Heating and ventilation systems Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises

Part B: Operational management and performance verification





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Part B: Operational management and performance verification

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Preface

About Health Technical Memoranda

Engineering Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

The focus of Health Technical Memorandum guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle. main source of specific healthcare-related guidance for estates and facilities professionals.

The core suite of nine subject areas provides access to guidance which:

- is more streamlined and accessible;
- encapsulates the latest standards and best practice in healthcare engineering;
- provides a structured reference for healthcare engineering.



Figure 1 Healthcare building life-cycle

Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Engineering Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to unnecessarily repeat international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Health Technical Memorandum guidance is the

Structure of the Health Technical Memorandum suite

The series of engineering-specific guidance contains a suite of nine core subjects:

- Health Technical Memorandum 00 Policies and principles (applicable to all Health Technical Memoranda in this series)
- Health Technical Memorandum 01 Decontamination
- Health Technical Memorandum 02 Medical gases

- Health Technical Memorandum 03 Heating and ventilation systems
- Health Technical Memorandum 04 Water systems
- Health Technical Memorandum 05 Fire safety
- Health Technical Memorandum 06 Electrical services
- Health Technical Memorandum 07 Environment and sustainability
- Health Technical Memorandum 08 Specialist services

Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc.

Example: Health Technical Memorandum 06-02 Part A will represent:

Electrical Services – Electrical safety guidance for low voltage systems

In a similar way Health Technical Memorandum 07-02 will simply represent:

Environment and Sustainability – $EnCO_2$ de.

All Health Technical Memoranda are supported by the initial document Health Technical Memorandum 00 which embraces the management and operational policies from previous documents and explores risk management issues.

Some variation in style and structure is reflected by the topic and approach of the different review working groups.

DH Estates and Facilities Division wishes to acknowledge the contribution made by professional bodies, engineering consultants, healthcare specialists and NHS staff who have contributed to the review.



Figure 2 Engineering guidance

Executive summary

Preamble

Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' is published in two parts: Part A deals with the design and installation of ventilation systems; Part B covers operational management.

The document gives comprehensive advice and guidance on the legal requirements, design implications, maintenance and operation of specialised ventilation in all types of healthcare premises.

The guidance contained in this Health Technical Memorandum applies to new installations and major refurbishments of existing installations.

Health Technical Memorandum 03-01 supersedes all previous versions of Health Technical Memorandum 2025 – 'Ventilation in healthcare premises'.

Who should use this guidance?

This document is aimed at healthcare management, estates managers and operations managers.

Main recommendations

- All ventilation plant should meet a minimum requirement in terms of the control of *Legionella* and safe access for inspection and maintenance.
- All ventilation plant should be inspected annually.
- The performance of all critical ventilation systems (such as those servicing operating suites) should be verified annually.

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University of Leeds

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1 Introduction

Preamble

- 1.1 Health Technical Memorandum 03-01 'Specialised ventilation in healthcare premises' is published in two parts: Part A deals with the design and installation of ventilation systems; Part B covers operational management.
- 1.2 The document gives comprehensive 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 in all types of healthcare premises.
- 1.3 The guidance contained in this Health Technical Memorandum applies to new installations and major refurbishments of existing installations.
- 1.4 Health Technical Memorandum 03-01 supersedes all previous versions of Health Technical Memorandum 2025 – 'Ventilation in healthcare premises'.

Ventilation in healthcare premises

- 1.5 Ventilation is used extensively in all types of healthcare premises to provide a safe and comfortable environment for patients and staff. More specialised ventilation is provided in areas such as operating departments, critical care areas and isolation facilities for primary patient treatment.
- **1.6** It is also installed:
 - to ensure compliance with the quality assurance requirements of items processed in pharmacies and sterile services departments;
 - to protect staff from harmful organisms and toxic substances (for example in laboratories).

Statutory requirements

Increased health risks to patients will occur if ventilation systems do not achieve and maintain the required standards. The link between surgical site infection and theatre air quality has been well established.

If the ventilation plant has been installed to dilute or contain harmful substances, its failure may expose people to unacceptable levels of contamination. Proven breaches of the statutory requirements can result in prosecution and may also give rise to a civil suit against the operators.

Health and Safety at Work etc Act 1974

1.7 The Health and Safety at Work etc Act 1974 is the core legislation that applies to ventilation installations. As these installations are intended to prevent contamination, closely control the environment, dilute contaminants or contain hazards, their very presence indicates that potential risks to health have been identified.

