

NHS Lothian

Internal Audit Report 2022/23

Critical Infrastructure Systems – Ventilation

Assurance Rating: **Limited Assurance**

Date: 11 November 2022

Contents

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Timetable

- Date closing meeting held: 7 October 2022
- Date draft report issued: 26 October 2022
- Date management comments received: 11 November 2022
- Date Final report issued: 11 November 2022
- Date presented to Audit and Risk Committee: 21 November 2022

This report has been prepared solely for internal use as part of NHS Lothian's internal audit service. No part of this report should be made available, quoted or copied to any external party without Internal Audit's prior consent.

Executive Summary

Introduction

Ventilation is used extensively in all types of healthcare premises to provide a safe and comfortable environment for patients and staff. It is provided to help control airborne infection risks in areas such as operating departments, critical care facilities, isolation rooms and treatment areas.

The Scottish Health Technical Memorandum (SHTM) 03-01 - Specialised ventilation for healthcare premises provides comprehensive advice and guidance to healthcare management, design engineers, estate managers and operations managers on the statutory and legal requirements, design implications, maintenance and operation of general and specialised ventilation in all types of healthcare premises.

SHTM 03-01 is published in two parts: Part A deals with the concept, design, specification, installation and acceptance testing of ventilation systems; Part B covers the management, operation, maintenance and routine testing of existing healthcare ventilation systems, and gives advice and guidance to healthcare management, design engineers, estates managers and operations managers on the legal requirements, design implications, maintenance and operation of specialised ventilation.

NHS Lothian management are responsible for ensuring that inspection, service and maintenance activities are carried out safely and to the correct specifications. To achieve this, staff will adhere to the requirements of SHTM 03-01, while also referencing the industry definitive standard for building maintenance specifications to be referred to when carrying out routine maintenance.

Scope

The Audit evaluated the adequacy of internal controls in place around the ongoing maintenance and repair of critical healthcare ventilation systems and the Hospital Sterilisation Decontamination Unit (HSDU). While the review will focus on the Western General and St John's acute sites. We will also seek to obtain the necessary assurances that an adequate control framework is in place at the Royal Infirmary of Edinburgh.

Approach

Through our planning work we identified the following risks which formed the basis of the audit work undertaken.

- Individuals required to monitor and/or maintain ventilation equipment are not competent to do so
- Roles and responsibilities for the management of ventilation systems have not been clearly defined and there is no appropriate oversight at a senior management or Board level
- An inventory of all ventilation systems installed and in use or capable of being used is not maintained
- Critical Healthcare Ventilation Systems are not subject to routine inspection and maintenance
- Records of ventilation systems and their performance are not kept and cannot be accessed when necessary (this is a legal requirement)

A complete list of staff involved in the audit and documents reviewed can be seen at Appendix 1.

Acknowledgments

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

Limitations in Scope

Please note that our conclusion is limited by scope. It is limited to the risks outlined above. Other risks that exist in this process are out with the scope of this review and therefore our conclusion has not considered these risks. Where sample testing has been undertaken, our findings and conclusions are limited to the items selected for testing.

This report does not constitute an assurance engagement as set out under ISAE 3000.

Executive Summary

Summary of Findings

We have concluded that the controls in place in respect of ongoing maintenance and repair of critical healthcare ventilation systems and the Hospital Sterilisation Decontamination Unit (HSDU), provides a **LIMITED** level of assurance. The table below provides a summary of the findings. The ratings assigned are based on the agreed internal audit rating scale (**Appendix 2**).

Detailed findings, recommendations and agreed management actions are found in Section 2 of this report.

Limited Assurance			
HIGH	MEDIUM	LOW	ADVISORY
2	5	1	-

Ref	Issue	H	M	L	A
2.1	<p>Risk area as per scope:</p> <p>Critical Healthcare Ventilation Systems are not subject to routine inspection and maintenance</p> <p>Planned maintenance is not being carried out as and when required, or to the appropriate instruction</p>	1	-	-	-
2.2	<p>Risk area as per scope:</p> <p>Critical Healthcare Ventilation Systems are not subject to routine inspection and maintenance</p> <p>Actions arising from the annual inspection of critical ventilation systems are not subject to ongoing monitoring and review</p>	1	-	-	-
2.3	<p>Risk area as per scope:</p> <p>Individuals required to monitor and/or maintains ventilation equipment are not competent to do so</p> <p>The appointment of staff to their respective roles is unclear or incomplete</p>	-	1	-	-
2.4	<p>Risk area as per scope:</p> <p>Individuals required to monitor and/or maintains ventilation equipment are not competent to do so</p> <p>The provision of training is incomplete, has lapsed or could not be confirmed</p>	-	1	-	-

