Internal Audit

Hospital Sterilisation Decontamination Unit

November 2019

Internal Audit Assurance assessment:

Objective One	Objective Two	Objective Three	Objective Four	Objective Five
Moderate Assurance	Significant Assurance	Moderate Assurance	Significant Assurance	Significant Assurance

Timetable

Date closing meeting held: 15th October 2019

Date draft report issued: 5th November 2019

Date management comments received: 11th November 2019

Date Final report issued: 12th November 2019

Date presented to Audit and Risk Committee: 25th November 2019

Contents

1. Introduction

1.1 The Hospital Sterilisation Decontamination Unit (HSDU) supports up to 60 operating theatres in NHS Lothian. The HSDU also supports sterile equipment for wards, treatment rooms and dental procedures, providing sterile procedure packs. With only this unit supporting Lothian, the unit must be kept operational at all times to service theatres and wards. Failure could cause closure of operating theatres in Lothian and subsequent cancellation of patient operations, meaning patients may not receive the care they need.

1.2 In November 2018, NHS Greater Glasgow and Clyde had to temporarily shut its decontamination unit due to an external inspection highlighting several issues with the fabric of their facility. These issues did not relate to the unit's processes for sterilising equipment, however, forced closure of the unit. This resulted in a total of 1075 procedures being cancelled. NHS Greater Glasgow and Clyde are currently investigating the reasons behind the suspension of the site certificate and any further corrective actions to be taken.

1.3 Within NHS Lothian, there have been known issues with the sterilising unit being able to keep up with theatre demand, and several operations had to be cancelled as a result. To combat this, the Surgical Instrumentation Cycle (SIC) Programme Board was established. The Board is a management group (rather than a governance group) and has an aim of improving efficiencies related to the provision of surgical equipment through reducing non-conformity, rationalising tray content and improving the communication between theatres and the HSDU.

Scope

1.4 We considered NHS Lothian's arrangements to ensure the resources available to the HSDU to service theatres, including how NHS Lothian determined staffing and work patterns.

1.5 We reviewed contingency plans which have been developed for any unforeseen closures or partial closures of the HSDU to ensure cancellations are minimised as far as possible and that the unit remains resilient. We have considered the HSDU's resilience plan currently in place; including activation and escalation of the plan; increasing capacity; communications; learning and improving and setting out the roles and responsibilities of staff. The assurance provided within our report is limited to the controls in place to develop and test these plans within NHS Lothian and it should be recognised that a high inherent risk remains present should the unit have an unforeseen closure. This is due to the reliance placed on other Health Boards to process trays in such instances, which may be impacted by their own capacity and operations. Therefore, we are unable to provide assurance on this from a national perspective. The national fragility of the contingency plans across sterilisation units in Scotland was noted within the National Services Scotland report of lessons learned and recommendations following the closure of NHS Greater Glasgow and Clyde's sterilisation unit.

1.6 Additionally, we considered the work of the Surgical Instrumentation Cycle Programme Board and that the project streams within its scope are applicable and its work in reducing the number of non-conformities of instrumentation trays. We also considered the ability of the HSDU to respond to major incidents or high levels of demand, and processes put in place, based on the continuity plans in place.

1.7 Recognising that Lothian are currently working on a process (Track and Trace) to inform HSDU what surgical trays are required for upcoming surgeries, but that this is not yet in place, we have not included this in our scope, but note this work is referenced within management responses to our recommendations.

Acknowledgements

1.8 We would like to thank all staff consulted during this review, for their assistance and cooperation.

2. Executive Summary

Summary of Findings

2.1 The table below summarises our assessment of the risks and the adequacy and effectiveness of the controls in place to meet each of the risk areas agreed for this audit. Definitions of the ratings applied to each action are set out in Appendix 2.

