clean room through separate dedicated gowning rooms provided with hand hygiene facilities?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category _____							

	3.3.18		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Is the area managed by trained staff whose sole or primary responsibility is management of the decontamination unit?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category _____							

**Suitability of decontamination facilities**

	3.3.19		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is the environment in which decontamination of RIMD takes place cleaned in accordance with procedures and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Nurse)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.20		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is dedicated cleaning provision (both equipment and storage) provided for the clean room and the wash room?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	3.3.21		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Are there are sufficient electricity supply, computer terminal points and work stations in the department?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Suitability of decontamination facilities**

	3.3.22		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Are the finishes on the walls and other surfaces flush, smooth, non-linting, water resistant and able to withstand frequent cleaning?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

	3.3.23		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Are the junctions between the walls and floors covered and flush?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

	3.3.24		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Are the fitments (where possible) flush with wall surfaces?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

**Suitability of decontamination facilities**

	3.3.25		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p><b>Are floors covered in a washable non-slip material which is securely sealed?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
		Yes	No	Partial		A	B	C	Total score									
		Score 10	Score 0		Score 8	Score 5	Score 2											

	3.3.26		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p><b>Is there adequate lighting available to permit good working practices and visual examination of RIMD?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
		Yes	No	Partial		A	B	C	Total score									
		Score 10	Score 0		Score 8	Score 5	Score 2											

	3.3.27		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p><b>Are task lighting and magnification in situ?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
		Yes	No	Partial		A	B	C	Total score									
		Score 10	Score 0		Score 8	Score 5	Score 2											

**Suitability of decontamination facilities**

	3.3.28		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Are all work surfaces, fittings, fixtures and furniture made of easily cleanable and robust material and maintained in good condition?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category _____							

	3.3.29		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Are the workstations equipped for the preparation of single or composite packs? Are they of adequate size to accommodate the wrapping material to be used and height adjustable?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category _____							

	3.3.30		<b>Y</b>	<b>P</b>	<b>N</b>				
I O D	<input type="checkbox"/>	<b>Is there adequate space between workstations for equipment and staff movement?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category _____							



**Suitability of decontamination facilities**

	3.3.31		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b> <b>O</b> <b>D</b>	<input type="checkbox"/>	Is the shelving of sufficient depth for all the materials to be held and not more than two metres high, unless special provision is made for loading and un-loading higher shelves?																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
		Yes				No	Partial	A	B	C	Total score								
Score 10	Score 0		Score 8	Score 5	Score 2														
Supporting Evidence/Comments																			
		Risk Category_____																	

	3.3.32		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b> <b>O</b> <b>D</b>	<input type="checkbox"/>	Are the wash room, clean room and steriliser unloading area free from 'opening' windows, ledges, and uncleanable areas?																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
		Yes				No	Partial	A	B	C	Total score								
Score 10	Score 0		Score 8	Score 5	Score 2														
Supporting Evidence/Comments																			
		Risk Category_____																	

	3.3.33		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b> <b>O</b> <b>D</b>	<input type="checkbox"/>	Are the wash area and clean room designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.)?																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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Score 10	Score 0		Score 8	Score 5	Score 2														
Supporting Evidence/Comments																			
		Risk Category_____																	

## Suitability of decontamination facilities—Standard Report Form

### Standard 3 Report Form

<b>Standard 3: Suitability of decontamination facilities</b>
Decontamination facilities shall be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination on clean and disinfected RIMD. For guidance see PD CEN ISO/TR 14969:2005. Additional detailed guidance is available in Health Building Note 13 (Sterile Service Departments)/Health Building Note 36 (Dental Facilities) and Health Building Note 52 (Endoscopy Units).
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

## Decontamination equipment

### Standard 4: Decontamination equipment

All decontamination equipment that does not meet the requirements of current standards shall be identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment shall be procured in conformance with extant harmonized standards. All decontamination equipment shall be validated, maintained, periodically tested and monitored to current standards.

4.3.1		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does the organisation have a specialist group in place to consider the decontamination equipment in the organisation? (See Standard 4, page 14, Part 2).</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> <tr> <th>Score 10</th> <th>Score 0</th> <th>Score 8</th> <th>Score 5</th> <th>Score 2</th> <th></th> </tr> </thead> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	
4.3.2		Y	P	N													
I O D	<input type="checkbox"/>	<p>Are key representatives represented on the specialist group? (See Standard 4, page 15, Part 2).</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> <tr> <th>Score 10</th> <th>Score 0</th> <th>Score 8</th> <th>Score 5</th> <th>Score 2</th> <th></th> </tr> </thead> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	
4.3.3		Y	P	N													
I O D	<input type="checkbox"/>	<p>Has the specialist group identified all decontamination equipment that needs to be replaced?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> <tr> <th>Score 10</th> <th>Score 0</th> <th>Score 8</th> <th>Score 5</th> <th>Score 2</th> <th></th> </tr> </thead> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

**Decontamination equipment**

	4.3.4		<b>Y</b>	<b>P</b>	<b>N</b>													
I  O  D	<input type="checkbox"/>	<p><b>Has the specialist group formulated a plan to replace or upgrade this equipment?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	4.3.5		<b>Y</b>	<b>P</b>	<b>N</b>													
I  O  D	<input type="checkbox"/>	<p><b>Has the plan been submitted to the senior management team and revised annually by the decontamination coordinator (or designated officer)?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	4.3.6		<b>Y</b>	<b>P</b>	<b>N</b>													
I  O  D	<input type="checkbox"/>	<p><b>Is there sufficient decontamination equipment available to meet the needs of the decontamination unit(s)?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Decontamination equipment**

	4.3.7		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p>Are there clearly defined policies and procedures for maintaining, testing, validating and day to day operation of decontamination equipment?</p> <table border="1" style="width:100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="width:15%;">Yes</td> <td style="width:15%;">No</td> <td style="width:15%;">Partial</td> <td style="width:10%;">A</td> <td style="width:10%;">B</td> <td style="width:10%;">C</td> <td style="width:15%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No		Partial	A	B	C	Total score												
Score 10	Score 0			Score 8	Score 5	Score 2													
<b>O</b>	<input type="checkbox"/>																		
<b>D</b>	<input type="checkbox"/>																		

	4.3.8		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p>Is the operational management of each item of decontamination equipment the defined responsibility of a named person (usually the decontamination unit manager)?</p> <table border="1" style="width:100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="width:15%;">Yes</td> <td style="width:15%;">No</td> <td style="width:15%;">Partial</td> <td style="width:10%;">A</td> <td style="width:10%;">B</td> <td style="width:10%;">C</td> <td style="width:15%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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Score 10	Score 0			Score 8	Score 5	Score 2													
<b>O</b>	<input type="checkbox"/>																		
<b>D</b>	<input type="checkbox"/>																		

	4.3.9		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p>Is the validation and periodic testing carried out by qualified personnel?</p> <table border="1" style="width:100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="width:15%;">Yes</td> <td style="width:15%;">No</td> <td style="width:15%;">Partial</td> <td style="width:10%;">A</td> <td style="width:10%;">B</td> <td style="width:10%;">C</td> <td style="width:15%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No		Partial	A	B	C	Total score												
Score 10	Score 0			Score 8	Score 5	Score 2													
<b>O</b>	<input type="checkbox"/>																		
<b>D</b>	<input type="checkbox"/>																		