Ref	Issue	H	M	L	A
2.5	<p>Risk area as per scope:</p> <p>Roles and responsibilities for the management of ventilation systems have not been clearly defined and there is no appropriate oversight at a senior management or Board level</p> <p>The remit of the Ventilation Safety Group requires formal approval and ratification</p>	-	1	-	-
2.6	<p>Risk area as per scope:</p> <p>Critical Healthcare Ventilation Systems are not subject to routine inspection and maintenance</p> <p>Permits to Work and risk assessments for inspections, maintenance or repairs are incomplete</p>	-	1	-	-
2.7	<p>Risk area as per scope:</p> <p>Critical Healthcare Ventilation Systems are not subject to routine inspection and maintenance</p> <p>Actions arising from the review of the HSDU's operational issues are not developed into an effective action plan</p>	-	1	-	-
2.8	<p>Risk area as per scope:</p> <p>Roles and responsibilities for the management of ventilation systems have not been clearly defined and there is no appropriate oversight at a senior management or Board level</p> <p>The Ventilation Systems Policy should be updated to include the role of the Ventilation Safety Group</p>	-	-	1	-
TOTAL		2	5	1	-

Executive Summary

Conclusion

Through discussions held and evidence obtained, internal audit can confirm that some procedures are being followed to enable NHS Lothian to comply with the technical requirements for specialised ventilation for healthcare premises. However, some issues have been noted around the completeness of professional expertise and appointments, planned maintenance requirements and the governance framework in place.

Improvement opportunities have also been identified around the Board's management of recommendations arising from the review of the operation of the air handling units within HSDU.

These findings are discussed in full within our Management Action Plan below.

Follow up

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

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.

Management Action Plan

Risk area as per scope: Critical Healthcare Ventilation Systems are not subject to routine inspection and maintenance

HIGH

Finding 2.1 – Planned maintenance is not being carried out as and when required, or to the appropriate instruction

Control

SHTM 03-01, advises that the loss of service of critical ventilation systems would seriously degrade the ability of the premises to deliver optimal healthcare. In order to ensure reliable service provision, critical systems should be subject to a quarterly inspection and maintenance regime. Inspections should be a simple visual check and include within the schedule of planned maintenance.

Scheduled maintenance has been categorised within Agility as monthly, quarterly, six-monthly and annual tasks.

Observation

Both the St. John's Hospital and Western General Hospital sites have reported that the schedule of planned maintenance for the critical ventilation systems at these sites is incomplete. For the months May 2022 - July 2022, Western General Hospital completed an average of 20% of all planned mandatory maintenance of the critical ventilation units (116 of 588 tasks). In the same period, St. John's Hospital completed an average of 31% of all planned mandatory maintenance of the critical ventilation units (113 of 383 tasks).

Under the terms of the Project Agreement agreed between NHS Lothian and Consort for the Royal Infirmary of Edinburgh, Consort are required each month to submit Performance Scorecards, which include the following Performance Standard:

- 1.4.4 - Were all Maintenance Works, e.g. Schedule of Programmed Maintenance or a PMM carried out in accordance therewith?

For the same timeframe, the Royal infirmary of Edinburgh has reported an average of 17% PPM activities that were late or failed (119 of 683 tasks).

Furthermore the Project Agreement currently requires Consort to maintain all ventilation systems to SHTM 2025. This does not specifically distinguish between critical and non-critical healthcare ventilation systems, so the distinction of what ventilation systems have been subject to planned mandatory maintenance is less clear than would be preferred. It is noted however that all maintenance activities are completed in accordance with Good Industry Practice and, at the time the contract was signed, SHTM 2025 was deemed to be Good Industry Practice.

A Service Change Order Request has been prepared and submitted to Consort to instruct EQUANS (Consort's estates service provider) to carry out verifications and inspections on the 68 critical ventilation systems as identified within the current critical ventilation schedule in compliance with SHTM 03 01-Part B.

It was also noted from review of the Performance Scorecard that for the current contract year, there has been no Schedule of Programmed Maintenance prepared in accordance with the Project Agreement and approved within the Review Procedure.

Risk

Without adhering to an agreed schedule of maintenance for all critical ventilation systems, there is an increased risk of the breakdown of these systems, which is likely to have a knock on effect on the clinical activities of the hospital.