No.	Control Objectives	Assurance Level	Number of findings			
			Critical	High	Medium	Low
1	The decontamination unit has adequate resources to service the needs of theatres	Moderate Assurance	-	-	-	2
2	There are appropriate business continuity plans in place for closure/partial closure of the decontamination site, ensuring potential cancellations are minimised	Significant Assurance	-	-	-	-
3	There is a low level of non-conformity and wastage in surgical instrumentation trays, resulting in theatres having the right equipment available to them at the right time	Moderate Assurance	-	-	2	-
4	The HSDU have appropriate plans in place to respond to major incidents, aligning to NHS Lothian's major incident response plan	Significant Assurance	-	-	-	1
5	The SIC Programme Board's workstreams align to the greatest areas for improvement within HSDU and theatres.	Significant Assurance	-	-	-	-
TOTAL			**-**	**-**	**2**	**3**

Conclusion

2.2 The area under review comprised of 5 control objectives, of which 3 received Significant Assurance, and 2 received Moderate Assurance.

2.3 As noted within paragraph 1.5 of our report, we are only able to provide assurance over the controls in place to develop and test NHS Lothian's HSDU's resilience plans. The significant level of assurance provided within our report to Control Objective 2 is limited to our review of these controls. It should be recognised that a high inherent risk remains present to NHS Lothian should a full or partial closure of the unit occur. This is due to the reliance placed on other Health Boards to process trays in such instances, which may be impacted by their own capacity and operations. Therefore, we are unable to provide assurance on this from a national perspective.

2.4 There has been a significant amount of investment in the HSDU with processes being put in place locally by the HSDU and by the SIC Programme Board to improve the effective and efficient processing and maintenance of re-usable surgical equipment. This includes local improvements such as the introduction of din-baskets, resulting in improved production by 500 trays per week and a reduction of the backlog of trays, agreed funding for the replacement of missing instruments in trays, improving air quality checks through the purchase of borescopes and air samplers. The SIC Programme Board are working towards the planned introduction of the Track and Trace system to inform HSDU of what trays are required for upcoming surgeries.

2.5 Whilst it should be recognised that improvements have been made to the HSDU processes, there are some opportunities for improvement including the processes of reporting non-conformities to the HSDU and addressing the root causes of any reported incidents.

2.6 Additionally, it is expected that the requirements of the HSDU will change going forwards with the opening of the St John's short stay elective unit and due consideration is required at this early stage.

Main Findings

2.7 Although there has been a reduction in the HSDU backlog of trays, this has increased again over the past 9 months due to demand pressures and there is a risk that this will continue to increase before the Track and Trace system is implemented. This position should be closely monitored to ensure there are as few cancellations to surgeries as possible.

2.8 Management have determined that HSDU staffing is thought to be operating at a sufficient level for current operations, however, it is expected that the opening of the St John's Short Stay Elective Centre will increase the requirement of trays by 300-400 per week (a 16% increase in production). The requirement for additional resources should be considered now, with an action plan put in place to address any concerns. Additionally, the HSDU major incident plans currently only consider trauma patients

being directed to the RIE and this may change as a result of the elective centre opening. Major incident response plans should, therefore, be updated and the readiness of the HSDU to respond to these assessed.

2.9 There are defined processes in place for the reporting of non-conformities in trays provided to theatres. However, two reporting methods are used to do this and there is a risk that if reporting is made via DATIX that HSDU staff will not identify and correct issues on receipt of trays back from theatres. Additionally, multiple incidents of 'dirty instruments' are reported by theatres, and the current root-cause action for this of retraining staff has not resulted in a corresponding decrease to the number of incidents reported.

3. Management Action Plan

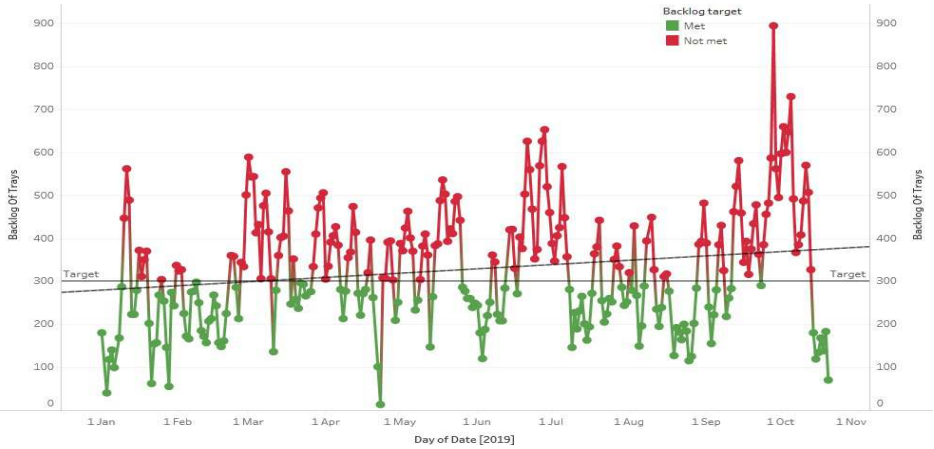
Control objective 1: The decontamination unit has adequate resources to service the needs of theatres	
Finding 1.1 – The backlog position should be closely monitored following the implementation of Track and Trace to ensure this addresses issues.	**Low**

