Microbiological Air Sampling in Conventional Operating Theatres (Including Cardiac Cath Lab / Interventional Radiology) V1.0

Cornwall Partnership NHS Foundation Trust document reference code: IC/044/25

This is a joint policy between Cornwall Partnership NHS Foundation Trust and Royal Cornwall Hospitals NHS Trust.

Purpose: This standard operating procedure (SOP) has been developed to provide staff with the necessary information and knowledge to effectively identify the need and then request microbiological air sampling. The aim, to reduce the risk of introducing infection within operating theatres.

Target audience: All staff, service users and contractors associated with Royal Cornwall Hospitals NHS Trust and Cornwall Partnership NHS Foundation Trust.

Document sponsor and role: Graham Kaye, Senior IPAC Specialist Practitioner.
Document sponsors contact details: 01872 254969.

Document definition: Standard operating procedure.

Audience:
☒ Cornwall Partnership NHS Foundation Trust
☒ Royal Cornwall Hospitals NHS Trust

Freedom of information: Can be released under the Freedom of Information Act 2000. This document will be published on the internet and intranet.

Key words: air sampling, theatres,

Royal Cornwall Hospitals NHS Trust approval process

General manager confirming approval processes: Joanne Taylor.
Governance lead confirming approval process: Joanne Taylor.

Supporting committee: Infection prevention and control subcommittee
Supporting chairperson: Louise Dickinson, Director of Nursing and AHP's
Executive director responsible for the policy: Chief Nursing Officer (Dual)

Approved at: Ventilation Group and IPAC Committee
Date approved: 26 August 2025

Approved at: Royal Cornwall Hospitals NHS Trust Policy Ratification Group
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Document Library folder and sub-folder: Corporate / Infection Prevention and Control.

Cornwall Partnership NHS Foundation Trust approval process

Accountable Executive: Chief Nursing Officer (Dual)

Supporting committee: Infection Prevention and Control Subcommittee
Supporting chairperson: Louise Dickinson, Director of Nursing and AHP's

Approved at (if applicable): Infection Prevention and Control Subcommittee
Date: 26 August 2025

Accountable Executive approved: Chief Nursing Officer (Dual)
Date: 16 September 2025

Document library section: Safety and risk, infection control

Ratification

Start date: 16 September 2025

Review date: 1 March 2028 (6 months prior to the expiry date).

Expiry date: 1 September 2028 (3 years after ratification unless there are any changes in legislation or changes in NICE guidance or national standards).

Version control summary

Version	Date	Author and/or reviewer	Changes (key points) Include Section or page number.
1.	February 2025	G. Kaye, Senior IPAC Specialist Practitioner	New standard operating procedure.

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Data Protection Act 2018 (UK General Data Protection Regulation Legislation)