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4.3.10		Y	P	N				
I O D	<input type="checkbox"/>	Are the validation and periodic testing data adequately audited quarterly by a qualified person (decontamination) registered with the Health Service Executive?						
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
		Supporting Evidence/Comments						
		Risk Category _____						

4.3.11		Y	P	N				
I O D	<input type="checkbox"/>	Does the department have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost?						
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
		Supporting Evidence/Comments						
		Risk Category _____						

4.3.12		Y	P	N				
<b>Manual Washing</b>								
I O D	<input type="checkbox"/>	Is manual washing used only when required by manufacturers' instructions or as a pre-treatment prior to reprocessing through a Washer-Disinfector (WD)?						
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
		Supporting Evidence/Comments						
		Risk Category _____						

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	4.3.13	<b>Manual Washing</b>	<b>Y</b>	<b>P</b>	<b>N</b>														
I O D	<input type="checkbox"/>	Are dedicated manual cleaning equipment and accessories available for specified RIMD that cannot be cleaned in an automated cleaning process?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category _____																		

	4.3.14	<b>Manual Washing</b>	<b>Y</b>	<b>P</b>	<b>N</b>														
I O D	<input type="checkbox"/>	Are separate sinks provided for washing and rinsing?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category _____																		

	4.3.15	<b>Manual Washing</b>	<b>Y</b>	<b>P</b>	<b>N</b>														
I O D	<input type="checkbox"/>	Is the detergent used one that is specified by the manufacturer for the manual cleaning of RIMD?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category _____																		

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	4.3.16	<b>Manual Washing</b>					<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Are means provided to control the concentration of detergent?</b>										
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
		<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments										
		Risk Category_____										

	4.3.17	<b>Manual Washing</b>					<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Is a pass-through drying cabinet with inter-locking doors provided for hot-air drying of manually washed RIMD that cannot be processed through a Washer-Disinfector?</b>										
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
		<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments										
		Risk Category_____										

	4.3.18	<b>Ultrasonic Cleaning</b>					<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Is a stand-alone ultrasonic cleaner provided for cleaning those RIMD which are required to be cleaned by this method according to the manufacturers' instructions or as a pre-treatment for RIMD prior to processing through a Washer-Disinfector?</b>										
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
		<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments										
		Risk Category_____										



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	4.3.19	Ultrasonic Cleaning					Y	P	N		
I O D	<input type="checkbox"/>	Is the ultrasonic cleaner equipped with the facility for automatic filling and emptying directly to the drain?									
	<input type="checkbox"/>	Yes	No	Partial	A	B				C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5				Score 2	
<input type="checkbox"/>	Supporting Evidence/Comments										
		Risk Category_____									

	4.3.20	Ultrasonic Cleaning					Y	P	N		
I O D	<input type="checkbox"/>	Is the ultrasonic cleaner fitted with a lid which is interlocked to prevent operation of the ultrasonic cleaner when the lid is open?									
	<input type="checkbox"/>	Yes	No	Partial	A	B				C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5				Score 2	
<input type="checkbox"/>	Supporting Evidence/Comments										
		Risk Category_____									

	4.3.21	Ultrasonic Cleaning					Y	P	N		
I O D	<input type="checkbox"/>	Is the detergent used one specified by the manufacturer for the ultrasonic cleaning of RIMD?									
	<input type="checkbox"/>	Yes	No	Partial	A	B				C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5				Score 2	
<input type="checkbox"/>	Supporting Evidence/Comments										
		Risk Category_____									

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	4.3.22	Ultrasonic Cleaning					<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Are means provided to control the concentration of detergent?</b>										
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
		Score 10	Score 0		Score 8	Score 5	Score 2					
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments										
		Risk Category_____										

	4.3.23	Ultrasonic Cleaning					<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Is the ultrasonic cleaner used in accordance with the manufacturers instructions?</b>										
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
		Score 10	Score 0		Score 8	Score 5	Score 2					
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments										
		Risk Category_____										

	4.3.24	Ultrasonic Cleaning					<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Is the ultrasonic cleaner is validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1, 2006?</b>										
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
		Score 10	Score 0		Score 8	Score 5	Score 2					
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments										
		Risk Category_____										

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	4.3.25	<b>Ultrasonic Cleaning</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	Is the temperature of the cleaning solution in the ultrasonic cleaner thermostatically controlled?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

	4.3.26	<b>Washer-Disinfectors</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	Does the specification of the washer-disinfector comply with requirements of EN ISO 15883, parts 1 &2?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

	4.3.27	<b>Washer-Disinfectors</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	Are washer-disinfectors double ended with the clean side discharging into the inspection area of the clean room?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

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	4.3.28	Washer-Disinfectors	Y	P	N														
I O D	<input type="checkbox"/>	Is each washer-disinfector fitted with an independent process monitoring system in accordance with EN ISO 15883, part 1?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	4.3.29	Washer-Disinfectors	Y	P	N														
I O D	<input type="checkbox"/>	When lumened devices are being reprocessed, is the washer-disinfector provided with load carriers that permit the irrigation of the lumened device?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	4.3.30	Washer-Disinfectors	Y	P	N														
I O D	<input type="checkbox"/>	Are washer-disinfectors and accessories specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1,2 & 5?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

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	4.3.31	Washer-Disinfectors	Y	P	N														
I O D	<input type="checkbox"/>	Is the Washer-Disinfector subject to planned preventative maintenance?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	4.3.32	Steam Steriliser	Y	P	N														
I O D	<input type="checkbox"/>	Does the specification of the steam steriliser comply with requirements of EN 285 and is the steriliser fitted with an air-detector?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	4.3.33	Steam Steriliser	Y	P	N														
I O D	<input type="checkbox"/>	Is the steam steriliser fitted with a process monitoring system independent of the automatic controller?																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

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	4.3.34	Steam Steriliser	Y	P	N														
I	<input type="checkbox"/>	Is the sterilisation hold period at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

	4.3.35	Steam Steriliser	Y	P	N														
I	<input type="checkbox"/>	Are steam sterilisers double ended with the loading side in the clean room?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

	4.3.36	Steam Steriliser	Y	P	N														
I	<input type="checkbox"/>	Are sterilizers and accessories specified, installed, commissioned, tested and operated in accordance with the current standard EN 285 and EN ISO 17665, part 1?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

**Decontamination equipment**

	4.3.37	<b>Steam Steriliser</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<b>Are the steam sterilisers subject to planned preventative maintenance?</b>																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category _____																

	4.3.38	<b>Low Temperature Sterilisers</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<b>Are low temperature sterilisation methods only used where the manufacturers' instructions do not permit steam sterilisation?</b>																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category _____																

	4.3.39	<b>Low Temperature Sterilisers</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<b>Is low temperature sterilisation carried out using vapour phase Hydrogen Peroxide or Hydrogen Peroxide Plasma processes?</b>																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category _____																