Background

Within the HSDU, there is a continual backlog of trays, with a target for backlog being set at 300 trays at any time. The number of backlog trays within HSDU is the number of 'dirty' trays in HSDU at the beginning of each day waiting to be sterilised. The target represents the number of trays before processing and the unit want to be in a backlog position, as they should always have trays to be processed.

HSDU performed an exercise in 2017 to determine if the right number of trays were available to theatres by speaking to each department and ensuing there was 75% of trays on the shelf at any one time, with 25% left over for processing at the HSDU.

An analysis of the backlog position from the 1st of January 2019 to the 21st of October 2019 can be seen below:



Observation and risk

It can be seen that the number of backlog trays has increased over the period with the backlog being closer to 400 trays per day in October. The greatest backlog position noted is 900 trays on the 1st of October, however, this related to a unique period where high levels of sickness were present within the department. The backlog decreased to its normal pattern once staffing levels had returned to normal.

The increased backlog is often due to increased scheduling of surgeries out-with the expectations of the HSDU. At present, there is not a system in place to inform the HSDU of upcoming surgeries and the number of trays held throughout the HSDU is based on estimates (agreed with theatres as part of the 2017 exercise). This lack of communication results in an

increase to the backlog as the HSDU is in a reactive position to theatre requirements, rather than a proactive position of being informed of upcoming surgeries and required kits for these. It should be noted that the SIC Programme Board are currently working on a process (Track and Trace) to inform HSDU what surgical trays are required for upcoming surgeries, but that this has not yet been implemented. There is a risk that there will be a continued increase in backlog before this is implemented, resulting in potential theatre cancellations and there is currently no assurance that the Track and Trace system will improve the backlog position.	
Recommendation Once the Track and Trace system is implemented, if a corresponding reduction in the backlog is not seen then this should be addressed by a review of the number of trays required for theatres to operate, to ensure the right number of trays are available for theatres.	
Management Response Agreed Management Action This action will be picked up directly by the tracking and traceability project group.	
Responsibility: Programme Director	Target date: Following final roll out of Track and Trace system.

Control objective 1: The decontamination unit has adequate resources to service the needs of theatres	
Finding 1.2 – HSDU staffing requires updating for consideration of the St John's short stay elective centre	**Low**

Background

A staffing review was performed for the HSDU by management in 2015 to determine ways to reduce the number of agency workers within the department. This resulted in a change to shift patterns within the HSDU and a reduction in the number of agency or bank workers, with these now being used to utilise short falls in staff, where required.

At present the HSDU contract out the processing of 200 trays per week (around 9% of total weekly output) to an external provider to supplement the work done within the department. This contract is taken on short term extensions of 13 weeks and provides the department with flexibility in its arrangements and costs, given that this has not increased the requirement for permanent staff.

