Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report of the unannounced inspection at University of Limerick (UL) Hospital Ennis, Co Clare.

Monitoring of decontamination and reprocessing of reusable medical devices in public acute hospitals.

Date of on-site inspection: 27 September 2018

A programme designed to additionally supplement HIQA's approach to monitoring against the *National Standards for the*

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services —** Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation —** Registering and inspecting designated centres.
- **Monitoring Children's Services —** Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality —** Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment —** Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information —** Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

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1.0 Introduction

HIQA monitors the implementation of the *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services*[1] in public acute hospitals in Ireland to determine if hospitals have effective arrangements in place to protect patients from acquiring healthcare-associated infection. The *National Standards for the prevention and control of healthcare-associated infections in acute healthcare services* will be referred to as the National Standards in this report.

In 2017, HIQA commenced a revised monitoring programme against the National Standards. The aim of this revised monitoring programme is to assess aspects of the governance, management and implementation of designated programmes to prevent and control healthcare-associated infections in hospitals. This monitoring programme comprises Phases One, Two and Three:

Phase One

All public acute hospitals were requested to complete and return a self-assessment tool to HIQA during April and May 2017.

Phase Two

Phase 2 commenced in May 2017 and involved unannounced inspections in public acute hospitals, focusing on elements of the prevention and control of healthcare-associated infection in line with National Standards.[2]

In light of the ongoing national public health emergency[*] in relation to Carbapenemase-Producing *Enterobacteriales* (CPE)[†] the focus of these inspections was on systems to detect, prevent and respond to healthcare-associated infections and multidrug-resistant organisms. It is anticipated that this phase will continue throughout 2018 and 2019 in parallel with Phase 3.

[*]A National Public Health Emergency Plan was activated on 25 October 2017 by the Minister for Health in response to the increase and spread of CPE in Ireland. As a result a National Public Health Emergency Team was convened and they have been meeting on a weekly basis since 02 November 2017. Please refer to the Department of Health webpage for further details: http://health.gov.ie/national-patient-safety-office/patient-safety-surveillance/antimicrobial-resistance-amr-2/public-health-emergency-plan-to-tackle-cpe/nphet-press-releases-minutes-of-meetings/

[†]Carbapenemase-Producing *Enterobacteriales* (CPE), are Gram-negative bacteria that have acquired resistance to nearly all of the antibiotics that would have historically worked against them. They are therefore much more difficult to treat.

Phase Three

From quarter 3 2018 onwards the programme focussed on decontamination and reprocessing of critical and semi-critical reusable medical devices.[‡] HIQA will focus, in the first instance, on decontamination facilities[§] outside of a designated controlled decontamination unit[**] to ensure structures, systems, processes and outcomes in these facilities are aligned to national standards and guidelines.

Additional information can be found in the *Guide to HIQA's programme of monitoring of the decontamination and reprocessing of reusable medical devices in public acute hospitals*[3] which was published in July 2018 and is available on HIQA's website: www.hiqa.ie

Information about this inspection

This inspection report was completed following an unannounced inspection carried out at Ennis Hospital by Authorised Persons from HIQA; Kathryn Hanly and Noreen Flannelly Kinsella. The inspection was carried out on 27 September 2018 between 08:55 hrs and 13:45 hrs.

Prior to this inspection, authorised persons reviewed the hospital's completed self-assessment tool and related documentation submitted to HIQA earlier in May 2017.

During this inspection inspectors spoke with hospital managers and staff, and representatives from the University of Limerick Hospitals Group Decontamination Committee. Inspectors requested and reviewed documentation, data and observed practice within a satellite decontamination facility in the outpatients department where decontamination of reusable medical devices was carried out.

HIQA would like to acknowledge the cooperation of the hospital management team and all staff who facilitated and contributed to this unannounced inspection.