COSHH

- 1.8 The Control of Substances Hazardous to Health (COSHH) Regulations 2002 place upon management an obligation to ensure that suitable measures are in place to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a specialised ventilation system. In laboratories the requirements are often met by the provision of fume cupboards and microbiological safety cabinets.
- 1.9 Where specialised ventilation plant is provided as part of the protection measures, there is a statutory requirement that it be correctly designed, installed, commissioned, operated and maintained. The local exhaust ventilation (LEV) section of COSHH requires that the system be examined and tested at least every 14 months by a competent person and

that management maintain comprehensive records of its performance, repair and maintenance.

1.10 Certain substances have workplace exposure limits (WELs) set out in the Health and Safety Executive's (2005) Guidance Note EH40 – 'Workplace exposure limits: containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended)'. If specialised ventilation systems are provided in order to achieve these standards, they will be subject to the COSHH Regulations as above.

Fire regulations

- 1.11 The fire regulations require that, if ventilation ductwork penetrates the fabric of a building, it should be designed and installed so as to contain the spread of fire (see Health Technical Memorandum 05-02 'Guidance in support of functional provisions for healthcare premises' for further guidance).
- **1.12** It is management's responsibility to ensure that the standards applied during the design and installation are not reduced during the subsequent operation and maintenance of the equipment.

Plants installed in units manufacturing medicinal products

- 1.13 Plants installed in units manufacturing medicinal products to the standards set out in the current European guide to good manufacturing practice (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev4.htm) may also be subject to particular legislation with regard to their operation and maintenance.
- 1.14 There are specific requirements under the Medicines Act 1968 to maintain accurate records of plant performance, room conditions and maintenance events. Such records would need to be preserved for up to 35 years as part of a quality assurance audit trail.

Plants installed in laboratories

1.15 Specialised ventilation plants installed in laboratories dealing with research, development or testing, whether involving drugs, animals or genetically modified organisms, may be subject to particular legislation with regard to their operation in addition to that mentioned above.

Codes of practice and guidance

- 1.16 All ventilation systems should conform to the principles set out in the Health and Safety Commission's Approved Code of Practice and guidance document 'Legionnaires' disease: the control of *Legionella* bacteria in water systems' (commonly known as L8), and Health Technical Memorandum 04-01 – 'The control of *Legionella*, hygiene, "safe" hot water, cold water and drinking water systems'.
- 1.17 The Department of Health publication 'The Health Act 2006: code of practice for the prevention and control of healthcare associated infections' is a code of practice that has been brought out to help NHS bodies to plan and implement how they can prevent and control healthcare-associated infections. It sets out criteria by which managers of NHS organisations are to ensure that patients are cared for in a clean environment and where the risk of healthcareassociated infections is kept as low as possible. Specialised ventilation systems often play a central role in achieving this objective.

Management responsibilities – general

- **1.18** It is a management responsibility to ensure that inspection, service and maintenance activities are carried out safely without hazard to staff, patients or members of the public.
- **1.19** Those required to monitor and/or maintain ventilation equipment will need to show that they are competent to do so (see Chapter 2).
- **1.20** Maintenance procedures should be reviewed periodically to ensure that they remain appropriate.

System information

- 1.21 When new ventilation systems are accepted for use, full information as to their designed mode of operation together with recommended maintenance procedures should be provided as part of the handover procedure.
- 1.22 In many existing systems, original design and commissioning information will not be available. It will therefore be necessary to determine a suitable level of system performance based on the function, purpose and age of the installation.
- **1.23** Part A of this Health Technical Memorandum gives design parameters for new installations.

- **1.24** Chapter 3 of this document sets out the minimum standards for all air-handling units (AHUs) and their air distribution systems.
- 1.25 Ventilation system records and logbooks should be kept of the commissioning information, operational management routine, monitoring and maintenance. The Health and Safety Executive and other interested bodies have a statutory right to inspect them at any time. All records should be kept for at least five years.
- **1.26** In the event of a reportable incident connected with ventilation equipment or the area that it serves, all records and plant logbooks will need to be collected as evidence.
- 1.27 A set of specimen maintenance checklists is given in Appendix 1.

Frequency of inspections and verifications

- **1.28** All ventilation systems should be subject to, at least, a simple visual inspection annually.
- 1.29 Ventilation systems serving critical care areas should be inspected quarterly and their performance measured and verified annually. The quarterly inspection should be a simple visual check; the annual verification will be a more detailed inspection of the system together with the measurement of its actual performance.
- 1.30 The LEV section of the COSHH regulations contains a statutory requirement that systems installed to contain or control hazardous substances be examined and tested at least every 14 months by a competent person.
- 1.31 Regular tests, at intervals agreed with the local fire prevention officer, will need to be carried out in order to demonstrate the continuing efficiency of the fire detection and containment systems. These may be in addition to the inspections detailed above. Records of these tests should be kept.