**Decontamination equipment**

	4.3.40	Low Temperature Sterilisers	Y	P	N													
I	<input type="checkbox"/>	Have low temperature sterilisation methods been validated and are they subject to periodic testing in accordance with ISO 14937?																
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
Yes	No	Partial				A	B		C	Total score								
Score 10	Score 0		Score 8	Score 5	Score 2													
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																

	4.3.41	Low Temperature Sterilisers	Y	P	N													
I	<input type="checkbox"/>	Are low temperature sterilisers subject to planned preventative maintenance?																
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
Yes	No	Partial				A	B		C	Total score								
Score 10	Score 0		Score 8	Score 5	Score 2													
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																

	4.3.42	Drying Cabinet	Y	P	N													
I	<input type="checkbox"/>	Is a pass-through drying cabinet provided between the wash-room and the clean room? Are the doors of the drying cabinet interlocked to prevent direct connection between the wash room and the clean room?																
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
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Score 10	Score 0		Score 8	Score 5	Score 2													
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																



### Decontamination equipment

	4.3.43	Drying Cabinet	Y	P	N													
I O D	<input type="checkbox"/>	<p>Is the drying cabinet fitted with a temperature indicator and/or re-corder independent of the controller?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	4.3.44	Drying Cabinet	Y	P	N													
I O D	<input type="checkbox"/>	<p>Is the drying temperature throughout the cabinet within <math>\pm 5^\circ</math> Celsius of the set temperature?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	4.3.45	Drying Cabinet	Y	P	N													
I O D	<input type="checkbox"/>	<p>Is the drying cabinet fitted with an over-temperature cut-out such that if the temperature in the cabinet exceeds the set temperature by more than <math>10^\circ</math> Celsius the heating source is isolated?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Decontamination equipment**

	4.3.46	Drying Cabinet	Y	P	N														
I	<input type="checkbox"/>	Is the air in the cabinet mechanically circulated and are items placed throughout the cabinet dried uniformly?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

	4.3.47	Drying Cabinet	Y	P	N														
I	<input type="checkbox"/>	Is the drying cabinet subject to planned preventative maintenance?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

	4.3.48	Heat Sealer	Y	P	N														
I	<input type="checkbox"/>	Where heat seal packaging is to be used, is a rotary heat sealer provided?																	
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

**Decontamination equipment**

	4.3.49	Heat Sealer		<b>Y</b>	<b>P</b>	<b>N</b>												
I O D	<input type="checkbox"/>	<p>Is heat-sealing equipment used as part of the terminal packaging process maintained and tested to manufacturer’s performance criteria?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	4.3.50	Heat Sealer		<b>Y</b>	<b>P</b>	<b>N</b>												
I O D	<input type="checkbox"/>	<p>Is the heat sealer validated and tested daily to verify the efficacy of the seal?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	4.3.51	Heat Sealer		<b>Y</b>	<b>P</b>	<b>N</b>												
I O D	<input type="checkbox"/>	<p>Is the heat sealer subject to planned preventative maintenance?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

## Decontamination Equipment—Standard Report Form

### Standard 4 Report Form

<b>Standard 4: Decontamination equipment</b>
All decontamination equipment that does not meet the requirements of current standards shall be identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment shall be procured in conformance with extant harmonized standards. All decontamination equipment shall be validated, maintained, periodically tested and monitored to current standards.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

**Procurement of reusable invasive medical devices**

**Standard 5: Procurement of reusable invasive medical devices (RIMD)**

Decontamination issues are considered prior to the acquisition of RIMD.

		<b>5.3.1</b>		<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Does the organisation have a specialist group in place to consider the procurement of RIMD?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A	B		C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5		Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

		<b>5.3.2</b>		<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Are key representatives represented on the specialist group? (see Standard 5, Page 19, Part 2).</b>							
	<input type="checkbox"/>	Yes	No	Partial	A	B		C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5		Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

		<b>5.3.3</b>		<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Does the organisation have a documented procurement policy?</b>							
	<input type="checkbox"/>	Yes	No	Partial	A	B		C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5		Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

**Procurement of reusable invasive medical devices**

	5.3.4		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Does the procurement policy comply with the Irish Medicines Board (IMB) recommendations on the procurement of RIMD?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
		Risk Category_____								

	5.3.5		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Is the procurement of RIMD based on agreed specifications and does the procurement of RIMD comply with the documented procurement policy?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
		Risk Category_____								

	5.3.6		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Is there a detailed specification for each RIMD which complies with current standards?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
		Risk Category_____								

**Procurement of reusable invasive medical devices**

	5.3.7		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p>Are sufficient RIMD and accessories purchased to allow adequate time for reprocessing in the decontamination unit(s) without adversely affecting throughput?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
		Yes	No	Partial		A	B	C	Total score									
		Score 10	Score 0		Score 8	Score 5	Score 2											
Supporting Evidence/Comments																		
Risk Category_____																		

	5.3.8		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p>Is a decontamination assessment undertaken prior to the purchase of RIMD to ensure that the organisation has the facilities to reprocess the RIMD in accordance with the manufacturers instructions?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
		Yes	No	Partial		A	B	C	Total score									
		Score 10	Score 0		Score 8	Score 5	Score 2											
Supporting Evidence/Comments																		
Risk Category_____																		

	5.3.9		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p>Are value for money issues considered when purchasing RIMD?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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		Score 10	Score 0		Score 8	Score 5	Score 2											
Supporting Evidence/Comments																		
Risk Category_____																		

**Procurement of reusable invasive medical devices**

	5.3.10		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	Are goods and services purchased from suppliers in line with HSE procurement policy?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

	5.3.11		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	Are all RIMD and accessories CE marked?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

	5.3.12		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	Are suppliers selected based on their ability to supply RIMD in accordance with the specified requirements and provide service support over the lifetime of the RIMD, where applicable?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																



**Procurement of reusable invasive medical devices**

	5.3.13		Y	P	N														
I	<input type="checkbox"/>	Are there means to ensure that where parts are single-use or have restricted use that this information is provided prior to purchasing?																	
O	<input type="checkbox"/>	<table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
D	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																	

## Procurement of reusable invasive medical devices—Standard Report Form

### Standard 5 Report Form

Standard 5: Procurement of reusable invasive medical devices (RIMD)
Decontamination issues shall be considered prior to the acquisition of RIMD.
Standard Summary
Summary of Main Findings of the Audit
Conformance in the area:  Non-conformance in the area:
Standard Score:

## Decontamination process

### Standard 6: Decontamination process

RIMD e.g. surgical instruments, powered devices, rigid and flexible endoscopes, etc. shall be decontaminated in accordance with the recommendations of the manufacturers validated instructions for decontamination (Ref. EN ISO 17664:2004) current legislation and quality system standards.