[‡]The Spaulding classification, dating back to the 1950s, is a widely used classification system which is used to determine the level of decontamination a reusable medical device requires. The level of decontamination required is dependent on the equipment's purpose, and ranges from cleaning, through disinfection to a requirement for sterilisation. Devices may be classified as 'critical' (presenting a high risk of infection transmission if not fully cleaned, disinfected and sterilised), 'semi-critical' or 'non-critical' (presenting a low risk).

[§]Decontamination facilities refers to the physical infrastructure where decontamination of reusable medical devices is provided.

[**]A controlled decontamination unit, such as a Central Decontamination Unit or Endoscope Reprocessing Unit, is a designated unit which has defined governance arrangements and is designed, constructed, maintained and controlled with structures, systems, processes and outcomes that are continuously monitored, measured and validated to provide assurances that reusable medical devices are safely and effectively reprocessed consistently in accordance with legislation, manufacturer's instructions, national decontamination standards and guidelines, National Standards and best practice guidance.

2.0 Profile

Ennis General Hospital is part of the University of Limerick Hospitals Group and provides a range of services including non-complex care to medical and surgical patients. In addition to 50 inpatient beds there are also 12 day beds, seven endoscopy beds, a local injuries unit and a medical assessment unit. The University of Limerick Hospitals Group also includes University Hospital Limerick, University Maternity Hospital Limerick, Nenagh Hospital, Croom Hospital and St. John's Hospital. Four clinical directorates with responsibility for daily operations relating to specific specialties across the six hospital sites were in place.

Table 1.0 Overview of decontamination services

Spaulding risk categorisation	Reusable medical device and location of decontamination
Critical items Items that enter sterile tissues/ sterile body areas or the vascular system	Surgical instruments used in the general theatre department were decontaminated and reprocessed in the central sterilisation and disinfectant unit (HSDU) within Ennis hospital.
Semi-critical items Items in contact with mucous membranes or non-intact skin.	Flexible endoscopes were decontaminated centrally in the Endoscopy Decontamination Unit (EDU). Nasopharyngeal endoscopes used in the outpatient department were decontaminated with manual chlorine dioxide multi-wipe system between uses and were reprocessed using Automated Endoscope Reprocessors (AER) in the EDU at the end of the ear nose and throat (ENT) clinic list. A transvaginal ultrasound probe in the outpatient department had not been commissioned for use at the time of the inspection.
Non-critical items Items in contact with intact skin but not mucous membranes or not in contact with the patient	A non-invasive ultrasound probe used in the x-ray department was decontaminated using low level disinfection after use within the department.

3.0 Findings at Ennis Hospital

3.1 Governance and management structures

Site governance in Ennis Hospital was provided by the operational director of nursing supported by the site administrator.

Strong expert leadership in decontamination is essential for effective decision-making, efficient use of resources and ensuring the provision of high quality, safe, effective, person-centred care. Inspectors were informed that the University of Limerick hospitals group decontamination co-ordinator had recently retired and had not yet been replaced. Inspectors also found that responsibility for decontamination within Ennis Hospital was fragmented with no local decontamination lead within the hospital.

Governance structures for decontamination of reusable medical devices in the University of Limerick hospitals group were reconfigured in 2018. It was explained that the University of Limerick Hospitals Group Decontamination Users Committee reported to the University of Limerick Hospitals Group Pan Directorate Decontamination Committee. The Pan Directorate Decontamination Committee in turn reported through the University of Limerick Hospitals Group Infection Control Committee (HICC) to the Groups Quality and Patient Safety Executive Committee (Qualsec). A revised organogram showing the reporting relationships between these committees was provided (appendix 3).

However, on the day of inspection inspectors noted that there was ambiguity amongst staff with respect to these revised governance structures and leadership roles for decontamination. Inspectors sought clarification regarding the formalised governance structures. HIQA was informed that the revised structures were pan directorate to reflect the fact that decontamination of critical and semi-critical medical devices was also undertaken outside of the central hospital decontamination facilities in a number of satellite decontamination facilities across the directorates. Inspectors were also informed that the Decontamination Users Committee membership had recently expanded in an effort to include representation from all central and satellite decontamination facilities across the University of Limerick Hospitals Group.