2 Functional responsibilities

Management responsibilities

- 2.1 Clear lines of managerial responsibility should be in place so that no doubt exists as to who is responsible for the safe operation and maintenance of the equipment.
- 2.2 A periodic review of management systems should take place in order to ensure that the agreed standards are being maintained.
- 2.3 Those required to inspect, verify or maintain ventilation equipment will need 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.
- 2.4 It is anticipated that training in the validation and verification of specialised healthcare ventilation systems for Authorised Persons and Competent Persons will become available during the life of this Health Technical Memorandum.

Designated staff functions

2.5 A person intending to fulfil any of the staff functions specified below should be able to prove that they possess sufficient skills, knowledge and experience to be able to safely perform the designated tasks.

Management

2.6 Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the safe operation of premises.

Designated Person

2.7 This person provides the essential senior management link between the organisation and professional support. The Designated Person should also provide an informed position at board level.

Authorising Engineer (Ventilation) (AE(V))

2.8 The AE(V) is defined as a person designated by Management to provide independent auditing and advice on ventilation systems and to review and witness documentation on validation.

Authorised Person (Ventilation) (AP(V))

2.9 The AP(V) will be an 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 AE(V)), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of ventilation systems.

Competent Person (Ventilation) (CP(V))

2.10 The CP(V) is defined as a person designated by Management to carry out maintenance, validation and periodic testing of ventilation systems.

Infection Control Officer

- 2.11 The Infection Control Officer (or consultant microbiologist if not the same person) is the person nominated by management to advise on monitoring the infection control policy and microbiological performance of the systems.
- 2.12 Major policy decisions should be made through an infection control committee. The infection control committee should include representatives of the user department and estates and facilities or their nominated representative (that is, the Authorised Person).

Plant Operator

2.13 The Plant Operator is any person who operates a ventilation installation.

User

2.14 The User is the person responsible for the management of the unit in which the ventilation

system is installed (for example head of department, operating theatre manager, head of laboratory, production pharmacist, head of research or other responsible person).

Contractor

2.15 The Contractor is the person or organisation responsible for the supply of the ventilation equipment, its installation, commissioning or validation. This person may be a representative of a specialist ventilation organisation or a member of the general manager/chief executive's staff.

Records

- 2.16 A record should be kept of those appointed to carry out the functions listed above. The record should clearly state the extent of the postholder's duties and responsibilities, and to whom they are to report.
- 2.17 Substitute or replacement staff should be designated in order to cover for sickness, holidays and staff transfers.

Training

- 2.18 Routine inspection and maintenance procedures can cause risks to the health of staff carrying out the work and those receiving air from the plant. All those involved should be made aware of the risks, and safe systems of work should be agreed. Suitable safety equipment should be provided as necessary, and training in its use should be given.
- **2.19** Any training given should be recorded, together with the date of delivery and topics covered.
- 2.20 Training in the use of safety equipment and a safe system of work will need to be repeated periodically in order to cater for changes in staff.

Specific health and safety aspects

- 2.21 Staff engaged in the service and maintenance of extract ventilation systems from pathology departments, mortuaries, laboratories, sourceprotected isolation facilities and other areas containing a chemical, biological or radiation hazard may be particularly at risk. In these cases, the risk should be identified and assessed.
- 2.22 The means by which the system can be rendered safe to work on should be determined, and a permit-to-work on the system implemented.
- 2.23 Training in the exact procedures should be given to all staff involved.
- 2.24 Some healthcare facilities may contain specialised units that are subject to access restrictions (for example pharmacy aseptic suites). Estates or contract staff requiring access may need additional training or to be accompanied when entering the unit.

See also the following guidance published by the Health and Safety Commission's Health Services Advisory Committee:

- a. 'Safe working and the prevention of infection in clinical laboratories and similar facilities';
- b. 'The management, design and operation of microbiological containment laboratories';
- c. 'Safe working and prevention of infection in the mortuary and post-mortem room'.

3 Ventilation systems – minimum requirements

General requirements

- 3.1 All ventilation systems should be inspected annually to ensure conformity with minimum requirements, which are designed to:
 - a. ensure safe access when carrying out routine service and maintenance activities;
 - b. prevent or control risks associated with *Legionella* and other potential hazardous organisms;
 - c. check that the system remains fit for purpose.
- 3.2 Every effort should be made to ensure that all AHUs achieve the minimum requirement set out below.