Furthermore, without adhering to the most relevant technical memorandum and the reporting of performance data relating specifically to the function and operation of the Board's critical ventilation systems, it cannot be assured that maintenance activities within the Royal Infirmary of Edinburgh are sufficient in ensuring that there is no unexpected breakdown of these systems.

Recommendation

Management within Estates should ensure that planned mandatory maintenance activities are increased and conducted in accordance with the requirements of SHTM 03-01. To support this an action plan should be developed with clear ownership for increasing the number of activities recorded, alongside the prioritisation of higher risk areas. Thereafter actual activity against the planned should continue to be reviewed by the Sector Managers, with issues escalated to senior management / the Ventilation Safety Group as appropriate.

The issue around adhering to the most appropriate SHTM at the Royal Infirmary of Edinburgh should also be resolved as soon as possible and a Schedule of Programmed Maintenance agreed from this.

Finding 2.1 – Continued

Management Response

Management accept this finding and recommendation.

Management Action

Planned mandatory maintenance of the critical ventilation systems for each acute site will be reviewed and a comprehensive maintenance plan developed for each to ensure coverage and adherence to SHTM-03.

Once done this will be approved by the pan-Lothian Ventilation Safety Group and progress reported at each meeting of the Group thereafter.

Management will also work to resolve the technical discrepancy with the Royal Infirmary of Edinburgh and obtain the necessary assurances from Consort that the planned maintenance activities at the site are aligned with SHTM-03. Once concluded, a schedule of planned maintenance will be agreed and reported against.

Responsibility:

Head of Operations Hard FM

Interim Facilities Lead, RIE

Target Date:

31 March 2023

Finding 2.2 – Actions arising from the annual inspection of critical ventilation systems are not subject to ongoing monitoring and review

Control

SHTM 03-01, advises that all critical healthcare ventilation systems should be verified at least annually although in some circumstances the verification may need to be carried out more frequently. The purpose of the annual verification will be to additionally ensure that the system:

- Achieves minimum standards specific to the application;
- Is operating to an acceptable performance level;
- Remains fit for purpose.

Appointed Authorising Engineers are also required to perform their own annual assessment the Board's continued management of its ventilation systems and the staff with responsibility for maintaining them.

Observation

Of the 29 critical air handling units in operation at the Western General Hospital, 14 had been inspected within the last 12 months. However only four reports from the Authorising Engineer could be obtained through the Ventilation Documentation System on the shared drive.

Of the 27 critical air handling units identified for St. John's Hospital, 19 had been inspected within the last 12 months. Reports were in place for all.

The Authorising Engineer for the Royal Infirmary of Edinburgh reviewed the annual verifications and has noted that they are of a good standard and consistent in appearance. They reveal a number of common issues and these have been taken forward into the Authorising Engineer report action plan for further discussion.

The Authorising Engineers for each of the three sites have also carried out their own independent audits on the following dates:

- Western General Hospital – 8 February 2022
- St. John's Hospital – 12 January 2022
- Royal Infirmary of Edinburgh – 26 May 2022

While the common issues and actions arising from the Authorising Engineer report for the Royal Infirmary of Edinburgh, including those from the annual verifications have been taken forward into an Authorising Engineer report action plan for further review and discussion by the site's Ventilation Safety Group, nothing similar has been prepared for the Western General Hospital and St. John's Hospital sites.

The Western General Hospital Authorising Engineer audit from 8 February 2022 identified 19 action points, of which 16 were from the previous year's audit, with 3 rated as very high and all of which had passed their due date. This review has been unable to determine whether a tracker is in place to monitor and review progress against the actions. This site has in place a spreadsheet titled "WGH Critical Vent Review Nov 2020", which lists all of the actions required following the audit of this site in August 2020. However, this document has not been updated since then.

The St. John's Hospital audit from 12 January 2022 identified 26 action points, of which 22 were from the previous year's audit and had all passed their due date. Similarly, This review has been unable to determine whether a tracker is in place to monitor and review progress against the actions.

It has also been noted that the output from these exercises have not been routinely reported to the NHS Lothian Ventilation Safety Group.

Risk

Without an effective means of recording and reviewing the actions and improvements arising from the annual verifications and accompanying Authorising Engineer independent audits, there is a risk that management are unable to ensure that the critical ventilations systems and accompanying control framework are being adequately maintained.

Finding 2.2 – Continued

Recommendation

Management should ensure that all annual verification reports are maintained for each site within the relevant folder of the shared drive. Furthermore the schedule of annual verifications of all critical ventilation systems at the Western General Hospital and St. John's Hospital should be adhered to.