Overall HIQA found that the revised governance arrangements had not yet fully embedded in practice at the time of this inspection. Both the Decontamination Users Committee and the Pan Directorate Decontamination Committee were in the process of updating the terms of reference which outlined the committee's objectives, membership, frequency of meetings and accountability and reporting relationships. However, committee minutes reviewed did not clearly outline discussions and actions

arising from the meetings, persons responsible or timeframes afforded to actions identified.

Inspectors were informed that accreditation status of the endoscopy unit had been deferred following a Joint Advisory Group (JAG)[††] accreditation assessment site visit on 17 November 2017, and was subject to a number of items being implemented within a six month timeframe. The report highlighted a weak approach to quality and governance in the endoscopy service. An action plan was developed following the inspection however inspectors identified that slow progress was being made collectively to resolve issues identified in the JAG accreditation report. The endoscopy user group needs to review and respond to local audit data and key performance indicators in a timely manner.

3.2 Risk management

Inspectors were informed that a risk management system was in place to identify the hazards associated with the decontamination process, to estimate, evaluate and control the risks and monitor the effectiveness of the controls. Issues considered to potentially compromise safe decontamination of reusable medical devices were risk assessed and included in local departmental risk registers and escalated to directorate level or higher as required.

Inspectors were informed that a number of decontamination risks were escalated from Ennis Hospital to the University of Limerick Hospitals Group corporate risk register. Risks in relation to decontamination outlined by hospital management on the day of inspection included:

- Infrastructure of decontamination facilities
- Ageing decontamination equipment
- Staffing deficits in HSDU and the EDU.

Inspectors were informed that the infrastructure of the HSDU in Ennis Hospital was not in compliance with the Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices[4,5] and was not in compliance with the *National Standards*.[1] It was explained that the University of Limerick Hospitals Group had commissioned an externally-led strategic review of decontamination facilities across the hospital group. Senior management informed inspectors that the costs and issues involved in developing site-specific options as opposed to centralisation or outsourcing of decontamination services would be considered following this review.

[††] JAG accreditation is the formal recognition that an endoscopy service has demonstrated that it has the competence to deliver against the criteria set out in the JAG standards.

Furthermore, it was reported to inspectors that the staff operative involved in the reprocessing of surgical instruments in the HSDU was also assigned to general cleaning duties within the unit and to the delivery of hospital linen to hospital wards. The area should be staffed by trained personnel whose sole or primary responsibility is reprocessing of surgical instruments. Management need to be assured that dual responsibilities do not dilute the effectiveness of both roles.

The national medical devices eAlert system[‡‡] had been implemented in the hospital. Inspectors were informed that the operational director of nursing was responsible for internal hospital distribution to the relevant personnel for implementation of the recommended actions.

Monitoring and evaluation including audit

The hospital had an inventory of reusable medical device and decontamination equipment used hospital-wide in line with national guidelines. This highlighted the current life cycle status of the current in use decontamination equipment within the hospital.

Environmental hygiene audits were carried out by infection prevention and control staff and formed part of the management of environmental cleaning. Microbiological monitoring of the environment within the HSDU included the air and contact surfaces. However, in the absence of a surgical site infection surveillance programme, the hospital should have appropriate mechanisms in place to assure itself that identified infrastructural risks in the HSDU did not negatively impact on patients from an infection prevention and control perspective.

Front-line staff, with responsibility for performing high level disinfection of nasopharyngeal endoscopes in the outpatients department were routinely monitored to assure that all steps were being conducted thoroughly and accurately. However audits did not measure manual disinfection times. Inspectors also noted audit findings were held locally and were not disseminated to the decontamination users committee.