Location and access

- 3.3 AHUs should be secured from unauthorised access.
- 3.4 Units located on roofs should have a safe and permanent means of access. Suitable precautions must be in place to prevent personnel or equipment from falling during maintenance activities.
- 3.5 Units located outside at ground level should be secured within a compound to prevent unauthorised access. Vehicles should be excluded from the vicinity to ensure that exhaust fumes will not be drawn into intakes.
- **3.6** All parts of the AHU should be easily and safely accessible for routine inspection and service.
- 3.7 The area around an AHU within a building should be tanked to prevent water penetration to adjacent areas, and should be adequately drained.
- **3.8** Fire precautions should be in accordance with Firecode.
- 3.9 Combustion equipment must not be located in a fire compartment that houses air-handling equipment.
- **3.10** Plantrooms that house AHUs should not be used for general storage. Care should be taken to ensure

that combustible material is not kept in the plantroom.

Basic requirements

- 3.11 The plant must not contain any material or substance that could support the growth of microorganisms.
- 3.12 The plant must not contain any material or substance that could cause or support combustion.
- 3.13 Access to items that require routine service, such as filters, fog coils and chiller batteries, should be via hinged doors.
- 3.14 Items requiring infrequent access such as attenuators may be via clipped or bolted-on lift-off panels.
- 3.15 All doors and panels should be close-fitting and without leaks.
- **3.16** Every effort should be made to ensure that access is via fixed ladders and platforms or pulpit-style movable steps.
- 3.17 Electrical and mechanical services should not restrict or impede access to those parts of the AHU that require inspection.
- **3.18** Viewing ports and internal illumination should be fitted in order to inspect filters and drainage trays.
- **3.19** Internal illumination should be provided by fittings to at least IP55 rating. Fittings should be positioned so that they provide both illumination for inspection and task lighting.
- 3.20 A single switch should operate all of the lights in a unit.

AHU intakes and discharges

3.21 Intake and discharge points should not be situated where they will cause vitiated air to be drawn into a system (see paragraphs 3.57–3.68 in Part A, which give detailed information). In existing systems, it may be necessary to extend the intake or discharge point to a suitable position.

- 3.22 Each intake and discharge point should be fitted with corrosion-resistant weatherproof louvres or cowls to protect the system from driving rain. The inside of the louvres should be fitted with a mesh of not less than 6 mm and not more than 12 mm to prevent infestation by vermin and prevent leaves being drawn in.
- 3.23 The duct behind a louvre should be self-draining. If this is not practicable, it should be tanked and provided with a drainage system. Cleaning access must be provided either from the outside via hinged louvres or by access doors in the plenum behind the louvre. Where a common plenum is provided, cleaning access should be via a walk-in door.

AHU drainage system

- 3.24 All items of plant that could produce moisture must be provided with a drainage system. The system will comprise a drip-tray, glass trap, air break and associated drainage pipework.
- 3.25 Some existing units may not have been mounted far enough above the floor to permit the correct installation of a drainage system. If the AHU cannot be raised to an adequate height, an alternative arrangement (such as a pump-out system) must be provided.
- 3.26 The drip-tray should be constructed of a corrosionresistant material (stainless steel is preferred) and be so arranged that it will completely drain. To prevent "pooling", it is essential that the drain connection should not have an up-stand and that a slope of approximately 1 in 20 in all directions should be incorporated to the drain outlet position. The tray must be completely accessible or, for smaller units, easily removable for inspection and cleaning.
- 3.27 Each drip-tray should be provided with its own drain trap. The drain trap should be of the clear (borosilicate) glass type. This permits the colour of the water seal to be observed, thus giving an early indication of corrosion, biological activity or contamination within the duct (see Table 3).
- 3.28 The trap should have a means for filling and should incorporate couplings to facilitate removal for cleaning. It should be located in an easily visible position where it will not be subject to casual knocks. The pipework connecting it to the drainage tray should have a continuous fall of not less than 1 in 20.

- 3.29 Traps fitted to plant located outside or in unheated plantrooms may need to be trace-heated in winter. The trace heating should be checked for operation and must not raise the temperature of water in the trap above 5°C.
- 3.30 Water from each trap must discharge via a clear air gap of at least 15 mm above the unrestricted spill-over level of either an open tundish connected to a drainage stack via a second trap, or a floor gully (or channel). A support should be provided to ensure that the air gap cannot be reduced. More than one drain trap may discharge into the tundish, providing each has its own air break.
- 3.31 Drainage pipework may be thermoplastic, copper or stainless steel. Glass should not be used. The pipework should be a minimum diameter of 22 mm and have a fall of at least 1 in 60 in the direction of flow. It should be well supported, and located so as not to inhibit access to the AHU.