All corrective actions and recommendations arising from the annual verifications and Authorising Engineer audits for the St. John's Hospital and Western General Hospital sites should be collated into an action trackers. This should be subject to regular review and update, with progress also reported to the NHS Lothian Ventilation Safety Group.

Management Response

Management accept this finding and recommendation and have also noted that there is a key issue with the validation of ventilation systems in that the asset listing as it stands does not specifically list all critical ventilation air handling units. With no contract currently in place with a specialist ventilation organisation to validate their remains a gap between what is and is not categorised as critical with the asset listing.

Management Action

Management will appoint an appropriate specialist organisation to validate the critical ventilation systems within the asset listing of Agility.

Thereafter a schedule of verification inspections will be developed and the Authorising Engineer requested to carry out annual inspections in accordance with this.

Output reports from the annual verification inspections will be stored centrally in the Ventilation Documentation system within the shared drive. All corrective actions arising from the inspections will be recorded in an action plan alongside those raised by the Authorising Engineer from their annual audits. Progress against the actions will be monitored and reported to the Ventilation Safety Group.

Responsibility:

Head of Operations Hard FM

Target Date:

31 March 2023

Risk area as per scope: Individuals required to monitor and/or maintains ventilation equipment are not competent to do so

Medium

Finding 2.3 – The appointment of staff to their respective roles is unclear or incomplete

Control

SHTM 03-01, Part B, advises that those required to inspect, verify or maintain ventilation equipment are required to show that they are competent to do so. As a minimum they should have sufficient knowledge of its correct operation to be able to recognise faults.

The role of Designated Person for ventilation provides an informed position at board level and confirms the appointment of any person intending to fulfil any of the staff functions specified in SHTM 03-01. All post holders should be appointed in writing by the Designated Person and a record kept of those appointed to carry out their function. The record should clearly state the extent of the post holder's duties and responsibilities, and to whom they are to report.

An Authorised Person is recorded in SH-TM 03-01 as individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the Designated Person (in conjunction with the advice provided by the Authorising Engineer), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of ventilation systems. Certification of Recommendation prepared by the Authorising Engineer is valid for an initial 3 years, then subject to annual review thereafter.

Competent Persons are defined by SHTM 03-01 as a person designated by management to carry out maintenance and periodic testing of ventilation systems. Appointment of Competent Persons to their role has been delegated by the Designated Person to the appropriate Authorising Person.

Observation

The Western General Hospital and St. John's Hospital sites each have three Authorised Persons in place. The Royal infirmary of Edinburgh has two Authorised Persons.

It was noted that one Authorised Person at the Western General Hospital had not had their appointment to their role certified by the Authorising Engineer. Certification for one of the other two Authorised Persons had expired on 09/02/2022. The review also could not locate evidence of appointment to the role by the Board's Designated Person for one Authorised Person.

Similarly, Certification for one Authorised Person at St. John's Hospital had expired on 16/01/2020, with no evidence of certification available for the other two. Appointment to the role by the Board's Designated Person also could not be located for two Authorised Persons.

Western General Hospital has 10 Competent Persons currently in place, however there is no evidence on file formally appointing them to the role. Similarly, St. John's Hospital has 10 Competent Persons, although only four members of staff have been formally appointed to the role, which had been done by one of the Authorised Persons for that site.

Of the two Authorised Persons in place at the Royal Infirmary of Edinburgh, only one had been formally appointed.

Risk

Without the relevant documentation in place and up-to-date supporting the appointment of staff to their respective roles, there is a risk that there is a lack of sufficient knowledge to perform their duties and recognise faults when they occur.

Recommendation

Management should ensure that all Competent Persons and Authorised Persons are formally appointed to their roles, with certification provided by the Authorising Engineer where necessary. Where Certification of Recommendation has lapsed, action should be taken to confirm the postholders duties and responsibilities with the Authorising Engineer.

Management Action Plan

Finding 2.3 – Continued

Management Response

Management accept this finding and recommendation.

Management Action

Management will review all appointments to the Authorising Person and Competent Person roles for all sites and ensure that they have been formally appointed to their roles, with certification provided by the Authorising Engineer where necessary. Where Certification of Recommendation has lapsed, action will be taken to confirm the postholders duties and responsibilities with the Authorising Engineer.

