Operational Directive

Subject: Microbiological Air Sampling of Operating Rooms in Western Australian Healthcare Facilities

This Operational Directive describes the requirements for microbiological air sampling of operating rooms as part of the commissioning process for any new or refurbished facility. Compliance with this Operational Directive is mandatory for all Western Australian public healthcare facilities and those licensed private healthcare facilities contracted to provide services to public patients.

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Microbiological Air Sampling of Operating Rooms in Western Australian Healthcare Facilities
Microbiological Air Sampling of Operating Rooms in Western Australian Healthcare Facilities Policy

1. Background

Surgical site infection (SSI) is a major complication following surgery and is associated with increased morbidity and mortality, as well as increased costs.\(^1\) The function of operating room (OR) ventilation is to prevent airborne microbial contaminants from entering surgical wounds. Under normal circumstances, the main source of airborne microbial contamination is microscopic skin fragments contaminated with bacteria, shed by healthcare workers (HCWs) in the OR. Another potential source of airborne microorganisms are air supplies that are not properly filtered.\(^2\)

The need for routine microbiological sampling of ORs is controversial. There is no national or international consensus on the methods, frequency, types of sampling or acceptable levels of microbial contamination. However, there is evidence to support microbiological air sampling of ORs as part of the commissioning process of a new facility or following major refurbishment, as an adjunct to other heating, ventilation and air conditioning (HVAC) quality assurance controls. The purpose of microbiological air sampling is to gauge the efficacy of the HVAC systems, including high-efficiency particulate air (HEPA) filters following installation or after major structural refurbishment.\(^2-7\)

2. Scope

This policy has relevancy to all healthcare facilities (HCFs) in Western Australian (WA) that have ORs.

3. Policy statement

Active microbiological air sampling, in accordance with the procedural requirements described in Appendix 1, will be undertaken:

- As part of the commissioning process of new ORs and includes sterile stock storage and supply rooms and designated sterile set-up rooms that are located within the operating suite.

- Following any major structural refurbishment (excluding routine HEPA filter changes) of an existing OR. A risk assessment should be undertaken for minor refurbishment projects to assess if dust migration can be controlled as microbiological air sampling may still be required.

- As part of an investigation into increased surgical site infections if during investigation the evidence supports a link to the OR. Consultation and advice from a microbiologist should be sought prior to sampling.

The OR is not to be utilised until results of the air sampling have been confirmed. HCFs need to ensure they are aware of turnaround time and plan accordingly as air sampling results can take between 3-7 days to be finalised.
There is no evidence to support further microbiological sampling be undertaken in addition to air sampling and therefore this is not recommended e.g. passive sampling such as the use of settle plates or collection of environmental surface samples.

4. Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>HEPA Filter</td>
<td>A High Efficiency Particulate Air (HEPA) filter is a disposable, extended media, dry type filter in a rigid frame, having a minimum filtration efficiency of 99.97% and designed to remove particles greater than 0.3 microns.⁸</td>
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<tr>
<td>Laminar Airflow</td>
<td>Laminar airflow refers to the delivery of air in a manner that provides uniform, directional, non-turbulent airflow at consistent velocity across the operating zone that does not readily mix or become entrained with other room air until lower velocities are achieved after passing through the operating zone.⁹-¹³</td>
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<tr>
<td>Minor Refurbishment</td>
<td>Type A and B construction activity types as defined by the Australasian Health Care Facility Guidelines (refer Appendix 2).¹⁴</td>
</tr>
<tr>
<td>Major Refurbishment</td>
<td>Type C and D construction activity types as defined by the Australasian Health Care Facility Guidelines (refer Appendix 2).¹⁴</td>
</tr>
<tr>
<td>Operating Room</td>
<td>The room in which a surgical procedure is performed, with or without administration of an anaesthetic and there is use of microbiologically controlled air supply.</td>
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<td>Operating Room - Conventional Ventilation</td>
<td>Refers to an OR with general turbulent airflow (non-laminar). Air supply can be delivered via a terminal HEPA filter. Supply airflow is not necessarily restricted to the operating zone, but is distributed throughout the operating room.⁹-¹³</td>
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<tr>
<td>Operating Room - Ultra Clean Ventilation</td>
<td>Refers to an OR where a terminal HEPA filter delivers air via organised (laminar) flow and it is delivered uniformly over the operating zone with minimal entrainment of room air. Proprietary ultra clean ventilation canopies can be provided to deliver this function.⁹-¹³</td>
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5. Roles and responsibilities

- Executive Directors of HCFs are responsible for ensuring implementation and compliance with this Operational Directive (OD).
- Private HCFs contracted to provide care to public patients are required to submit microbiological air sampling results to the Licensing, Accreditation and Regulatory Unit prior to use of any new or refurbished OR and in accordance with licensing requirements.
- Each HCF will have a nominated health professional, who is responsible for the coordination and delivery of microbiological air sampling. Air sampling must be performed in collaboration with infection prevention and control service, the surgical services, and the pathology service.
6. Compliance

This policy is mandatory for all public hospitals and for those licensed private healthcare facilities that are contracted to provide care to public patients.

7. Evaluation

Evaluation of this policy will be carried out by the HAIU every two years. A questionnaire to WA HCF’s on the key principles of this policy to include but not limited to:

- number and type of ORs in the HCF
- occasions air testing have been required and evidence of results
- any concerns with surgical site infections and OR air flows.