Dampers

3.32 AHUs serving critical areas and those areas that are shut down out of hours should be fitted with motorised low-leak shut-off dampers located immediately behind the intake and discharge of each supply and extract system.

Fan drives

- 3.33 Fan-drive trains, whether supply or extract, should be easily visible without the need to remove access covers. Protecting the drive train with a mesh guard is the preferred option. For weatherproof units designed to be located outside, the fan drive should be enclosed. It should be easily visible through a viewing port with internal illumination and be accessed via a lockable, hinged door.
- 3.34 The motor windings of induction-drive "plug" motor arrangements and in-line axial fans having a pod motor within the air stream must be protected from over-temperature by a thermistor and lockout relay.
- 3.35 It is necessary to ensure that should the computer control system or its software develop a fault – the fan can be switched to a direct start with fixed speed and manual operation. This is particularly important for critical care systems serving operating suites, high dependency care units of any type, isolation facilities, laboratories and pharmaceutical production suites.

Heater-batteries

- **3.36** Access for cleaning must be provided to both sides of all fog coils and heater-batteries.
- 3.37 Where auxiliary wet heater-batteries are located in false ceilings, they should be fitted with a catch tray and leak alarm. The catch tray should be installed under both the battery and the control valve assembly to protect the ceiling from leaks. A moisture sensor and alarm should be fitted in the tray.

Cooling coils

- 3.38 All cooling coils whether with the AHU or with a branch duct – must be fitted with their own independent drainage system as specified above. A baffle or similar device must be provided in the drip-tray to prevent air bypassing the coil, and the tray should be large enough to capture the moisture from the eliminator, bends and headers.
- 3.39 The cooling-coil control valve should close upon selection of low speed, system shut-down, low air flow or fan failure.
- **3.40** Where auxiliary wet-cooling coils are located in false ceilings, they should be fitted with a catch tray and leak alarm. The catch tray should be installed under both the battery and the control valve assembly to protect the ceiling from leaks. A moisture sensor and alarm should be fitted in the tray.

Humidifiers

- 3.41 Humidifiers are not generally required. Where they are fitted, but have been out of use for a significant period of time, they should be removed. All associated pipework should also be removed back to its junction with the running main.
- 3.42 Where humidifiers are fitted and their use is still required, they should fully conform to the installation standard set out in Chapter 4 of Part A.
- 3.43 The section of ductwork containing the humidifier may need to be periodically decontaminated. Hinged access doors with viewing ports and internal illumination should be provided.
- 3.44 All humidifiers must be fitted with their own independent drainage system as detailed above.
- 3.45 Only steam-injection humidifiers, whether mains fed or locally generated, are suitable for use in

air-conditioning systems within healthcare facilities. Water humidifiers, if fitted, should be removed.

- **3.46** Self- and locally-generated steam humidifiers must be supplied with potable water. The installation should be capable of being isolated, drained and cleaned. Chapter 4 in Part A of this Health Technical Memorandum gives further details.
- 3.47 Some steam generators are of a type that requires regular cleaning and descaling. The installation should enable them to be physically isolated from the air duct in order to prevent contamination of the air supply by cleaning agents.
- 3.48 The humidifier control system should fully conform to the standard set out in Chapters 4 and 6 of Part A.

Filtration

- 3.49 Filters must be securely housed and sealed in well-fitting frames that minimise air bypass. Air bypass significantly reduces filter efficiency; the higher the filter grade, the greater the effect. Mounting frames should be designed so that the air flow pushes the filter into its housing to help minimise air bypass.
- 3.50 All filters should be of the dry type. Panel filters are generally used as prefilters and should be positioned on the inlet side of the supply fan, downstream of the frost coil. Where required, secondary filters (these will be bags or pleated paper) should be on the positive-pressure side of the fan.
- 3.51 The filter installation should provide easy access to filter media for cleaning, removal or replacement; therefore, a hinged access door should be provided. The upstream side of the filter should be visible for inspection through a viewing port with internal illumination.
- 3.52 All filters should be provided with a means of checking the differential pressure across them. Direct-reading dial-type gauges marked with clean and dirty sectors are preferred.