Observation and risk

The following pressure points were identified in relation to staffing of the HSDU:

- There is currently no staff operating the HSDU between 4.30pm and 9.30pm at the weekend. This is to allow for cleaning, repair and maintenance of the site. However, it is recognised that there is a risk that trays cannot be processed during this time, and that should a major incident occur during this time, the HSDU would be fully reliant on staff call-in procedures and would delay their readiness to respond to an event.
- Additionally, there is reduced staffing at the weekend, resulting in the target number of processing of trays not being met over this time, with a corresponding increase in backlog to be addressed. The backlog, therefore, usually does not meet its target until Wednesday or Thursday in the week, as the department are working to reduce the load from the weekend.
- The St John's elective centre is due to open in 2021 and it is estimated this will result in an increase in tray production required of 300-400 trays per week. The current staffing levels and contracted out processing of trays will not cover this requirement.
- The training required for new HSDU staff can take up to 9 months (to obtain the required qualification) and, therefore, if additional staff are recruited to the unit, there is a delay before the individual is fully capable of operating equipment. Therefore, the HSDU is sensitive to staff turnover and an increased workload requirement.
- The workforce skill-mix could be problematic with limited number of people being able to operate certain pieces of equipment (i.e. 8 members of staff able to operate steam generators) and there is a risk that there is not sufficient staff in to work the equipment over the full week. It is noted that this is currently being mitigated through only hiring staff signed up to a multi-skilled contract, who are able to operate more than one piece of equipment.

- The recruitment and retention of technical engineering staff is a challenge, with higher turnover levels and difficulty to recruit quickly.	
Recommendation The pressure points of staffing are known to the HSDU and facilities management, however, work should be done to ensure a staffing compliment is in place for the opening of the St John's short stay elective centre, including consideration of weekend shift patterns, to prevent increased backlog and potential surgical cancellations. The readiness of the unit for the changes need to be considered with an action plan put in place as soon as possible.	
Management Response Agreed Management Action To develop a resilience service and staffing model to ensure readiness for the SSEC.	
Responsibility: Associate Director of Operations (Facilities) Programme Director	Target date: Mid 2021

Control objective 2: There are appropriate business continuity plans in place for closure/partial closure of the decontamination site, ensuring potential cancellations are minimised

We identified no issues in relation to this control objective. However, it should be noted that the assurance provided within our report is limited to our review of NHS Lothian's HSDU's resilience plan.

There is a local resilience plan in place for HSDU which sets out guidance for how the department should respond to an emergency or disruptive incident. On review of this plan, all relevant areas were considered, including activation and escalation of the plan; increasing capacity; communications; resilience strategies; standing down; learning and improving and action cards, setting out the roles and responsibilities of staff. This plan also outlines which kits would be prioritised, focusing on those required for obstetrics, emergency and trauma procedures, in line with NHS Lothian's response plan.

There are service level agreements in place with various external providers to provide processing of kits to the HSDU in the event of a major incident or disruption to services. Additionally, there are 150 kits held off sites in case of emergencies which can be utilised in the case of a full shut down.

Practice exercises have been undertaken to simulate instances where the plan may be activated, with lessons being learned from these and incorporated into plans going forwards.

It should be recognised that a high inherent risk remains present to NHS Lothian should a full or partial closure of the unit occur. There is reliance on other Health Boards to process trays in such instances which may be impacted by their own capacity and operations. Therefore, we are unable to provide assurance on this from a national perspective. The national fragility of the contingency plans across sterilisation units in Scotland was noted within the National Services Scotland report of lessons learned and recommendations following the closure of NHS Greater Glasgow and Clyde's sterilisation unit. Whilst we cannot be assured that in the event of a disruption to the HSDU, cancellations would not occur, the controls and testing of business continuity plans are as we would expect.

Control objective 3: There is a low level of non-conformity and wastage in surgical instrumentation trays, resulting in theatres having the right equipment available to them at the right time

Finding 3.1 – The incident reporting SOP should be updated to require both DATIX reporting and tray list reporting for more serious incidents	**Medium**

Background

There is a standard operation procedure (SOP) for reporting incidents related to surgical instrumentation. Various incidents may occur with instrumentation including torn drapes, missing instruments, incorrect labelling of trays or dirty instruments. Reporting has been put in place to allow for theatres to inform HSDU of issues noted so that trends can be identified, investigated and corrective actions put in place.

There are two routes for reporting incidents:

- More serious incidents (which may have caused injury to patients) are reported via DATIX. This is so they can be logged and managed in line with NHS Lothian's adverse event procedures.
- Less serious incidents (such as missing items or blunt instruments) are managed through reporting via tray lists on trays. When trays are received back from theatres, the incident is validated by a supervisor and the kit set aside for immediate action to be taken. These are then logged on a database for consideration of root cause.