Responsibility:

Head of Operations Hard FM

Target Date:

31 March 2023

Risk area as per scope: Individuals required to monitor and/or maintains ventilation equipment are not competent to do so

Medium

Finding 2.4 – The provision of training is incomplete, has lapsed or could not be confirmed

Control

SHTM 03-01, Part B, advises that training in the validation and verification of specialised healthcare ventilation systems for Authorised Persons and Competent Persons is available from a variety of providers. While there is a duty on post holders to keep their knowledge up to date, as reflected for Authorised Persons in their CPD record, there is no requirement to routinely attend any specific refresher course.

At the Royal Infirmary of Edinburgh, Consort is obliged under the Project Agreement to ensure that all maintenance activities are completed in accordance with Good Industry Practice. This requires that a degree of skill, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person carrying out the activity.

Observation

Within the Western General Hospital site, all Authorised Persons received training appropriate to their role in 2021, with Competent Persons trained most recently during 2019. Authorised Persons working out of the St. John's Hospital site last received training in 2019 and Competent Persons also given training in that year.

The senior Authorised Person at the Royal Infirmary of Edinburgh was trained in 2019 and appointed in writing thereafter. The second Authorised Person to join the Board to assist with verifications and Authorised Person work at the site had completed their training in 2018. Also, during the time that the on-site and independent facilities management (Thomson FM) have been supporting NHS Lothian in respect of the commercial management of the Royal Infirmary of Edinburgh contract (three years), they have not seen any evidence provided by Consort to demonstrate the competencies, skill and experience of those individuals and / or sub-contractors who maintain the critical ventilation systems.

While senior staff at the Western General Hospital are in the process of arranging refresher training for their Competent Persons, no refresher training has been arranged for Competent Persons at St. John's Hospital.

Risk

Until training of all staff responsible for the ongoing maintenance of the critical ventilation systems can be evidenced as complete and up-to date, there is a risk that some staff may lack the required level of skill and expertise to perform their duties safely and to the required standard.

Recommendation

Management should schedule refresher training for the Competent Persons and Authorised Persons at the St. John's Hospital site, considering the importance of the role and their CPD requirements. Ensuring that the training of staff is appropriately aligned across both the Western General Hospital and St. John's Hospital.

It is also recommended also that refresher training for the second Authorised Person at the Royal Infirmary of Edinburgh is also scheduled for completion as soon as possible. Alongside this, evidence of the expertise and qualifications of the Competent Persons employed at the site should be obtained.

Management Response

Management accept this finding and recommendation.

Finding 2.4 – Continued

Management Action

Alongside the management action for Finding 2.3, management will review the training status of all staff at St. John's Hospital and with a role in the maintenance and inspection of critical ventilation systems. Thereafter refresher training will be scheduled where required.

Confirmation will be requested that refresher training for the second Authorised Person at the Royal Infirmary of Edinburgh site has been completed. Alongside this, evidence of the expertise and qualifications of the Competent Persons employed at the site will be obtained.

Responsibility:

Head of Operations Hard FM

Sector Manager (SJH)

Interim Facilities Lead, RIE

Target Date:

31 March 2023

Risk area as per scope: Roles and responsibilities for the management of ventilation systems have not been clearly defined and there is no appropriate oversight at a senior management or Board level

Medium

Finding 2.5 – The remit of the Ventilation Safety Group requires formal approval and ratification

Control

SHTM 03-01, Part B advises that the management of the ventilation systems of a healthcare provider should be overseen by the Ventilation Safety Group. The Ventilation Safety Group should have clearly defined roles and responsibilities, be part of a healthcare organisation's governance structure and report to the designated person at Board level.

The Ventilation Safety Group should be a multidisciplinary group and should typically comprise:

- An Authorising Engineer / independent adviser for ventilation;
- An Infection Prevention and Control representative;
- Authorised Persons;
- Estates (operations and projects) staff;
- Clinicians and specialist departments (for example theatres, critical care, medical microbiology).
- Personnel from the finance department with accountability for capital and revenue evaluation;
- Other stakeholders as appropriate;
- Co-opted expertise, for example ventilation designers, consultants and suppliers.

Observation

While the membership of the NHS Lothian Ventilation Safety Group is broadly reflective of the SHTM 03-01 guidance, with standing agenda items identified for regular review and discussion, the Terms of Reference for the Group drafted in January 2022 have not yet been formally finalised and ratified. It has been noted by the Chair of the Group (NHS Lothian's Medical Director) through the Group's minutes that further work is required to establish the Ventilation Safety Group as a key governance group, with discussions ongoing around the its remit, agenda and membership. Specifically, the Group is not yet adhering to a regular schedule of meetings, with attendance by the Board's Authorising Engineer and estates & Facilities staff also not yet confirmed.