6.3.1		Y	P	N													
I O D	<input type="checkbox"/>	<b>Are all stages of the decontamination process clearly defined, documented, controlled and recorded?</b>															
	<input type="checkbox"/>																
	<input type="checkbox"/>																
<table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No	Partial	A		B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2												
Supporting Evidence/Comments  Risk Category _____																	

6.3.2		Y	P	N													
I O D	<input type="checkbox"/>	<b>Are all processes carried out in accordance with documented procedures?</b>															
	<input type="checkbox"/>																
	<input type="checkbox"/>																
<table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No	Partial	A		B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2												
Supporting Evidence/Comments  Risk Category _____																	

6.3.3		Y	P	N													
I O D	<input type="checkbox"/>	<b>Are all RIMD sets traced through the decontamination process to the patient?</b>															
	<input type="checkbox"/>																
	<input type="checkbox"/>																
<table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table>		Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
Yes	No	Partial	A		B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2												
Supporting Evidence/Comments  Risk Category _____																	

**Decontamination process**

	<b>6.3.4</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p><b>Are processing data retained for the lifetime of the equipment plus eleven years?</b></p>																	
<b>O</b>	<input type="checkbox"/>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:15%;">Yes</td> <td style="width:15%;">No</td> <td style="width:15%;">Partial</td> <td style="width:15%;">A</td> <td style="width:15%;">B</td> <td style="width:15%;">C</td> <td style="width:15%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																	

	<b>6.3.5</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p><b>Is there a regular review of all procedures and are any necessary changes implemented by a documented change in procedures?</b></p>																	
<b>O</b>	<input type="checkbox"/>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:15%;">Yes</td> <td style="width:15%;">No</td> <td style="width:15%;">Partial</td> <td style="width:15%;">A</td> <td style="width:15%;">B</td> <td style="width:15%;">C</td> <td style="width:15%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																	

	<b>6.3.6</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p><b>Are RIMD checked and reprocessed in accordance with the manufacturers' instructions?</b></p>																	
<b>O</b>	<input type="checkbox"/>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:15%;">Yes</td> <td style="width:15%;">No</td> <td style="width:15%;">Partial</td> <td style="width:15%;">A</td> <td style="width:15%;">B</td> <td style="width:15%;">C</td> <td style="width:15%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																	

**Decontamination process**

	<b>6.3.7</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p><b>Are all RIMD visually inspected for cleanliness prior to packing?</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																	
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	<b>6.3.8</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p><b>Are all RIMD inspected and/or tested for functionality prior to packing?</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																	
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	<b>6.3.9</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p><b>Is there a formal release procedure for sterile product to ensure that only RIMD that have been subjected to a satisfactory sterilisation cycle are released for use?</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																	
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

**Decontamination process**

	6.3.10		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p>Is all product released from the decontamination unit labelled with a clear indication of the pack contents, the expiry date and a unique number which can be used to trace the decontamination processes to which the device was subjected?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	

	6.3.11		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p>Are single use devices <i>not</i> reprocessed?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	

## Decontamination process—Standard Report Form

### Standard 6 Report Form

<b>Standard 6: Decontamination process</b>
RIMD e.g. surgical instruments, powered devices, rigid and flexible endoscopes, etc. shall be decontaminated in accordance with the recommendations of the manufacturers validated instructions for decontamination (Ref. EN ISO 17664:2004) current legislation and quality system standards.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>  <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

## Management and key personnel

### Standard 7: Management and key personnel

Appropriately qualified key personnel shall be in place to ensure that the decontamination service is provided effectively and efficiently.

7.3.1		Y	P	N				
I O D	<input type="checkbox"/>	<b>Has the <i>CEO/Manager</i> put in place arrangements to ensure effective decontamination of RIMD?</b>						
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments						
		Risk Category_____						

7.3.2		Y	P	N				
I O D	<input type="checkbox"/>	<b>Has a <i>Decontamination Coordinator</i> been appointed? Does s/he have formally defined responsibilities in accordance with these standards? Has s/he been provided with the necessary resource to discharge these responsibilities?</b>						
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments						
		Risk Category_____						

7.3.3		Y	P	N				
I O D	<input type="checkbox"/>	<b>Does each <i>Decontamination Unit</i> have a person appointed with responsibility for operational management of the unit, which may be in addition to other duties?</b>						
	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments						
		Risk Category_____						



### Management and key personnel

	7.3.4		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	<p><b>Are <i>Maintenance Personnel</i> (in-house or sub-contracted) available and is there documentary evidence to demonstrate competence in the maintenance of the decontamination equipment they will be dealing with?</b></p> <table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width:12.5%;">Yes</td> <td style="width:12.5%;">No</td> <td style="width:12.5%;">Partial</td> <td style="width:12.5%;">A</td> <td style="width:12.5%;">B</td> <td style="width:12.5%;">C</td> <td style="width:12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

	7.3.5		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	<p><b>Are <i>Test Personnel</i> (in-house or sub-contracted) available and is there documentary evidence to demonstrate competence in periodic testing of the decontamination equipment which they will be dealing with?</b></p> <table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width:12.5%;">Yes</td> <td style="width:12.5%;">No</td> <td style="width:12.5%;">Partial</td> <td style="width:12.5%;">A</td> <td style="width:12.5%;">B</td> <td style="width:12.5%;">C</td> <td style="width:12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

	7.3.6		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	<p><b>Is a <i>Microbiologist</i> available to advise on microbiological aspects of decontamination?</b></p> <table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width:12.5%;">Yes</td> <td style="width:12.5%;">No</td> <td style="width:12.5%;">Partial</td> <td style="width:12.5%;">A</td> <td style="width:12.5%;">B</td> <td style="width:12.5%;">C</td> <td style="width:12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

### Management and Key Personnel

	7.3.7		Y	P	N														
I  O  D	<input type="checkbox"/>	Is an <i>Infection Prevention and Control Nurse</i> available to advise on all aspects of infection surveillance, prevention and control?																	
	<input type="checkbox"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	7.3.8		Y	P	N														
I  O  D	<input type="checkbox"/>	Has the Decontamination Unit Manager designated <i>Operatives</i> to be responsible for each aspect of the decontamination process and has s/he ensured that these personnel have been trained to the necessary standard of competence?																	
	<input type="checkbox"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No				Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	7.3.9		Y	P	N														
I  O  D	<input type="checkbox"/>	Is a <i>Biomedical Engineer/Clinical Engineer</i> available and designated by management for the testing and validation of decontamination equipment?																	
	<input type="checkbox"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
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Score 10	Score 0		Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

**Management and key personnel**

	7.3.10		Y	P	N														
I O D	<input type="checkbox"/>	<p>Is the <i>Qualified Person (decontamination)</i> used by the organisation a person registered as an Authorised Person (Sterilisers) with the Institute of Healthcare Engineering and Estates Management and registered with the Health Service Executive as competent to discharge the duties of a Qualified Person (decontamination) in Ireland?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th>Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

**Management and key personnel—Standard Report Form**

Standard 7 Report Form

<b>Standard 7: Management and key personnel</b>
Appropriately qualified key personnel shall be in place to ensure that the decontamination service is provided effectively and efficiently.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
Conformance in the area:  Non-conformance in the area:
Standard Score:

### Education and training

#### Standard 8: Education and training

Education and Training in relevant aspects of decontamination practice shall be provided to all new, temporary and existing staff members.