Although the focus of inspection was on decontamination facilities outside of designated controlled decontamination units, inspectors sought assurances in relation to monitoring and evaluation systems implemented at the central EDU in Ennis hospital. [6,8] Inspectors were informed that the EDU was designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities. Inspectors were also informed that validation, maintenance, periodic testing and monitoring of decontamination equipment was carried out in accordance

[‡‡] The national eAlert system receives notification directly from the HPRA of all medical device safety / hazard notifications or any internally generated HSE safety notifications for distribution.

with documented procedures as recommended by the manufacturers' instructions. Documentation reviewed indicated that an annual self-assessment audit was undertaken by the endoscopy manager against the national standards outlined in the HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices.[7]

A 2014 HIQA inspection identified that protein residue tests[§§] and automated control tests[***] were not completed in the endoscopy department in line with hospital policy. During the 2016 HIQA inspection inspectors were assured that endoscopy decontamination periodic testing was now aligned with national standards for endoscopy reprocessing units.[8] However the 2017 JAG accreditation report again highlighted that weekly protein testing was not consistently conducted. On the day of inspection inspectors were informed that this issue had been resolved and that adherence to weekly protein testing was been monitored.

Information technology (IT) systems were in place to record the decontamination process used on surgical instruments, endoscopes and accessories (tracking) and link them with service users on which they had been used (tracing). [5,8]

Inspectors were informed that off-site contingency plans to cover decontamination service disruptions were in place for the HSDU and the EDU. However the plan reviewed by inspectors was basic and did not detail the hospitals groups capability to respond to incidents and disruptions in order to continue business operations at acceptable pre-defined levels within agreed timeframes.

3.3 Staff training and education

Technical and user training was provided by the manufacturers of endoscope and ultrasound probe decontamination equipment and training records were maintained. In addition, individual competencies of staff in the HSDU were assessed by the unit manager.

The majority of staff in the outpatients department had completed online training for the use of the manual chlorine dioxide multi-wipe system for nasopharyngeal endoscope disinfection. [†††]

[§§] To test for protein residue in channelled endoscopes to ensure that there are no microbiological contamination within the endoscopes after processing.

[***] Endoscope washer disinfectors automatic control test is performed to verify that the control instrumentation on the endoscope washer disinfector is working within validated parameters, such as time and temperature, using the machines own indicated measurements on the display.

[†††] Manual disinfection system with wipes uses one wipe for the high-level disinfection process, a wipe for the predisinfection cleaning step and one for the post disinfection rinsing step.

Inspectors were informed that approximately 50% of personnel with a responsibility for device decontamination within the HSDU and EDU had completed a formalised academic decontamination training programme in line with HSE recommendations.

Material safety data sheets were available to staff who used potentially hazardous chemicals. Inspectors were informed that staff completed chemical safety training annually.

3.4 Policies, procedures, protocols and guidelines

Current HSE policy states that hospital policies, procedures and guidelines should be reviewed every three years.[9] Inspectors were informed that the majority of policies, procedures, protocols and guidelines decontamination were due for review at the time of the inspection.

3.5 Decontamination of Semi-critical Medical Devices in Satellite decontamination Facilities.

Inspectors visited the ear, nose and throat (ENT) outpatient's clinic to review structures, systems and processes of nasopharyngeal endoscope decontamination. Nasopharyngeal endoscopes are considered semi critical medical devices for which the risk of infection is intermediate and for which high-level disinfection is required.[8]

Decontamination facilities for nasopharyngeal endoscope decontamination within the department did not meet the standards outlined in HSE Standards and Recommended Practices for Endoscope Reprocessing Units.[8] Inspectors were informed that plans for the provision of a new outpatients department located on a green-field site had been approved. However, the proposed new hospital development will take a year to complete. In the interim, changes and measures to address the issues identified and to enhance decontamination practices need to identified and be progressed.

Nasopharyngeal endoscopes were decontaminated at point of care using a manual chlorine dioxide multi-wipe system between patients. Inspectors were informed that a local risk assessment was performed in line with national guidance as this system is the least preferred method of high level disinfection. The wipes were for single use and permitted tracking of the decontamination procedure to monitor its correct execution. Sterile protective sheaths were also used.