Elsewhere, the Royal Infirmary of Edinburgh has a separate Ventilation Safety Group in place and is meeting fortnightly.

All meetings are following a set agenda a membership includes a number of representatives from NHS Lothian, including individuals who also sit on the NHS Lothian Ventilation Safety Group.

An Estates and Facilities Improvement Group has been established by NHS Lothian to provide adequate competent resource to ensure the key clinical activities across Royal Infirmary of Edinburgh campus are receiving adequate support and engagement with the Estates and Facilities function; and that the interface between Estates & Facilities critical activities, and clinical activities is effectively planned and managed at all times. This includes critical ventilation works as necessary.

Risk

Until the NHS Lothian Ventilation Safety Group is formally established to provide an appropriate level of oversight to the performance of the Board's critical ventilation infrastructure, there is a risk that critical performance criteria are not being appropriately scrutinised and action taken to ensure that necessary improvements are in place and taken forward.

Recommendation

The role of the Ventilation Safety Group, including the agenda and membership should be ratified as soon as possible by the NHS Lothian Board. Thereafter, a schedule of meetings should be agreed and adhered to, attended by all relevant individuals.

Management Response

Management accept this finding and recommendation.

Finding 2.5 – Continued

Management Action

The role of the Ventilation Safety Group, including the agenda and membership will be ratified as soon as possible by the appropriate the NHS Lothian Board Committee. Thereafter, a schedule of meetings will be agreed and adhered to. Attendance at meetings of the Ventilation Safety Group will be monitored to ensure that all relevant individuals are in attendance.

Responsibility:

Medical Director (Chair of NHSL VSG)

Target Date:

31 March 2023

Finding 2.6 – Permits to Work and risk assessments for inspections, maintenance or repairs are incomplete

Control

SHTM 03-01, advises that all inspection and maintenance activities are risk-assessed to ensure that they do not create a hazard for those who undertake the work or for those who could be affected by it. Furthermore, an equipment release or permit-to-work certificate should be completed to ensure that taking the ventilation system out of service does not compromise the activities of the user department.

It is expected that all verification and inspections that require the unit to be isolated and switched off will have an accompanying Permit to Work (PTW).

Observation

Testing was carried out on a sample of Permits to Work, to confirm that they had been completed by:

- Competent Person (before and after completion);
- Authorised Person (before and after completion);
- Clinical Representative.

Three of four PTWs selected for review for the Western General Site were completed by the Authorised Person and Competent Person (from a population of 14 covering the previous 12 months), however one had not been signed by the clinical representative after the works had been completed.

The Sector Manager for St. John’s Hospital has advised that due to the severe staffing shortages at the site (they currently have a Team Leader and three fitters where they should have eight plus a Team Leader), they are restricted to maintenance that they can achieve and as such we are only covering some of the monthly checks which don't involve a shut down and PTW. The most recent PTW on critical plant maintenance was completed in 2021, with the most recent permit completed on 17 August 2022 for a breakdown repair.

Of the two reviewed, one had not been signed by the clinical representative after the works had been completed.

It is also noted through the Authorising Engineer Reports for both the St John’s Hospital and Western General Hospital sites that no risk assessments or are being conducted prior to work commencing. Review of the Ventilation Document Register for both the Western General Hospital and St. John’s Hospital sites on the shared drive has confirmed that risk assessments are inconsistent, with none completed since 2020.

Risk

Unless the PTWs are fully completed, there is a risk that the work carried out has not been completed to a standard that is acceptable to the clinical area and the reinstatement of services delayed.

Without the completion of risk assessments or method statements alongside the maintenance works, there is a risk that Inspection and maintenance activities may hazardous for those who undertake the work or for those who could be affected by it.

Recommendation

Where required, management should ensure that PTWs are fully completed and that risk assessments should be produced for all work activity including planned maintenance of ventilation systems. These should be communicated to staff and recorded in the appropriate Ventilation Document Register.

Management Response

Management accept this finding and recommendation.

Finding 2.6 – Continued

Management Action

Management will remind staff to ensure that Permits to Work are completed in full and that risk assessments are carried using the agreed template and support the work that is being undertaken.

Completed risk assessments will be stored within the appropriate folders in the Ventilation Document Systems on the shared drive.

Responsibility:

Sector Estates Managers

Target Date:

31 March 2023

Risk area as per scope: Critical Healthcare Ventilation Systems are not subject to routine inspection and maintenance

MEDIUM

Finding 2.7 – Actions arising from the review of the HSDU’s operational issues are not developed into an effective action plan

Control

The HSDU facility at Royal Infirmary of Edinburgh is responsible for reprocessing re-usable surgical instruments and trays for all of NHS Lothian’s operating theatres.