	<b>8.3.1</b>		<b>Y</b>	<b>P</b>	<b>N</b>															
<b>I</b>	<input type="checkbox"/>	<p><b>Does the organisation have a general induction training programme that includes the areas as outlined in Standard 8, Page 25, Part 2?</b></p>																		
	<input type="checkbox"/>					<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td style="text-align: center;">Score 10</td> <td style="text-align: center;">Score 0</td> <td></td> <td style="text-align: center;">Score 8</td> <td style="text-align: center;">Score 5</td> <td style="text-align: center;">Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes					No	Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2															
<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

	<b>8.3.2</b>		<b>Y</b>	<b>P</b>	<b>N</b>															
<b>I</b>	<input type="checkbox"/>	<p><b>Are the issues as outlined in Standard 8, Page 26, Part 2 addressed in the training of clinical staff?</b></p>																		
	<input type="checkbox"/>					<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td style="text-align: center;">Score 10</td> <td style="text-align: center;">Score 0</td> <td></td> <td style="text-align: center;">Score 8</td> <td style="text-align: center;">Score 5</td> <td style="text-align: center;">Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes					No	Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2															
<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

	<b>8.3.3</b>		<b>Y</b>	<b>P</b>	<b>N</b>															
<b>I</b>	<input type="checkbox"/>	<p><b>Are the issues as outlined in Standard 8, Page 27, Part 2 addressed in the training of staff who work in decontamination units?</b></p>																		
	<input type="checkbox"/>					<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td style="text-align: center;">Score 10</td> <td style="text-align: center;">Score 0</td> <td></td> <td style="text-align: center;">Score 8</td> <td style="text-align: center;">Score 5</td> <td style="text-align: center;">Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes					No	Partial	A	B	C	Total score									
Score 10	Score 0		Score 8	Score 5	Score 2															
<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																			

**Education and training**

	<b>8.3.4</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p><b>Is induction training recorded in the relevant individuals training record?</b></p>																	
<b>O</b>	<input type="checkbox"/>	<table border="1" style="width:100%; border-collapse: collapse; margin-bottom: 5px;"> <tr> <td style="width:15%;">Yes</td> <td style="width:15%;">No</td> <td style="width:15%;">Partial</td> <td style="width:10%;">A</td> <td style="width:10%;">B</td> <td style="width:10%;">C</td> <td style="width:25%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																	

	<b>8.3.5</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p><b>Is there a continuing programme of training and education for staff?</b></p>																	
<b>O</b>	<input type="checkbox"/>	<table border="1" style="width:100%; border-collapse: collapse; margin-bottom: 5px;"> <tr> <td style="width:15%;">Yes</td> <td style="width:15%;">No</td> <td style="width:15%;">Partial</td> <td style="width:10%;">A</td> <td style="width:10%;">B</td> <td style="width:10%;">C</td> <td style="width:25%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																	

	<b>8.3.6</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<p><b>Is training supported with adequate resources and facilities?</b></p>																	
<b>O</b>	<input type="checkbox"/>	<table border="1" style="width:100%; border-collapse: collapse; margin-bottom: 5px;"> <tr> <td style="width:15%;">Yes</td> <td style="width:15%;">No</td> <td style="width:15%;">Partial</td> <td style="width:10%;">A</td> <td style="width:10%;">B</td> <td style="width:10%;">C</td> <td style="width:25%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																	

**Education and training**

	<b>8.3.7</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	Are individual competencies assessed and are records kept in the unit?																	
<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																	

	<b>8.3.8</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	Is there a formal appraisal system in place to monitor staff performance and to identify individual training needs?																	
<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No	Partial	A	B	C	Total score													
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																	

**Education and training—Standard Report Form**

Standard 8 Report Form

<b>Standard 8: Education and training</b>
Education and training in relevant aspects of decontamination practice shall be provided to all new, temporary and existing staff members.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>
<b>Standard Score:</b>



## Quality management system

### Standard 9: Quality management system

Central decontamination units shall operate a quality management system in accordance with EN ISO 13485. Endoscope and local decontamination units shall operate a quality system in accordance with the key operational elements of EN ISO 13485.

	9.3.1		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p><b>Do the Central Decontamination Units in the organisation operate a quality management system in accordance with EN ISO 13485?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	
		<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

	9.3.2	<b>Endoscope and Local Decontamination Units</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p><b>Does the organisation have documented policies, procedures and records for all the key elements of the decontamination process? For each decontamination unit, are key policies, procedures and guidelines (where relevant) in place as outlined in Standard 9, Page 29, Part 2?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	
		<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

	9.3.3	<b>Endoscope and Local Decontamination Units</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p><b>Do all policies and procedures associated with decontamination of RIMD comply with current standards, legislation and Health Service Executive guidance?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	
		<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

**Quality management system**

	9.3.4	Endoscope and Local Decontamination Units					Y	P	N												
I	<input type="checkbox"/>	Does the quality and risk committee (or appropriate committee) approve policies, procedures and guidelines for decontamination of RIMD in the organisation?																			
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>					Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2			
Yes	No	Partial	A	B	C	Total score															
Score 10	Score 0		Score 8	Score 5	Score 2																
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category _____																			

	9.3.5	Endoscope and Local Decontamination Units					Y	P	N												
I	<input type="checkbox"/>	Is there a system to ensure each department or service has a current copy of the approved decontamination of RIMD policies, procedures and guidelines pertinent to its activities?																			
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>					Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2			
Yes	No	Partial	A	B	C	Total score															
Score 10	Score 0		Score 8	Score 5	Score 2																
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category _____																			

	9.3.6	Endoscope and Local Decontamination Units					Y	P	N												
I	<input type="checkbox"/>	Are all relevant staff required to read the decontamination of RIMD policies and procedures relevant to their area of work and to sign a statement to indicate that they have read, understood and will comply with same?																			
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>					Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2			
Yes	No	Partial	A	B	C	Total score															
Score 10	Score 0		Score 8	Score 5	Score 2																
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category _____																			

**Quality management system**

	9.3.7	<b>Endoscope and Local Decontamination Units</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<b>Are all policy and procedure documents associated with decontamination of RIMD controlled showing the date of issue and revision number?</b>																
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
Yes	No	Partial				A	B		C	Total score								
Score 10	Score 0		Score 8	Score 5	Score 2													
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category _____																

	9.3.8	<b>Endoscope and Local Decontamination Units</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<b>Are master copies kept in a secure location?</b>																
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
Yes	No	Partial				A	B		C	Total score								
Score 10	Score 0		Score 8	Score 5	Score 2													
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category _____																

	9.3.9	<b>Endoscope and Local Decontamination Units</b>	<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<b>Are obsolete documents removed from all points of use?</b>																
O	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
Yes	No	Partial				A	B		C	Total score								
Score 10	Score 0		Score 8	Score 5	Score 2													
D	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category _____																

**Quality management system**

	<b>9.3.10</b>	<b>Endoscope and Local Decontamination Units</b>					<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Is there a biennial review of all policies, procedures and documents associated with decontamination of RIMD undertaken to check their relevance and issue status?</b>										
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<b>D</b>	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
		Supporting Evidence/Comments										
		Risk Category_____										

	<b>9.3.11</b>	<b>Endoscope and Local Decontamination Units</b>					<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Is there a computerised documentary system available within each decontamination unit to allow the provision of appropriate information to senior management as required? Are decontamination unit personnel proficient in the application and operation of such systems?</b>										
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<b>D</b>	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
		Supporting Evidence/Comments										
		Risk Category_____										