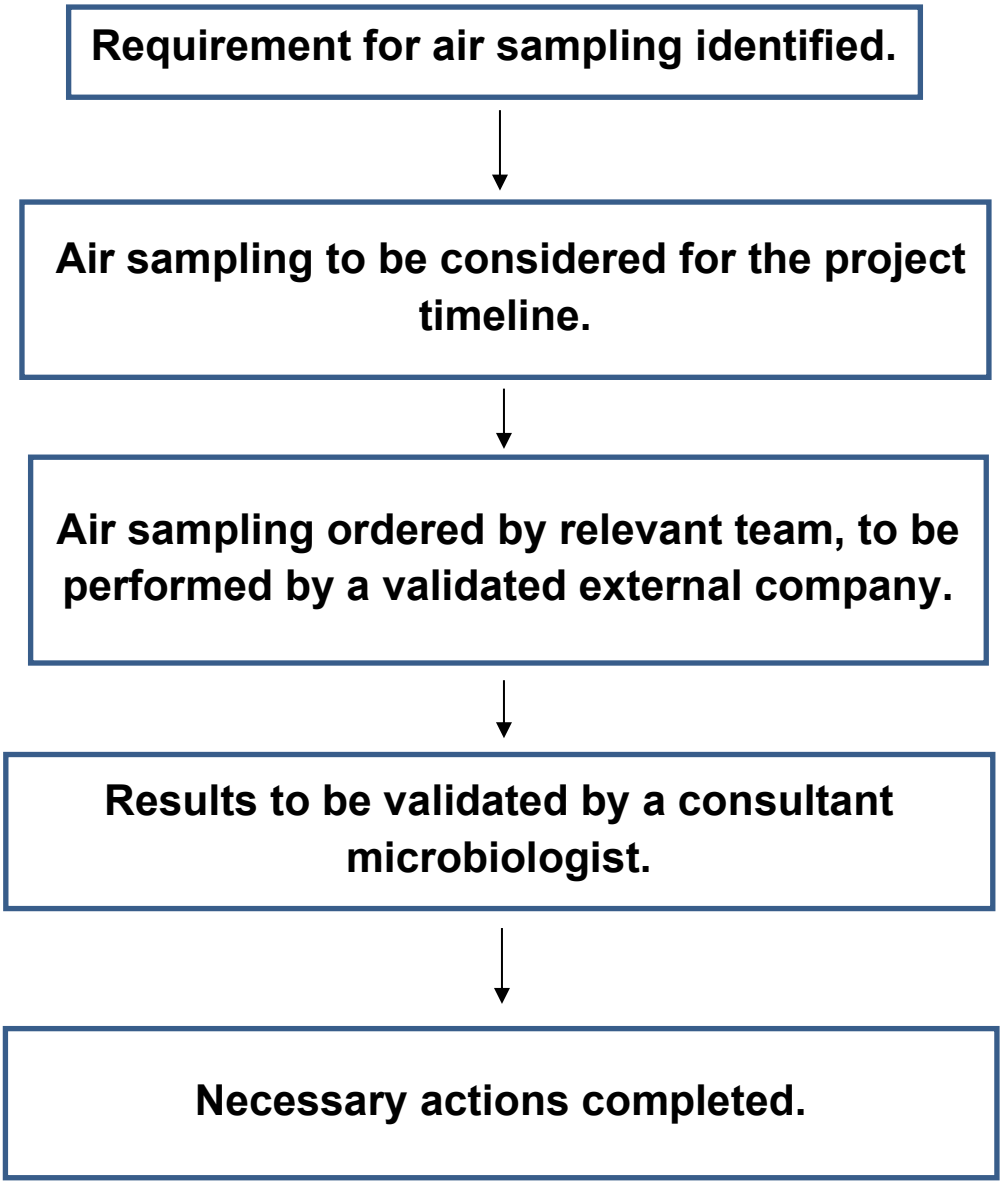
The Trusts have a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opted in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679, contact the Information Governance team.

- Cornwall Partnership NHS Foundation Trust: Email cpn-tr.infogov@nhs.net
- Royal Cornwall Hospitals NHS Trust: Email rch-tr.infogov@nhs.net

Summary


Requirement for air sampling identified.
Air sampling to be considered for the project timeline.
Air sampling ordered by relevant team, to be performed by a validated external company.
Results to be validated by a consultant microbiologist.
Necessary actions completed.

1. Introduction

Limited guidance is available regarding air sampling within operating theatres. This document aims to provide best practice and standardised air sampling recommendations for use within Royal Cornwall Hospitals NHS Trust and Cornwall Partnership NHS Foundation Trust.

This version supersedes any previous versions of this document.

2. Scope

This Standard Operating Procedure applies to conventionally ventilated, empty operating theatres and all staff, service users and contractors associated with Royal Cornwall Hospitals NHS Trust and Cornwall Partnership NHS Foundation Trust.

3. Definitions and glossary

IPAC: Infection prevention and control

VSG: Ventilation safety group

UCV: Ultra clean ventilation

4. Ownership and responsibilities

4.1. Role of the Trust board's Ventilation Safety Group

- To oversee governance of this SOP.

4.2. Role of the Infection Prevention and Control Team

- The IPAC team are responsible for the development and implementation of this SOP, in conjunction with support and co-operation from Estates and the ventilation safety group.

4.3. Role of the Consultant Microbiologist

- Final air sampling results should always be reviewed and interpreted by a Consultant Microbiologist.

4.4. Role of the Project Manager

- To incorporate into the project plan and initiate sampling. Testing is currently not available “in house” an external ISO approved company should be sought. Turnaround times should be considered when looking to make areas operational.