On 20th July 2022 a failure was identified in the Air Handling Unit. Loss of clean room pressure lasted for a duration of four hours and the unit was close to being taken out of service. This could have resulted in major clinical impact as surgical procedures would have to have been suspended.

This issue has occurred previously on 11 October 2021 when an SBAR was completed and extensive investigation carried out. With a Significant Event Review carried out in December 2021.

In response to the most recent failure, the Decontamination Lead and Associate Director of Operations – Facilities produced an SBAR recording several recommendations and subsequent air pressure query actions.

Observation

It is noted that the reprovision of the service remains a long-term goal and is progressing through the Board’s capital planning arrangements. However, a number of other medium term recommendations arising from the December 2021 report remain outstanding.

Elsewhere, progress around the reported actions has been made through the recent completion of a Single Points of Failure report and it is also anticipated that a planned lessons learned process will be completed in December 2022.

However, while there is evidence of ongoing discussion by the Royal Infirmary of Edinburgh Ventilation Safety Group , it has been noted that a comprehensive action plan has not been developed to track all required actions arising from the SBAR and Significant Event Review.

While Consort has consolidated some into an overarching Corrective Actions Schedule, review of this document has indicated that the status and target completion date have not yet been added.

Risk

The loss of the operation of the HSDU remains a significant corporate risk for the Board, with a clear reputational impact were there to be a shut down of the service in future.

Recommendation

While the audit has noted the progress to date, with oversight provided by the Ventilation Safety Group and the Estates Senior Management Team, it is recommended that a comprehensive action plan is developed to capture all actions arising from the Significant Events Review, SBAR and Single Points of Failure reports, with responsibilities and timescales included. All action recorded as closed should have the approval of the Ventilation Safety Group.

Thereafter, further actions from the lessons learned exercise should be incorporated.

Management Response

Management accept this finding and recommendation.

Finding 2.7 – Continued

Management Action

All completed and outstanding corrective actions relating to the HSDU and accompanying SBAR will be formally reviewed by NHS Lothian/Consort at the upcoming Critical Systems meeting. Thereafter an action plan will be developed to capture all remaining actions arising from the SBAR exercise and the planned lessons learned exercise. Progress against the action plan will be monitored and reported at the meeting of the RIE Ventilation Safety Group.

Responsibility:

NHS Lothian Decontamination Lead
Interim Estates Manager, RIE

Target Date:

31 March 2023

Risk area as per scope: Roles and responsibilities for the management of ventilation systems have not been clearly defined and there is no appropriate oversight at a senior management or Board level

LOW

Finding 2.8 – The Ventilation Systems Policy does not include the role of the Ventilation Safety Group

Control

According to SHTM 03-01, the Ventilation Safety Group is required to produce a ventilation policy document for the Board, which should follow the guidance contained therein.

The Assurance and Compliance Team within Estates produced a Ventilation Systems Policy in February 2021 and this has been approved for publication by the Board’s Policy Approvals Group. This Policy applies to all staff, service users and contractors associated with NHS Lothian and covers all maintenance activities on ventilation (Critical & Non-Critical), air conditioning and Local Exhaust Ventilation plant within NHS Lothian, and anywhere NHS Lothian is responsible for the maintenance of ventilation equipment.

Observation

However, there is no evidence to indicate that this had also been reviewed and approved by the Ventilation Safety Group. Additionally, while the Policy has recorded the responsibilities of the individual’s listed in SHTM 03-01 (Designated Person, Authorising Engineer etc), the role of the Ventilation Safety Group has not been included.

Risk

Without appropriate oversight of the Policy by the Ventilation Safety Group, there is a risk that all necessary information is recorded and staff are unaware through this document of all the relevant roles and responsibilities of all groups and individuals for the management of the Board’s critical ventilation systems.

Recommendation

The current Ventilation Systems Policy should be updated to record the role of the Ventilation Safety Group, thereafter the Policy should be presented to the Group for review and further update/approval.

Management Response

Management accept this finding and recommendation.

Management Action

The NHS Lothian Ventilation Systems Policy will be updated to record the role of the Ventilation Safety Group, thereafter the policy will be reviewed by the Ventilation Safety Group before further ratification by the Policy Approval Group.