Inspectors were informed that nasopharyngeal endoscopes were sent to the EDU for reprocessing in an automated endoscope reprocessor at the end of each patient list. It was explained that this was an interim solution until an automated validated system was available for all nasopharyngeal endoscope decontamination. Inspectors were informed that prior to introducing automated decontamination for nasopharyngeal endoscopes, additional nasopharyngeal endoscopes would be

required to maintain clinical service. However there was no agreed funding or timeframe for this development at the time of this inspection.

Following decontamination, nasopharyngeal endoscopes were returned to the outpatients department and stored inappropriately in a wall mounted cabinet located within a clinical treatment room. Storage facilities for decontaminated endoscopes should be secure, to reduce the risk of environmental contamination and only accessible to personnel who have a legitimate need.

Inspectors observed an ultrasound machine with semi-critical ultrasound probes within the outpatients department. However this equipment not been commissioned for used at the time of the inspection.

4.0 Conclusion

National standards[1] recommend that governance and communication arrangements need to be clearly defined and communicated to relevant staff to ensure that there is clarity on individual roles and responsibilities in addition to reporting lines and accountability. Findings on inspection evidenced a lack of clarity in relation to reporting relationships. In line with national guidance, the hospital should ensure that a designated person with responsibility for reusable invasive medical device reprocessing within Ennis Hospital is in place.

In line with national guidance[5,8] audits to monitor adherence to decontamination and reprocessing procedures for critical and semi-critical devices must be routinely undertaken and supported by, and reported through, the clinical governance structures. Management need to ensure adherence to national guidelines with a system of feedback to the quality and risk committee (or appropriate committee) on the action taken by wards and departments.

National guidelines[5,8] recommend that decontamination services should be provided within central locations such as EDUs and HSDUs to remove the need for decontamination to take place in or near patient areas. The hospital was disadvantaged in terms of suboptimal size and location of the HSDU and the decontamination facilities within the outpatients department. It is acknowledged that the hospital had also identified and escalated these risks in line with the HSE risk management system. It was evident to inspectors that staff in the outpatients department worked to the best of their ability to manage the process safely within existing environmental constraints.

It is recommended that the hospital reviews decontamination technologies in order to facilitate the recommended national standards[6,8] of disinfection for nasopharyngeal endoscope decontamination.

Ennis Hospital, as a member of the Limerick University Hospitals Group needs to be supported within group and national structures to effectively address issues in relation to decontamination and reprocessing of reusable medical devices in order to comply with the National Standards[1] and other national decontamination standards.[4-8]