4.5. Role of the Care group management team

- To ensure this SOP has been followed prior to opening theatres.

5. Standards and practice

5.1. When to carry out air sampling:

- After any work that may result in bacterial or fungal contamination of the air supply, e.g. alterations or damage to the fabric of the theatre.
- After any modifications or remedial works that may affect airflow supply rates or distribution patterns, e.g. changes to the ductwork distribution.
- Validation of new Pharmacy aseptic preparation facilities.
- As part of a wider investigation into possible theatre-acquired infections with a suspected airborne element – this may involve sampling within an active theatre environment after discussion with the duty Consultant Microbiologist.
- Where more than one ceiling tile is removed.
- If someone enters the ceiling space via a hatch / roof tile.
- Targeted air sampling is enacted as part of enhanced surveillance requests.
- To meet the requirements of evidence collection connected with a Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) reportable event.

5.2. When not to carry out air sampling:

- As routine.
- For the routine commissioning of UCV operating theatres and Inspection, assembly, and packing (IAP) rooms in sterile services departments (provided the system is performing as per HTM 03-01). There is little value in performing microbiological sampling in an empty operating theatre supplied with ultra clean ventilation. Filter challenge tests, air velocity measurements and entrainment test will have proved that the system operates satisfactorily and achieves the contracted level of performance.
- If only one ceiling tile is removed.
- Post works, If the air handling is turned off and sealed for the duration of works and the room is decontaminated using hydrogen peroxide vapour (red clean).

5.3. Who should request air sampling?

- The Trust board's Ventilation Safety Group.
- Infection Prevention and Control, Consultant Microbiologist and/or Infection Prevention and Control Specialist Practitioner.
- Theatre senior management.
- The project manager must incorporate into the project plan and initiate sampling. Testing is currently not available "in house" an external ISO approved company should be sought. Turnaround times should be considered when looking to make areas operational.

5.4. Interpretation of Results:

As an external laboratory will be used for testing, there will be requirement for operational consideration, and the generation of a suitable risk assessment supported by the Ventilation Safety Group (VSG). The purpose of this assessment will be to decide suitability of the external laboratory, (ISO accreditation for air sampling, the process to be followed for the procedure and interpretation and validity of results).

Final air sampling results should then be shared with the following for oversight, interpretation, and action where applicable:

- IPAC team
- VSG (if applicable)
- Final air sampling results should always be reviewed and interpreted by a Consultant Microbiologist at RCHT.

5.5. Acceptable levels

- Clean, empty, conventionally ventilated operating theatres, achieving the optimal engineering parameters by design should achieve an air quality with a bioburden of <10 aerobic colony forming units (CFUs) of bacterial and / or fungal CFUs per cubic metre.

5.6. Action levels:

Bacterial and fungal counts of > 10 CFU

- Check if the sampling process and engineering parameters are assured and bacterial or fungal counts of > 10 CFUs are accurate.
- Results identified as true require further intervention, investigation, remediation, the establishment of control measures and corrective actions.

- The higher the CFU count from 10 onwards, the higher the level of contamination present at the time of sampling.
- Bacterial, fungal or a combination of both >10 CFU are unsatisfactory consider suspension of theatre activity temporarily to identify the problem, resample, and undertake necessary rectifications.

6. Related legislation, national and local guidance

(Health Protection Surveillance Centre). National Guidelines for the Prevention of Nosocomial Aspergillosis: A report of the Aspergillosis Sub-committee of the Health Protection Surveillance Centre Scientific Advisory Committee. 2018

Health Technical Memorandum 03-01 Specialised ventilation for healthcare premises Part A: The concept, design, specification, installation and acceptance testing of healthcare ventilation systems Health Technical Memorandum 03-01 Part A

Health Technical Memorandum 03-01 Specialised ventilation for healthcare premises Part B: The management, operation, maintenance and routine testing of existing healthcare ventilation systems Health Technical Memorandum 03-01 Part B

Hoffman, P. N. et al., 2002. Microbiological commissioning and monitoring of operating suites: a report of a working party of the Hospital Infection Society. *Journal of Hospital Infection*. Vol 52, pp. 1-28.