Responsibility:
Head of Operations Hard FM

Target Date:
31 March 2023

Appendices

Appendix 1 – Staff Involved and Documents Reviewed

Staff Involved

- Business Manager, Estates & Facilities
- Head of Operations Hard FM
- NHSL Agility Project Manager
- Sector Estates Manager (WGH)
- Estates Officer (WGH)
- Area Manager Edinburgh Acute (WGH)
- Sector Managers (SJH)
- Head of Risk, Quality & Assurance - Estates and Facilities
- NHS Lothian Decontamination Lead
- Site Manager, RIE - PFI - PPP Contracts
- Interim Facilities Lead, RIE
- Associate Director/Building Surveyor, Capita Facilities Management
- Graduate Building Surveyors, Capita Facilities Management

Documents Reviewed

- NHS Lothian Ventilation Systems Policy
- Agility System Extracts:
 - Air Handling Plant Maintenance (SJH & WGH)
 - 12 Month Maintenance Planner (SJH & WGH)
 - Performance Reports July 2022 (SJH & WGH)
- Standard Operating Procedure – Agility Asset List Changes
- Authorising Engineer appointments and training records
- Authorising Engineer annual audit reports (WGH, RIE and SJH)
- Authorising Engineer reports action tracker
- Authorised Persons appointments and training records (WGH & SJH)
- Competent Persons appointment and training records (WGH & SJH)
- Designated Persons appointments
- Authorisation for Interruption/disconnection of ventilation services (Permit to Work)
- Annual Verification Reports (WGH & SJH)
- NHS Lothian Ventilation Safety Group:
 - Terms of Reference
 - Minutes – 12 January 2022 and 6 June 2022
- SBAR HSDU Air Handling Unit – 25 July 2022
- HSDU Ventilation Single Points of Failure (SPOF) and Systems Overview – 02 December 2021 and recommendations
- RIE Facilities Scorecard – May, June & July 2022
- Service Change Order Request No 230 – RIE Critical Ventilation
- RIE Ventilation Safety Group:
 - Terms of Reference
 - Minutes & Agendas – 21 July 2022, 18 August 2022 and 1 September 2022
- RIE Estates & Facilities Improvement Group:
 - Terms of Reference
 - Minutes & Dashboards – 12 July 2022, 26 July 2022, 9 August 2022 and 23 August 2022

Appendix 2 – Our IA Report assurance levels

The table below shows the levels of assurance we provide and guidelines for how these are arrived at. We always exercise professional judgement in determining assignment assurance levels, reflective of the circumstances of each individual assignment.

Rating	Definition	When Internal Audit will award this level
Significant assurance	<p>The Board can take reasonable assurance that the system(s) of control achieves or will achieve the control objective.</p> <p>There may be an insignificant amount of residual risk or none at all.</p>	<p>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)</p>
Moderate Assurance	<p>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.</p> <p>There remains a moderate amount of residual risk.</p>	<p>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".</p> <p>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)</p>
Limited Assurance	<p>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.</p>	<p>This may be used when:</p> <ul style="list-style-type: none"> 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. <p>The controls are deficient in some aspects and require management action (for instance one 'high' finding and a number of other lower rated findings)</p>
No assurance	<p>The Board cannot take any assurance from the audit findings. There remains a significant amount of residual risk.</p>	<p>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)</p>

Appendix 2 - Continued

The table below describes how we grade our audit recommendations based on risks

Rating	Description	Possible features
High	Findings that are fundamental to the management of risk in the business area, representing a weakness in the design or application of activities or control that requires the immediate attention of management	<ul style="list-style-type: none">▪ Key activity or control not designed or operating effectively▪ Potential for fraud identified▪ Non-compliance with key procedures / standards▪ Non-compliance with regulation
Medium	Findings that are important to the management of risk in the business area, representing a moderate weakness in the design or application of activities or control that requires the immediate attention of management	<ul style="list-style-type: none">▪ Important activity or control not designed or operating effectively▪ Impact is contained within the department and compensating controls would detect errors▪ Possibility for fraud exists▪ Control failures identified but not in key controls▪ Non-compliance with procedures / standards (but not resulting in key control failure)
Low	Findings that identify non-compliance with established procedures, or which identify changes that could improve the efficiency and/or effectiveness of the activity or control but which are not vital to the management of risk in the business area.	<ul style="list-style-type: none">▪ Minor control design or operational weakness▪ Minor non-compliance with procedures / standards
Advisory	Items requiring no action but which may be of interest to management or which represent best practice advice	<ul style="list-style-type: none">▪ Information for management▪ Control operating but not necessarily in accordance with best practice



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