Observation and risk

It was noted that where the DATIX reporting route was taken, the trays could be received back to the HSDU without a tray list report, and the tray would be re-processed and put back into production before the issue could be addressed. There is a risk in this instance that the error recurs and is not addressed immediately by the HSDU staff. Therefore, it would make more sense to report both via DATIX and via the trays so that a record of issue is kept alongside the tray reporting.

Recommendation

The reporting incidents SOP should be updated to ensure tray non-conformities are reported both via DATIX and tray forms for more serious events so that HSDU staff can address these on receipt of the tray and are not put back into production. Theatre teams should be notified of this change.

Management Response

Agreed

Management Action

To be addressed via the Technical User Group (TUG).

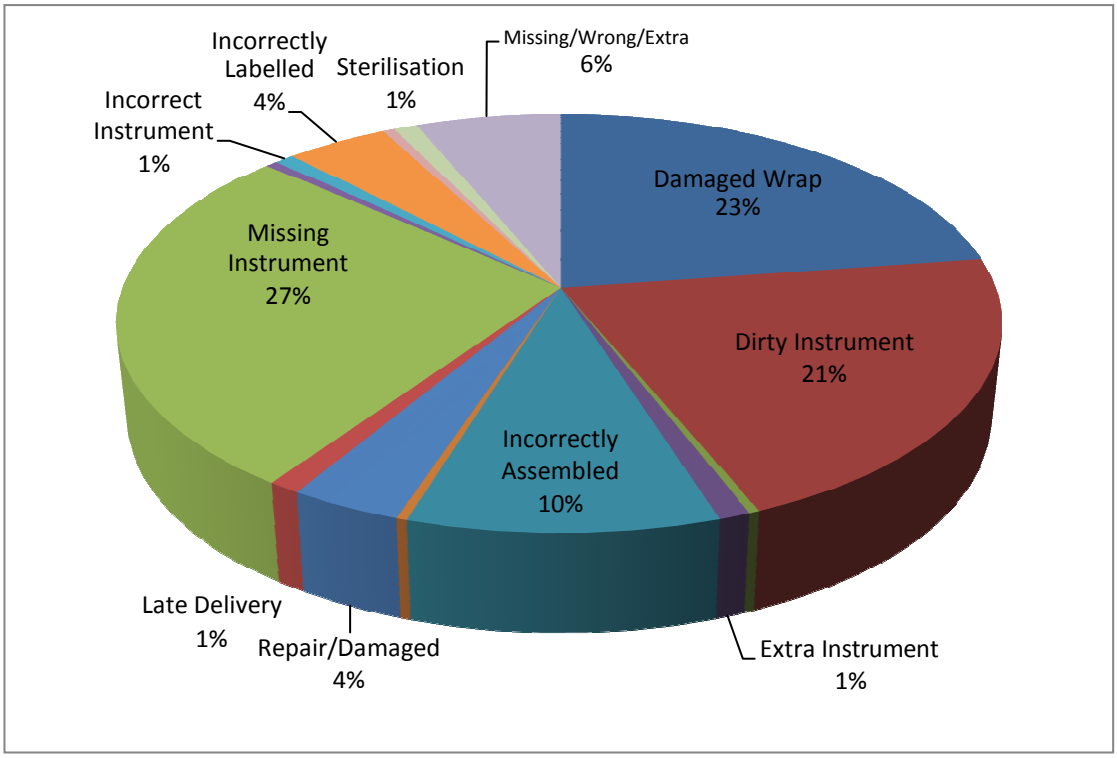
Responsibility:	Target date:
General Manager, ATCC Associate Director of Operations (Facilities)	Early to Mid-2020

Control objective 3: There is a low level of non-conformity and wastage in surgical instrumentation trays, resulting in theatres having the right equipment available to them at the right time

Finding 3.2 – There are recurring issues of non-conformities often to be addressed by retraining, however, these recur indicating the root cause has not been addressed	**Medium**

Background

Once an incident has been reported it is logged on a complaints database and are analysed for identification of root cause. Between January and July 2019, a total of 599 complaints were logged. It should be noted that this has reduced from previous years as a result of improvements made within the department. The root cause of complaints was analysed as shown below:



The three largest root causes for reported incidents over the period are Missing Instruments (27%), Damaged Wraps (23%) and Dirty Instruments (21%).