Humphreys, H., Coia, J.E., Stacey, A., Thomas, M., Belli, A.-M., Hoffman, P., Jenks, P. and Mackintosh, C.A., 2012. Guidelines on the facilities required for minor surgical procedures and minimal access interventions. *Journal of Hospital Infection*. Vol 80, pp. 103-109.

Public Health England. 2016. *Protocol for Environmental Sampling, Processing and Culturing of Water and Air Samples for the Isolation of Slow-Growing Mycobacteria Standard operating procedure*. [Online.] Available at: https://www.gov.uk/government/publications/isolation-of-slow-growing-mycobacteria-environmental-and-air-sampling

The Newcastle upon Tyne Hospitals NHS Foundation Trust. *Microbiological Air Sampling of Operating Theatres*. [Online]. Available at: http://www.newcastle-hospitals.org.uk/downloads/policies/Infection%20Control/MicrobiologicalAirSamplingOperatingTheatres201605.pdf

7. CFT Associated Trust policies and documents

- None

8. Training requirements

A least two microbiology consultants should have awareness, and corresponding training, of microbiological air sample results. This should be maintained and documented as applicable.

9. Implementation

This policy will be implemented via the following routes:

- Information regarding the policy will be disseminated to the Infection Prevention and Control team, estates department, capital projects and theatre management teams.
- The policy will be included in the Trust's Document Library.

10. Document Monitoring arrangements

As a minimum, detail the arrangements for the following:

Information category	Detail of process and methodology for monitoring compliance
Element to be monitored	Microbiological air sampling will be reviewed against works carried out
Lead	Consultant Nurse/DIPC
Tool	Review of all eligible works recorded on a Word or Excel template.
Frequency	Monthly
Reporting arrangements	To be reviewed and scrutinised at the ventilation safety group.
Acting on recommendations and lead(s)	The ventilation safety group will undertake subsequent recommendations and action planning for any or all deficiencies and recommendations within reasonable timeframes.
Change in practice and lessons to be shared	Required actions will be identified and completed within a week.

Will the monitoring arrangements result in a clinical audit: No

11. Environmental sustainability

The Trust is committed and obligated to reduce its environmental impacts. Healthier outcomes can be achieved for people, the planet and pounds by conducting our activities in a more environmentally sustainable manner.

Email cft.sustainability@nhs.net for more information and guidance.

12. Updating and review

This SOP will be reviewed within three years.

13. Equality and diversity

This document complies with the Cornwall Partnership NHS Foundation Trust and Royal Cornwall Hospitals NHS Trust equality and diversity statements. The statements can be found in the RCHT Equality Diversity And Inclusion Policy and CFT Equality, Diversity and Inclusion Statement.

The initial equality impact assessment screening form is at appendix 1.

Appendix 1: Equality Impact assessment Form

Title of policy or document for assessment: Microbiological Air Sampling in Conventional Operating Theatres Standard Operating Procedure V1.0

Who is affected by the document?

☒ Staff ☒ Patients ☐ Visitors ☐ Carers ☐ Other ☐ All

The document aims to improve access, experience and outcomes for all groups protected by the Equality Act 2010.

Concerns

Are there concerns that the procedural document could have a differential impact on the following areas?

If a negative impact has been identified, please complete a full EIA by contacting the Equality, Diversity, and Inclusion Team. For RCHT please contact rcht.inclusion@nhs.net and for CFT please contact cft.inclusion@nhs.net

Concern area	Response	If yes, what existing evidence (either presumed or otherwise) do you have for this?
Age	☐ Yes ☒ No	
Disability	☐ Yes ☒ No	
Sex	☐ Yes ☒ No	
Gender reassignment	☐ Yes ☒ No	
Pregnancy and maternity	☐ Yes ☒ No	
Race	☐ Yes ☒ No	
Religion and belief	☐ Yes ☒ No	
Sexual orientation	☐ Yes ☒ No	
Marriage and civil partnership	☐ Yes ☒ No	
Groups at risk of stigma or social exclusion such as offenders or homeless people	☐ Yes ☒ No	
Human rights	☐ Yes ☒ No	

Are there any associated objectives of the document? If yes, what existing evidence (either presumed or otherwise) do you have for this?

No.

Signature of person completing the equality impact assessment:

Name: Graham Kaye
Date: 2 July 2025