	<b>9.3.12</b>	<b>Endoscope and Local Decontamination Units</b>					<b>Y</b>	<b>P</b>	<b>N</b>			
<b>I</b>	<input type="checkbox"/>	<b>Is all data (electronic and manual) stored securely? Is electronic data backed up and audited in accordance with the organisations policy?</b>										
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C				Total score
	<b>D</b>	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2				
		Supporting Evidence/Comments										
		Risk Category_____										

**Quality management system**

	9.3.13	Endoscope and Local Decontamination Units					Y	P	N
I	<input type="checkbox"/>	Is access to data/records restricted to authorised named persons and is specified information maintained in line with the Data Protection Acts?							
O	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score	
D	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2		
		Supporting Evidence/Comments							
		Risk Category_____							

	9.3.14	Endoscope and Local Decontamination Units					Y	P	N
I	<input type="checkbox"/>	Are all records associated with the decontamination life cycle retained for the life-time of the equipment/RIMD plus eleven years?							
O	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score	
D	<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2		
		Supporting Evidence/Comments							
		Risk Category_____							

**Quality management system**

	9.3.15	Endoscope and Local Decontamination Units	Y	P	N														
I	<input type="checkbox"/>	<p>Are these records securely stored and readily accessible to permit traceability when required?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
Yes	No		Partial	A	B	C	Total score												
Score 10	Score 0			Score 8	Score 5	Score 2													
O	<input type="checkbox"/>																		
D	<input type="checkbox"/>																		

## Quality management system—Standard Report Form

### Standard 9 Report Form

<b>Standard 9: Quality management system</b>
Central decontamination units shall operate a quality management system in accordance with EN ISO 13485. Endoscope and local decontamination units shall operate a quality system in accordance with the key operational elements of EN ISO 13485.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>       <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

## Risk management system

### Standard 10: Risk management system

The organisation shall have a risk management system in place to identify the hazards associated with the decontamination process, to estimate and evaluate the risks, control the risks and monitor the effectiveness of the control.

	<b>10.3.1</b>		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p><b>Has the organisation compiled a list of foreseeable hazards associated with each stage in the decontamination process?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
	<input type="checkbox"/>	Supporting Evidence/Comments																
<b>D</b>	<input type="checkbox"/>	Risk Category_____																

	<b>10.3.2</b>		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p><b>Is the list of hazards maintained in a risk management file?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
	<input type="checkbox"/>	Supporting Evidence/Comments																
<b>D</b>	<input type="checkbox"/>	Risk Category_____																

	<b>10.3.3</b>		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p><b>Are all identified hazards documented as part of a risk register and systematically assessed and prioritised?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
	<input type="checkbox"/>	Supporting Evidence/Comments																
<b>D</b>	<input type="checkbox"/>	Risk Category_____																



**Risk management system**

	<b>10.3.4</b>		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Has the organisation identified and assessed all risks associated with all stages in the decontamination process?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
		Risk Category_____								

	<b>10.3.5</b>		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Has the organisation instituted control measures for identified risks?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
		Risk Category_____								

	<b>10.3.6</b>		<b>Y</b>	<b>P</b>	<b>N</b>					
<b>I</b>	<input type="checkbox"/>	<b>Does the organisation have a monitoring programme in place to verify conformance with policies and procedures?</b>								
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial		A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0			Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments								
		Risk Category_____								

**Risk management system**

	<b>10.3.7</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<b>Has the organisation documented arrangements for responding to emergencies?</b>																	
<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

	<b>10.3.8</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<b>Has the organisation identified, recorded and analysed ‘adverse events’ and ‘near misses’?</b>																	
<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

	<b>10.3.9</b>		<b>Y</b>	<b>P</b>	<b>N</b>														
<b>I</b>	<input type="checkbox"/>	<b>Does the organisation have a reporting procedure for reporting accidents and incidents to the relevant authorities? (See Standard 10, Page 33, Part 2)</b>																	
<b>O</b>	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
Yes	No	Partial				A	B	C	Total score										
Score 10	Score 0		Score 8	Score 5	Score 2														
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																	

**Risk management system**

	10.3.10		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p>Does the organisation have a documented decontamination policy with clear reference to risk management? (See Standard 10, Page 33, Part 2).</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
		Yes	No	Partial		A	B	C	Total score									
		Score 10	Score 0		Score 8	Score 5	Score 2											

	10.3.11		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p>Has the organisation taken measures to ensure that all relevant employees receive adequate information concerning matters relating to the Safety, Health and Welfare at Work Act, 2005?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
		Yes	No	Partial		A	B	C	Total score									
		Score 10	Score 0		Score 8	Score 5	Score 2											

	10.3.12		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p>Are Material Safety Data Sheets made available to all staff who are using potentially hazardous chemicals?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
		Yes	No	Partial		A	B	C	Total score									
		Score 10	Score 0		Score 8	Score 5	Score 2											

**Risk management system**

	10.3.13		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	Have chemical risk assessments been completed and brought to the attention of all relevant staff?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

	10.3.14		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	Does each department where decontamination of RIMD takes place have a Departmental Safety statement which documents physical, chemical, biological and psychological hazards and associated protective and preventative measures?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

	10.3.15		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	Does the organisation have a documented staff decontamination training programme to include induction of all new staff through to continual professional development for all other grades?																
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes	No				Partial	A		B	C	Total score							
Score 10	Score 0	Score 8	Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																	
		Risk Category_____																

## Risk Management System—Standard Report Form

### Standard 10 Report Form

<b>Standard 10: Risk management system</b>
The organisation shall have a risk management system in place to identify the hazards associated with the decontamination process, to estimate and evaluate the risks, control the risks and monitor the effectiveness of the control.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>   <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

## Health and safety

### Standard 11: Health and safety

Decontamination shall be carried out in a manner that minimizes the risk to patients and staff from contamination on used RIMD and process chemicals.

11.3.1		Y	P	N													
I O D	<input type="checkbox"/>	<p>Is each decontamination unit manager and their staff aware of and do they have access to current health and safety regulations and guidelines as they apply to the decontamination unit?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

11.3.2		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does each decontamination unit have a health and safety policy which is available and disseminated to staff. Is this policy up to date and regularly reviewed?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

11.3.3		Y	P	N													
I O D	<input type="checkbox"/>	<p>Does each decontamination unit has access to competent health and safety advice?</p> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

**Health and safety**

	11.3.4		<b>Y</b>	<b>P</b>	<b>N</b>														
I O D	<input type="checkbox"/>	<b>Has each decontamination unit identified the decontamination processes that may generate substances hazardous to health?</b>																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial		A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes	No	Partial	A			B	C	Total score										
Score 10	Score 0	Score 8		Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	11.3.5		<b>Y</b>	<b>P</b>	<b>N</b>														
I O D	<input type="checkbox"/>	<b>Are these processes contained by appropriate precautions?</b>																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial		A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes	No	Partial	A			B	C	Total score										
Score 10	Score 0	Score 8		Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