High-efficiency filters – HEPA and ULPA

- **3.53** Where fitted, HEPA filters should be of the replaceable-panel type with leak-proof seals. Their installation should permit the validation of the filter and its housing.
- 3.54 HEPA filters are sometimes used in extract systems for the containment of hazardous substances or

organisms. They may be fitted with prefilters to extend their service life.

3.55 When used for the containment of hazardous substances, the installation should incorporate design provision for the subsequent safe removal and handling of contaminated filters by maintenance staff.

Energy recovery

- **3.56** Energy recovery, where fitted, will require cleaning access to both sides of the device.
- 3.57 Whichever type of energy recovery device is fitted, the extract side should be protected by a G3 filter and provided with a drainage system to remove condensate.
- 3.58 The heat-recovery device should be controlled in sequence with the main heater-battery, and may need to incorporate a control to prevent the transfer of unwanted heat when the air-on condition rises above the plant's required set-point.

Attenuation

3.59 Cleaning access should be provided at both ends of any attenuator unit.

Identification and labelling

- **3.60** All supply and extract ventilation systems should be clearly labelled. The label should identify both the AHU and the area that it serves. The lettering should be at least 50 mm high and be mounted in an easily visible place near the fan of the unit. Any subsystems and the principal branch ducts should be similarly labelled.
- 3.61 The direction of air flow should be clearly marked on all main and branch ducts.
- **3.62** All air-flow test-points should be clearly identified, and the size of the duct given.

Pressure stabilisers

3.63 Pressure stabilisers should be unobstructed and silent in operation.

4 Annual inspection and verification requirements

Ventilation systems inspection

- 4.1 All ventilation systems should be subject to at least a simple visual inspection annually.
- 4.2 The purpose of the inspection is to establish that:
 - a. the system is still required;
 - b. the AHU conforms to the minimum standard (see Chapter 3);
 - c. the fire containment has not been breached;
 - d. the general condition of the system is adequate for purpose;
 - e. the system overall is operating in a satisfactory manner.
- 4.3 It is recommended that a simple check sheet be used to record the result of the inspection. Examples are given in Appendices 1 and 2.

Critical ventilation systems

- 4.4 All critical ventilation systems should be inspected quarterly and verified at least annually. In some circumstances the verification may need to be carried out more frequently.
- **4.5** The quarterly inspection should be as detailed in paragraphs 4.1–4.3.
- **4.6** The purpose of the annual verification will be to additionally ensure that the system:
 - achieves minimum standards specific to the application;
 - b. is operating to an acceptable performance level;
 - c. remains fit for purpose.

Definition of a critical system

- 4.7 Ventilation systems serving the following are considered critical:
 - a. operating theatres of any type, including rooms used for interventional investigations (for example catheter laboratories);

- b. patient isolation facility of any type;
- c. critical care, intensive treatment or highdependency unit;
- d. neonatal unit;
- e. Category 3 or 4 laboratory or room;
- f. pharmacy aseptic suite;
- g. inspection and packing room in a sterile services department;
- MRI, CAT and other types of emerging imaging technologies that require particularly stable environmental conditions to remain within calibration;
- j. any system classified as an LEV system under the COSHH Regulations;
- k. any other system that clearly meets the definition.
- 4.8 The loss of service from such a system would seriously degrade the ability of the premises to deliver optimal healthcare.

Annual verification

- 4.9 The annual verification is intended to establish that:
 - a. the system is still required;
 - b. the AHU conforms to the minimum standard (see Chapter 3);
 - c. the fire containment has not been breached;
 - d. the general condition of the ventilation system is adequate;
 - e. the fabric of the area served is satisfactory;
 - f. the system performance is adequate with respect to the functional requirement this will require:
 - (i) a full measure of the supply and extract air-flow rates;

- (ii) the calculation of room air-change rates if applicable;
- (iii) the measurement of room differential pressures if applicable;
- (iv) the measurement of room noise levels;
- (v) air-quality checks if appropriate;
- (vi) a check on the control functions.
- 4.10 An assessment should then be made as to whether the system overall is fit for purpose and operating in a satisfactory manner.

Fabric of the area served

- 4.11 The building elements in the room or rooms served by a critical ventilation system should also be suitable for the function. As an example, in a suite of rooms comprising an operating theatre complex, the following elements should be checked:
 - a. the ceiling should be complete and, if tiled, all tiles should be clipped down and sealed;
 - b. the walls and floors should be free from significant construction and finish defects;
 - c. windows and their trickle vents should be sealed and locked shut;
 - d. the doors should close completely and the door closers should be correctly adjusted to hold them against the room pressure;
 - e. all service penetrations and access panels should be sealed to prevent uncontrolled air flow between rooms and service voids;
 - f. steps should have been taken (if necessary) to prevent portable equipment and stock items from obstructing low-level supply, transfer or extract air-flow paths.
- **4.12** Failure to achieve a suitable standard will render even the most sophisticated ventilation system ineffective.
- 4.13 All fire dampers should be tested as part of the annual verification.
- 4.14 LEV systems will be subject to an examination and test by a competent person at least every 14 months.
- **4.15** Table 1 provides a model for the verification of critical ventilation systems.