8. References


9. Authority

<table>
<thead>
<tr>
<th>Title:</th>
<th>Healthcare Associated Infection Unit</th>
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<tbody>
<tr>
<td>Contact:</td>
<td>08 9388 4868</td>
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<tr>
<td>Directorate:</td>
<td>Communicable Disease Control Directorate</td>
</tr>
<tr>
<td>Version:</td>
<td>Date Published: 21/06/2015</td>
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<td>Date of Last Review:</td>
<td>21 June 2015</td>
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<tr>
<td>Date Next Review:</td>
<td>21 June 2020</td>
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Appendix 1

Procedure for Microbiological Air Sampling

The parameters used in this OD are based on current available evidence. It should be noted that there are no internationally agreed standards for microbiological air sampling.

1. PLANNING

- HCFs need to identify a National Association of Testing Authority (NATA) accredited laboratory for environmental testing and establish time lines for sample collection, processing and provision of results with that laboratory.

- HCFs must ensure adequate time is allowed for processing of results and the possible need for re-cleaning and re-testing prior to utilisation of the OR if results are outside acceptable parameters.

- Staff performing microbiological air sampling shall be trained in the use of the specific air sampler being used and the procedure for air sampling and transport of samples to the laboratory.

- The air sampler shall be checked to ensure it has been calibrated and serviced according to manufacturer’s instruction.

- The OR shall be empty of all non-fixed items, including supplies, sterile stock and any mobile equipment.

- No microbiological air sampling shall be conducted until:
  - all building and construction works have been completed
  - all HVAC commissioning procedures have been completed
  - all the ducting and air diffuser plates have been cleaned
  - the OR being sampled has been thoroughly cleaned, including ceiling spaces, service cavities, ventilation grills, all horizontal and vertical surfaces including ceilings and walls, and any fixed equipment in the OR
  - a second clean of all horizontal and vertical surfaces within the OR is recommended to ensure any contamination is removed
  - the HVAC system has been running continuously, on normal flow rates, for 24 hours following completion of all building and construction. Cleaning can be performed during this period of time.
2. SAMPLING SPECIFICATIONS

- A single sample of 1,000 litres (1m³) collected from each OR is the minimum requirement (a duplicate sample is useful for confirming unexpected results).

- The type of sampler used should be capable of sampling the volume of air without causing excessive drying of the recipient agar surface.

- Agar plates should be at room temperature prior to sampling.

3. PROCEDURE

- The air sampler shall be cleaned prior to use and run briefly prior to loading the agar strips/plates to blow any contamination out of the sampler.

- The OR being sampled, and any area that feeds air into the OR (e.g. preparation room, sterile stock store), shall be left vacant with closed doors for a minimum of 15 minutes, but preferably one hour, before sampling proceeds, to avoid false-positive results due to any recent OR activity, e.g. cleaning.

- Staff performing the air sampling shall wear theatre attire, a surgical mask and don sterile gloves after performing hand hygiene (NB- clothing is to be supplied by the HCF when external contractors are used).

- Using aseptic technique, proceed with setting up and placing the agar strips or plate into the sampler as per manufacturer's instructions.

- The air sampler is to be placed in the middle of the OR table or secured on a trolley where the OR table is usually located.

- When sampling ORs with laminar flow the air sampler should be operated by remote control from outside the uni-directional flow canopy to avoid compromising air quality.

- The OR doors must be kept closed and the OR empty of personnel until sampling is complete.

- Once air sampling is complete, aseptically remove the agar strip or plate, package to avoid contamination and label specific details including hospital name, OR number, volume of air sampled, date and time and transport to laboratory in a timely manner.

4. RESULTS and INTERPRETATION

- Preliminary results are generally not available until at least 48 hours after air sampling is completed. Results obtained at 24 hours may be misleading as many organisms will not grow visible colonies within this time frame.

- The acceptable level of colony forming units (CFUs) for the purpose of this operational directive is the same for all types of ORs.
• Aerobic cultures on non-selective media should not exceed 10 bacterial and or fungal CFUs per cubic metre (m3) of air sampled.

• If results received are outside of these limits, the OR should not be used. The results need to be discussed with a clinical microbiologist, infection prevention and control and surgical services personnel to initiate an appropriate course of action e.g. re cleaning of the environment and re testing.

• If repeat testing produces results above acceptable levels the HVAC systems should be reviewed by the appropriate personnel.
## Definitions of the Construction Activity Types\textsuperscript{14}

<table>
<thead>
<tr>
<th>Type A</th>
<th>Type B</th>
<th>Type C</th>
<th>Type D</th>
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<tbody>
<tr>
<td>Inspections and general upkeep activities</td>
<td>Small scale, short duration activities, which create minimal dust</td>
<td>Any work that generates a moderate to high level of dust</td>
<td>Major demolition and construction projects</td>
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<tr>
<td>Includes but not limited to: removal of ceiling tiles for visual inspection (limited to 1 tile per 5m(^2); painting (but not sanding); installation of wall covering; electrical trim work; minor plumbing; any activities that do not generate dust or require cutting into walls or access to ceiling other than for visual inspection.</td>
<td>Includes, but is not limited to, installation of telephone and computer cabling, access to chase spaces, cutting into walls or ceilings where the dust migration can be controlled.</td>
<td>Includes, but is not limited to, demolition or removal of built-in building components or assemblies, sanding of wall painting or wall covering, removal of floor covering/ wallpaper, ceiling tiles and casework, new wall construction, minor ductwork or electrical work above ceiling, major cabling activities.</td>
<td>Includes, but is not limited to, heavy demolition, removal of a complete ceiling system and new construction.</td>
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