	11.3.6		<b>Y</b>	<b>P</b>	<b>N</b>														
I O D	<input type="checkbox"/>	<b>Are there regular audits of conformance with the control measures?</b>																	
	<input type="checkbox"/>	<table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial		A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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Score 10	Score 0	Score 8		Score 5	Score 2														
<input type="checkbox"/>	Supporting Evidence/Comments																		
		Risk Category_____																	

**Health and safety**

	11.3.7		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Does each decontamination unit have procedures in place to deal with accidents, incidents and emergencies?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

	11.3.8		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Are flammable liquids and chemicals stored in flame-proof cupboards which are kept locked and closed?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

	11.3.9		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Are emergency treatment kits for contact with personnel/spillages provided and easily accessible in the work area?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																



**Health and safety**

	11.3.10		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p>Are there procedures in place to ensure that all decontamination equipment and accessories are specified, installed, commissioned, tested and operated in accordance with current standards?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	
		Supporting Evidence/Comments																
		Risk Category _____																

	11.3.11		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p>Is personal protective equipment provided and easily accessible in the work area?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	
		Supporting Evidence/Comments																
		Risk Category _____																

	11.3.12		<b>Y</b>	<b>P</b>	<b>N</b>													
I	<input type="checkbox"/>	<p>Is there a formal, documented release for sterile RIMD to ensure that the RIMD is only returned for use on a patient after it has been decontaminated using validated reprocessing equipment and in line with the manufacturers' instructions?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
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O	<input type="checkbox"/>																	
D	<input type="checkbox"/>																	
		Supporting Evidence/Comments																
		Risk Category _____																

**Health and safety**

	11.3.13		<b>Y</b>	<b>P</b>	<b>N</b>															
I O D	<input type="checkbox"/>	<b>Are current copies of approved infection prevention and control-policies and procedures in relation to decontamination of RIMD readily accessible to staff in each decontamination unit?</b>																		
	<input type="checkbox"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>					Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No	Partial	A	B		C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2															
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																			

	11.3.14		<b>Y</b>	<b>P</b>	<b>N</b>															
I O D	<input type="checkbox"/>	<b>Are occupational health services provided for all staff?</b>																		
	<input type="checkbox"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>					Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
	Yes	No	Partial	A	B		C	Total score												
Score 10	Score 0		Score 8	Score 5	Score 2															
<input type="checkbox"/>	Supporting Evidence/Comments  Risk Category_____																			

## Health and safety—Standard Report Form

### Standard 11 Report Form

<b>Standard 11: Health and safety</b>
Decontamination shall be carried out in a manner that minimizes the risk to patients and staff from contamination on used RIMD and process chemicals.
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

## Complaints management

### Standard 12: Complaints management

All complaints and comments shall be properly managed and shall be systematically recorded and analysed to identify trends and other performance information.

12.3.1		Y	P	N			
I O D	<input type="checkbox"/>	<b>Does the documented complaint system covers the areas as outlined in Standard 12, Page 36, Part 2?</b>					
	<input type="checkbox"/>	Yes Score 10	No Score 0	Partial A Score 8	B Score 5	C Score 2	Total score
	<input type="checkbox"/>	Supporting Evidence/Comments					
		Risk Category_____					

12.3.2		Y	P	N			
I O D	<input type="checkbox"/>	<b>Is corrective action implemented without undue delay when a finished product is found to be defective or is subject to adverse reports? (See Standard 12, Page 37, Part 2)</b>					
	<input type="checkbox"/>	Yes Score 10	No Score 0	Partial A Score 8	B Score 5	C Score 2	Total score
	<input type="checkbox"/>	Supporting Evidence/Comments					
		Risk Category_____					

12.3.3		Y	P	N			
I O D	<input type="checkbox"/>	<b>Is preventative action implemented to ensure as far as practicable that there will be no recurrence of the non-conformance? Is the efficacy of the preventative action verified?</b>					
	<input type="checkbox"/>	Yes Score 10	No Score 0	Partial A Score 8	B Score 5	C Score 2	Total score
	<input type="checkbox"/>	Supporting Evidence/Comments					
		Risk Category_____					

## Complaints management—Standard Report Form

### Standard 12 Report Form

<b>Standard 12: Complaints management</b>
All complaints and comments shall be properly managed and shall be systematically recorded and analysed to identify trends and other performance information
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

### Audit and monitoring

#### Standard 13: Audit and monitoring

Audits shall be carried out to ensure that the procedures for decontamination of RIMD conforms to the required standard, that the processes undertaken conform to the procedures and to identify opportunities for improvement.

13.3.1		Y	P	N													
I O D	<input type="checkbox"/>	<b>Does audit of decontamination of RIMD include:</b> <ul style="list-style-type: none"> <li>Accountability arrangements?</li> <li>Staff knowledge, expertise and resources?</li> <li>Processes, including risk management arrangements?</li> <li>Policies, procedures and guidelines?</li> </ul> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

13.3.2		Y	P	N													
I O D	<input type="checkbox"/>	<b>Is each decontamination unit manager responsible for preparing a written agreed programme which ensures that all aspects of the decontamination process and its management within the unit are audited at least once a year?</b> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

13.3.3		Y	P	N													
I O D	<input type="checkbox"/>	<b>Is each decontamination unit manager responsible for ensuring that the audit is conducted in accordance with this programme?</b> <table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> <th rowspan="2">Partial</th> <th>A</th> <th>B</th> <th>C</th> <th>Total score</th> </tr> </thead> <tbody> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </tbody> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>			Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2	
	Yes				No	Partial		A	B	C	Total score						
	Score 10				Score 0		Score 8	Score 5	Score 2								
<input type="checkbox"/>																	
<input type="checkbox"/>																	

**Audit and monitoring**

	13.3.4		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is each decontamination unit manager responsible for ensuring that remedial actions are carried out for any deficiencies found and for verifying the efficacy of remedial actions undertaken?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	13.3.5		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Is the quality and risk committee (or appropriate committee) responsible for ensuring that the audit activity, under the responsibility of each decontamination unit manager has been completed?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	13.3.6		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Are audit results fed back to the decontamination coordinator, the quality and risk committee (or appropriate committee), relevant staff and the Senior Management Team?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category _____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Audit and monitoring**

	13.3.7		<b>Y</b>	<b>P</b>	<b>N</b>				
<b>I</b>	<input type="checkbox"/>	<b>Are audit results included in the quality and risk management annual report (or appropriate annual report)?</b>							
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

	13.3.8		<b>Y</b>	<b>P</b>	<b>N</b>				
<b>I</b>	<input type="checkbox"/>	<b>Are audit results used to help to inform and improve practices in relation to decontamination of RIMD?</b>							
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

	13.3.9		<b>Y</b>	<b>P</b>	<b>N</b>				
<b>I</b>	<input type="checkbox"/>	<b>Are the audits carried out by appropriately trained auditors?</b>							
	<b>O</b>	<input type="checkbox"/>	Yes	No	Partial	A	B	C	Total score
		<input type="checkbox"/>	Score 10	Score 0		Score 8	Score 5	Score 2	
<b>D</b>	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