Critical ventilation systems – verification standards

- **4.16** Unless otherwise specified below, the ventilation system should achieve not less than 75% of the design air-change rate given in Appendix 2 of Part A, or its original design parameters.
- 4.17 The pressure regime should achieve not less than 75% of the design value given in Appendix 2 of Part A, or its original design parameters; and the pressure gradient relationships with regards to surrounding areas must be maintained.
- **4.18** The sound levels given in Table 2 are maximum permissible levels and should not be exceeded. Measurements should be made using at least a Type 2 sound meter fitted with a muff. Its accuracy should be checked using a calibration sound source before use.

Vertical ultra-clean operating theatres

- 4.19 The following additional measurements should be taken:
 - the average air velocity at the 2 m level under the canopy: it should achieve a minimum average of 0.38 m/s for a partial wall system and 0.3 m/s for a full wall system;
 - the air velocity within the inner zone at the 1 m level: every reading should achieve a minimum velocity of 0.2 m/s.
- 4.20 The air velocity measurements are to be taken using the equipment, test grid and method set out in Chapter 8 of Part A.

Note

There is no requirement to carry out filter scanning or entrainment tests at the annual verification unless the HEPA filters or recirculating air fans are changed, or the system is in some other significant way disturbed or altered. Changing the filters in the AHU or recirculating air filters does not constitute a significant disturbance to the ultra-clean ventilation (UCV) unit.

4.21 Should the UCV terminal fail to achieve a suitable standard, resulting in the need to disturb or replace the HEPA filters or recirculating air fans, the unit should be revalidated using the procedure given in Chapter 8 of Part A.

Step	Question	Information/standard required	Comment
1	Is the system still required?	Why was it installed?	Is that function still required?
2	Does the AHU achieve the minimum standard?	 Health and safety aspects Intake/discharge positions Inspection access <i>Legionella</i> control and drainage Fire and electrical safety Leaks, cleanliness and insulation Filtration 	Inspect to ascertain compliance with minimum standards set out in Chapter 3 of Health Technical Memorandum 03-01 (Part B)
3	Is the air distribution system satisfactory?	 Access Fire dampers Cleanliness Insulation Identification Room terminals Pressure stabilisers 	Inspect to ascertain continued fitness for purpose
4	Does the measured system performance still accord with the design intent and achieve a minimum acceptable standard?	 Design air velocities Design air-flow rates Room air-change rates Pressure differentials Noise levels Air quality 	Establish the design values Measure the system output to verify its performance
5	Does the control system function correctly?	Desired environmental conditionsControl sequence logicRun; set-back; off philosophy	Establish the design requirement Inspect/test to verify performance
6		e system "fit for purpose" and will it only to remain so until the next scheduled	Yes or No!
7	What routine service and maintenance will be required for the system to remain fit for purpose and function correctly until the next scheduled verification?	 Filter changes System cleaning Performance indication Performance monitoring Performance measurement 	Decide inspection frequency and maintenance schedule

Table 1 Operational management and routine verification process model

Table 2 Maximum sound levels (service noise only)

Location	Design sound level (NR)	Measured sound level (dB(A))
Ultra-clean operating room	50	55
Conventional operating room	40	45
All other non-specified rooms	40	45
Corridors	40	45
Recovery room	35	40
Ward areas; sleeping areas	30	35

Note: Health Technical Memorandum 08-01 gives detailed guidance on acoustics and the measurement of sound

Horizontal ultra-clean operating theatres

- 4.22 The following additional measurements should be taken:
 - the discharge velocity test at 1 m, 1.5 m and 2 m in front of the terminal: the average velocity should be not less than 0.4 m/s.
- 4.23 The measurements are to be taken using the equipment, test grid and method set out in Chapter 8 of Part A.

Note

There is no requirement to carry out filter scanning at the annual verification unless the HEPA filters or recirculating air fans are changed; or the system is in some other significant way disturbed or altered. Changing the filters in the AHU or recirculating air filters does not constitute a significant disturbance to the UCV unit.