5.0 References

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6.0 Appendices

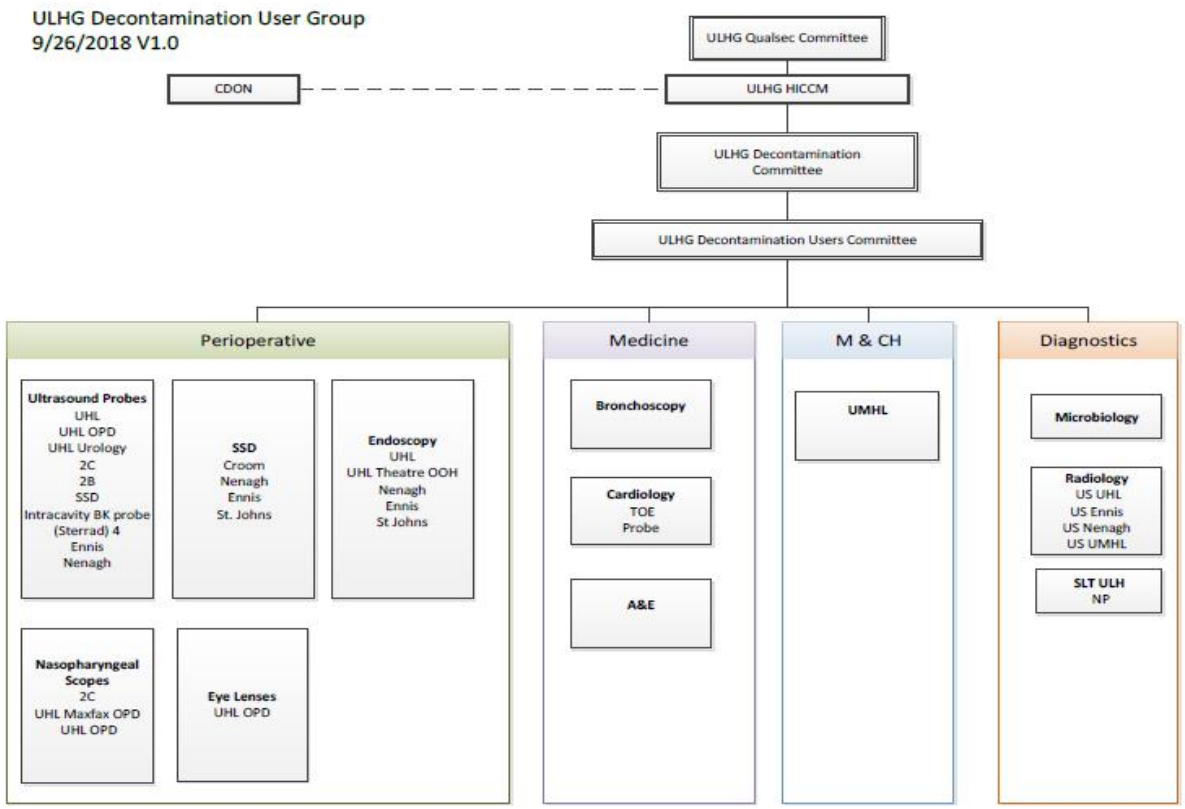
Appendix 1: Lines of enquiry for the monitoring of decontamination and reprocessing of reusable medical devices in public acute hospitals

Lines of Enquiry			Relevant national standards
1	**Governance and management structures**	The hospital has effective leadership, governance and management structures in place in relation to decontamination and reprocessing of reusable medical devices and has formalized and clear lines of accountability and responsibility at all levels of the service.	2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 5.2, 5.3, 5.4, 6.1, 7.1
2	**Monitoring and evaluation systems including audit and risk management**	The hospital has effective arrangements in place to respond to the ongoing monitoring and evaluation of decontamination and reprocessing processes to drive quality improvement. The hospital has a risk management system in place to identify, manage and report all hazards, adverse events, near misses and risks in relation to decontamination and reprocessing of reusable medical devices.	2.1, 2.3, 2.5, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.8,
3	**Education and training of key personnel**	The hospital ensures that key personnel have been appropriately trained to the necessary standard of competence and are supported with ongoing education and training reflecting national and international evidence in relation to decontamination and reprocessing of reusable medical devices.	2.1, 2.8, 3.1, 3.2, 3.3, 3.6, 6.1, 6.2
4	**Relevant policies, procedures, protocols and guidelines**	The hospital ensures that key personnel are implementing evidenced-based best practice in relation to decontamination and reprocessing of reusable medical devices with up to date policies, procedures, protocols and guidelines in line with relevant legislation and national guidelines.	2.1, 2.5, 3.1, 3.6, 3.8, 5.4, 7.2

Appendix 2: Spaulding risk categorisation table

Spaulding risk categorisation table Guide to classification of infection risk associated with the decontamination of reusable medical devices			
Risk	**Application**	**Recommendation**	**Examples**
Critical	Items that enter sterile tissues / sterile body areas or the vascular system	Cleaning followed by Sterilization	surgical instruments biopsy instruments forceps, laparoscopes, arthroscopes surgical dental instruments
Semi-critical	Items in contact with mucous membranes or non-intact skin	Sterilisation preferred but at minimum, requires high level disinfection	flexible endoscopes specula respiratory therapy equipment
Non-critical	Items in contact with intact skin but not mucous membranes or not in contact with the patient	Can be processed by cleaning (and low level disinfection where necessary)	blood pressure cuffs, oximeters, ecg leads, etc.

Appendix 3 Decontamination Governance Organogram



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