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**Audit and monitoring**

	13.3.10		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Does the Senior Management Team submit an annual assurance statement on audit findings for consideration and approval by the Network Manager/Assistant National Director Primary Community and Continuing Care (PCCC)?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	13.3.11		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Does the Network Manager/Assistant National Director PCCC submit annual assurance statements to the Director of the National Hospitals Office/Director of Primary, Community and Continuing Care?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	13.3.12		<b>Y</b>	<b>P</b>	<b>N</b>													
I O D	<input type="checkbox"/>	<p>Are external national audits of decontamination carried out as appropriate under the direction of the Assistant National Directors of Quality, Risk and Customer Care?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Audit and monitoring—Standard Report Form**

Standard 13 Report Form

<b>Standard 13: Audit and monitoring</b>
Audits shall be carried out to ensure that the procedures for decontamination of RIMD conforms to the required standard
<b>Standard Summary</b>
<b>Summary of Main Findings of the Audit</b>
<b>Conformance in the area:</b>          <b>Non-conformance in the area:</b>
<b>Standard Score:</b>

**Key performance indicators**

**Standard 14: Key performance indicators**

Key performance indicators that are capable of showing improvements in the efficacy of the decontamination process shall be used. The usefulness of the indicators shall be reviewed regularly

	14.3.1 -10		<b>Y</b>	<b>P</b>	<b>N</b>													
I  O  D	<input type="checkbox"/>	<p><b>Does the organisation meet the key performance indicators in relation to the Environment?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	14.3.11 -15		<b>Y</b>	<b>P</b>	<b>N</b>													
I  O  D	<input type="checkbox"/>	<p><b>Does the organisation meet the key performance indicators in relation to Equipment—Manual Washing?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

	14.3.16 -20		<b>Y</b>	<b>P</b>	<b>N</b>													
I  O  D	<input type="checkbox"/>	<p><b>Does the organisation meet the key performance indicators in relation to Equipment—Ultrasonic Cleaning?</b></p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<input type="checkbox"/>																		
<input type="checkbox"/>																		

**Key performance indicators**

	14.3.21-25		<b>Y</b>	<b>P</b>	<b>N</b>				
I  O  D	<input type="checkbox"/>	Does the organisation meet the key performance indicators in relation to Equipment–Washer-Disinfectors							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

	14.3.26-29		<b>Y</b>	<b>P</b>	<b>N</b>				
I  O  D	<input type="checkbox"/>	Does the organisation meet the key performance indicators in relation to Equipment–Steam Sterilisers?							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

	14.3.30-32		<b>Y</b>	<b>P</b>	<b>N</b>				
I  O  D	<input type="checkbox"/>	Does the organisation meet the key performance indicators in relation to Equipment–Low Temperature Sterilisers?							
	<input type="checkbox"/>	Yes	No	Partial	A		B	C	Total score
	<input type="checkbox"/>	Score 10	Score 0		Score 8		Score 5	Score 2	
	<input type="checkbox"/>	Supporting Evidence/Comments							
		Risk Category_____							

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### Key Performance Indicators

	14.3.33-35		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Equipment–Drying Cabinet?</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td style="text-align: center;">Score 10</td> <td style="text-align: center;">Score 0</td> <td></td> <td style="text-align: center;">Score 8</td> <td style="text-align: center;">Score 5</td> <td style="text-align: center;">Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

	14.3.38-41		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Utilities?</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td style="text-align: center;">Score 10</td> <td style="text-align: center;">Score 0</td> <td></td> <td style="text-align: center;">Score 8</td> <td style="text-align: center;">Score 5</td> <td style="text-align: center;">Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

	14.3.42-49		<b>Y</b>	<b>P</b>	<b>N</b>														
I  O  D	<input type="checkbox"/>	<p>Does the organisation meet the key performance indicators in relation to Management and Key Personnel?</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%;">Yes</td> <td style="width: 12.5%;">No</td> <td style="width: 12.5%;">Partial</td> <td style="width: 12.5%;">A</td> <td style="width: 12.5%;">B</td> <td style="width: 12.5%;">C</td> <td style="width: 12.5%;">Total score</td> </tr> <tr> <td style="text-align: center;">Score 10</td> <td style="text-align: center;">Score 0</td> <td></td> <td style="text-align: center;">Score 8</td> <td style="text-align: center;">Score 5</td> <td style="text-align: center;">Score 2</td> <td></td> </tr> </table> <p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2				
	Yes		No	Partial	A	B	C	Total score											
	Score 10		Score 0		Score 8	Score 5	Score 2												
<input type="checkbox"/>																			
<input type="checkbox"/>																			

**Key performance indicators**

	14.3.50-57		<b>Y</b>	<b>P</b>	<b>N</b>														
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	Does the organisation meet the key performance indicators in relation to Processes?																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
		Yes				No	Partial	A	B	C	Total score								
Score 10	Score 0		Score 8	Score 5	Score 2														
Supporting Evidence/Comments																			
		Risk Category_____																	

	14.3.58-60		<b>Y</b>	<b>P</b>	<b>N</b>														
I O D	<input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	Does the organisation meet the key performance indicators in relation to Service Quality?																	
		<table border="1"> <tr> <td>Yes</td> <td>No</td> <td>Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td></td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>				Yes	No	Partial	A	B	C	Total score	Score 10	Score 0		Score 8	Score 5	Score 2	
		Yes				No	Partial	A	B	C	Total score								
Score 10	Score 0		Score 8	Score 5	Score 2														
Supporting Evidence/Comments																			
		Risk Category_____																	



**Procedures relating to TSEs**

**Standard 15: Procedures relating to Transmissible Spongiform Encephalopathies (TSEs)**

The organisation shall have processes in place to minimize the exposure of patients and employees to TSE agents.

	15.3.1		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Is RIMD and equipment used on patients at increased risk of developing a TSE, single-use where possible?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

	15.3.2		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Does the organisation have written policies and procedures for the identification of patients at increased risk of developing a TSE?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																

	15.3.3		<b>Y</b>	<b>P</b>	<b>N</b>													
<b>I</b>	<input type="checkbox"/>	<p>Are these policies and procedures based on Irish TSE Infection Control Guidelines Final Version, Sept 2004?</p> <table border="1"> <tr> <td>Yes</td> <td>No</td> <td rowspan="2">Partial</td> <td>A</td> <td>B</td> <td>C</td> <td>Total score</td> </tr> <tr> <td>Score 10</td> <td>Score 0</td> <td>Score 8</td> <td>Score 5</td> <td>Score 2</td> <td></td> </tr> </table>	Yes	No	Partial	A	B	C	Total score	Score 10	Score 0	Score 8	Score 5	Score 2				
	Yes		No	Partial		A	B	C	Total score									
	Score 10		Score 0		Score 8	Score 5	Score 2											
<b>O</b>	<input type="checkbox"/>																	
<b>D</b>	<input type="checkbox"/>	<p>Supporting Evidence/Comments</p> <p>Risk Category_____</p>																







**Standard Scoring Summary Sheet**

6. STANDARD SCORING SUMMARY SHEET

Standard	Actual Standard Score (AS)	Maximum Standard Score (MS) Total Number of Question x Maximum Score (10)	Standard Score as a percentage (AS/MS x 100/1)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
<b>Overall Audit Score</b>			