Observation and risk

Through discussions it was identified that the high occurrence of damaged wraps was due to the introduction of a certain type of wrap in early 2019, for which, additional training from the supplier was provided to staff to address. This resulted in a decrease in incidents noticed from 45 in Feb to 11 in July.

For Missing Instruments, incidents were reported consistently over the 7-month period with an average of 23 incidents reported per month. CMT have recently approved funding for

additional equipment for replacements and a long-term lifecycle programme is being established to address this. For Dirty Instruments and other incidents reported, these are addressed predominantly by the retraining of staff, however, this has not resulted in a downward trend of these incidents being reported. Therefore, we could not be provided with assurance that the root cause of these incidents was being sufficiently addressed. There is a risk that staff retraining is not sufficient to prevent these errors recurring, additionally it was noted that given restrictions on resources it could often take over a month for the retraining to take place. Additionally, dirty instruments may cause harm to patients if not noted by the theatre staff.	
Recommendation The root cause of recurring Dirty Instruments should be considered. There should be robust training in place for all staff and additional checks and processes put in place to ensure dirty instruments are not provided to theatres.	
Management Response This is a very small number and may have only been exacerbated by the number of PHACO device issues there were late summer. Management Action Already in place but to be further reviewed; training in the use of boro scopes and micro scopes and additional checks.	
Responsibility: Associate Director of Operations (Facilities) Interim Services Manager, HSDU	Target date: Implemented, plus will be re-reviewed Jan 2020

Control objective 4: The HSDU have appropriate plans in place to respond to major incidents, aligning to NHS Lothian's major incident response plan	
Finding 4.1 – The HSDU major incident response plan should be updated to consider the new St John's short stay elective centre in advance of this opening	**Low**
Background Patients from major incidents are planned currently to be directed to the Royal Infirmary Edinburgh (RIE), as this is the site where trauma cases are handled. There have been practice exercises performed over the years to assess the readiness of the HSDU to respond to these, specifically for the RIE. Surgical kits are prioritised by the HSDU in line with NHS Lothian's priorities for major incidents (obstetrics, emergency and trauma). Responses to major incidents is considered within the local resilience plan and action cards in order to ensure these would be properly addressed. Observation and risk It was recognised that going forwards, major incidents, including trauma, are likely to be directed to St Johns once the new short-stay elective centre is established. Major incident response plans, including logistics for transportation will need to be considered by the HSDU as part of this.	
Recommendation The HSDU should consider how it will address major incidents handled at St John's and ensure that the resilience plans are up to date to accommodate this in due course. Additionally, it would be beneficial to perform practice exercises for responding to incidents at St John's in advance of the elective centre opening, to ensure lessons learned will be incorporated into plans and the readiness of the HSDU is assessed.	
Management Response Agreed Management Action Carry out a table-top exercise during late 2020 to test future resilience for St. John's.	
Responsibility: Associate Director of Operations (Facilities) Interim Services Manager, HSDU Head of Soft Facilities Management	Target date: Late 2020

Control objective 5: The SIC Programme Board's workstreams align to the greatest areas for improvement within HSDU and theatres.
We identified no issues in relation to this control objective. The SIC Programme Board performed an initial review of HSDU arrangements, challenges and opportunities. These were incorporated into an agreed Programme-level plan which considered what the key issues were, what actions should be put in place to address these and under which sub-committee of the programme these will be governed with actions monitored. We did not identify any issues in relation to HSDU which we considered priorities which are not already being addressed by the Programme Board.

4. Internal Audit Follow-up Process

4.1 Approximately two weeks following issue of the final Internal Audit report, a member of the Audit Team will issue an ‘evidence requirements’ document for those reports where management actions have been agreed.

4.2 This document forms part of the follow up process and records what information should be provided to close off the management action.

4.3 The follow-up process is aligned with the meetings of the Board’s Audit & Risk Committee. Audit Sponsors will be contacted on a quarterly basis with a request to provide the necessary evidence for those management actions that are likely to fall due before the next meeting of the Audit and Risk Committee.

5. Appendix 1 – Staff Involved and documents reviewed

Staff Involved:

- Director of Operations – Facilities
- Associate Director of Operations - Facilities
- Service Director for Diagnostics, Anaesthetics, Theatres and Clinical Care (DATCC)
- Head of Soft Facilities Management
- Services Manager (HSDU)
- Quality Manager (HSDU)
- Emergency Planning Officer

Documents Reviewed:

- NHS Template local resilience plan
- Major Incident Plan, RIE
- Strategic Incident Management Plan
- Local Resilience Plan (09.10.19)
- Resilience Assurance Report (October 2019)
- Black Start and Contingency HSDU RIE (August 2019)
- Various Service Level Agreements with external parties – BMI, NHS Borders, NHS Forth Valley, NHS Greater Glasgow and Clyde, Spire Hospital, NHS Tayside, BMI Glasgow
- Analysis of trays processed over Easter 2018 period
- Standard Operating Procedure – Reporting Incidents (27.02.18)
- Customer Complaint Database (July 2019)
- Sample of Customer Complaints received
- Priority Report Requests – WGH (23.10.19), Orthopaedics (24.10.19)
- Exercise Malcolm Feedback
- Staff Call Out list – Major Incident Plan
- Flow Chart – Escalation Procedures
- Action Card and Structure, HSDU
- Prompt cards – HSDU department
- Major Incident Protocol Log Form
- Major Incident Instrumentation Numbers (October 2018)
- HSDU Staff Rota (June 2019)
- Instrumentation Requirements by speciality (November 2017)
- Terms of Reference for Surgical Instrumentation Group (25.03.19)
- SIC Programme Plan (03.05.19)
- Reporting dashboard for SIC – April and September
- SIC Programme update, Clinical Management Group paper (April 2019)
- SIC sub-group progress reports

6. Appendix 2 - Definition of Ratings

Findings and management actions ratings

Finding Ratings	Definition
Critical	A fundamental failure or absence in the design or operating effectiveness of controls, which requires immediate attention
High	A key control failure has been identified which could be either due to a failure in the design or operating effectiveness. There are no compensating controls in place, and management should aim to implement controls within a calendar month of the review.
Medium	A control failure has been identified which could be either due to a failure in the design or operating effectiveness. Other controls in place partially mitigate the risk to the organisation, however management should look to implement controls to fully cover the risk identified.
Low	Minor non-compliance has been identified with the operating effectiveness of a control, however the design of the control is effective

Report ratings and overall assurance provided

Report Ratings	Definition	When Internal Audit will award this level
No assurance	The Board cannot take any assurance from the audit findings. There remains a significant amount of residual risk.	The controls are not adequately designed and / or operating effectively and immediate management action is required as there remains a significant amount of residual risk (for instance one Critical finding or a number of High findings)
Limited assurance	The Board can take some assurance from the systems of control in place to achieve the control objective, but there remains a significant amount of residual risk which requires action to be taken.	This may be used when: • There are known material weaknesses in key control areas. • It is known that there will have to be changes that are relevant to the control objective (e.g. due to a change in the law) and the impact has not been assessed and planned for. The controls are deficient in some aspects and require management action (for instance one 'high' finding and a number of other lower rated findings)
Moderate assurance	The Board can take reasonable assurance that controls upon which the organisation relies to achieve the control objective are in the main suitably designed and effectively applied. There remains a moderate amount of residual risk.	In most respects the "purpose" is being achieved. There are some areas where further action is required, and the residual risk is greater than "insignificant". The controls are largely effective and in most respects achieve their purpose with a limited number of findings which require management action (for instance a mix of 'medium' findings and 'low' findings)
Significant assurance	The Board can take reasonable assurance that the system(s) of control achieves or will achieve the control objective. There may be an insignificant amount of residual risk or none at all.	There is little evidence of system failure and the system appears to be robust and sustainable. The controls adequately mitigate the risk, or weaknesses are only minor (for instance a low number of findings which are all rated as 'low' or no findings)