4.24 Should the UCV terminal fail to achieve a suitable standard, resulting in the need to disturb or replace the HEPA filters or recirculating air fans, the unit should be revalidated using the procedure given in Chapter 8 of Part A.

Category 3 and 4 laboratories and rooms

- 4.25 These areas should conform to the requirements of current information published by the Advisory Committee on Dangerous Pathogens and the Health and Safety Executive:
 - 'The management, design and operation of microbiological containment laboratories';
 - 'Biological agents: managing the risks in laboratories and healthcare premises'; and
 - 'Biological agents: the principles, design and operation of Containment Level 4 facilities'.

Pharmacy aseptic suites

4.26 Pharmacy aseptic suites should conform to the requirements of the European guide to good manufacturing practice (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev4.htm) and the requirements of the Medicine Inspectorate if a licensed manufacturing unit.

Sterile services department – inspection and packing rooms

4.27 Inspection and packing rooms should conform to the requirements of BS EN ISO 14644 and any additional requirements for the processing of medical devices, if applicable (see also Health Building Note 13 – 'Sterile services department').

LEV systems

4.28 LEV systems should conform to the Health and Safety Executive's 'The maintenance, examination and testing of local exhaust ventilation'.

Critical system verification failure

- 4.29 Should a critical system be unable to achieve the standard set out above, it should be taken out of service. If healthcare provision needs prevent the system being taken out of service, the senior manager of the user department should be informed in writing that the system performance is suboptimal. A copy of the notice should be sent to the infection control committee.
- **4.30** If a critical system is refurbished in order to bring it to a suitable standard, it should be subject to the full validation procedure set out in Chapter 8 of Part A or other application-specific guidance as appropriate.

5 Inspection and maintenance

General

- 5.1 Inspection and maintenance activities should be 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.
- 5.2 The degree and frequency of maintenance should relate to the function of the system, its location, its general condition and the consequence of failure.
- 5.3 Specimen inspection and maintenance checklists are given in the Appendices.

Inspection and maintenance of critical systems

- 5.4 The loss of service of these systems would seriously degrade the ability of the premises to deliver optimal healthcare. In order to ensure reliable service provision, it is essential to inspect, verify and maintain these systems at appropriate intervals.
- 5.5 For many of these systems a permit-to-work will need to be completed to ensure that taking the ventilation system out of service does not compromise the activities of the user department. In any event, it will be necessary to liaise with the user department when switching the system off to carry out routine inspection and maintenance.

AHU drainage

5.6 AHU drainage systems comprise a drainage tray, glass trap, connecting pipework and an air break. The system should be inspected to ensure that it is clean and operating correctly. The cleanliness of the drainage tray and colour of the water in the trap will give an indication of a fault condition (see Table 3).

Filter changing

5.7 Dirty supply air filters may pose a general dust hazard when being changed.

Table 3 Colour of water in glass trap

Colour of water	Probable cause and comment			
Normal	Satisfactory			
Green	Copper corrosion of pipework Possible leak in battery tubing			
White	Aluminium corrosion of battery fins			
Black	General dirt Filter faulty allowing air bypass System is overdue for a thorough clean Urgent action required			
Brown/red	Iron corrosion (rust) within the duct May indicate a specific <i>Legionella</i> hazard Immediate action required			
Bubbly/slimy	Microbiological activity within the duct May indicate a specific <i>Legionella</i> hazard Immediate action required			

- 5.8 Dirty extract-and-return air filters may pose an increased level of hazard. This will relate to the particular contamination within the air that they have filtered. Filters handling extract air from general areas are unlikely to present a significantly greater hazard than that posed by dirty supply air filters.
- 5.9 Care should be taken to protect staff from inhaling the dust. If there is a need to enter the duct when changing filters, a dust mask should be worn.
- 5.10 Dirty filters should be carefully removed and placed in the box that contained the replacement filters or in a plastic bag. On completion of the work, the dirty filters should be removed from the plantroom and disposed of appropriately.
- 5.11 The duct in the area of the filter housing should be carefully vacuumed before fitting the replacement filters. This will prevent particles (that is, those that are shed when the dirty filters are disturbed) being blown into the system downstream.
- **5.12** It is important to ensure that replacement filters are fitted the right way round. Most panel filters are manufactured with a membrane or wire support mesh on their downstream side. Alternatively they

may be colour-coded. The manufacturer's instructions regarding fitting should be followed.

5.13 Bag filters should be fitted with the pockets vertical. Care should be taken to remove any transit tapes and to ensure that the individual pockets are separate and free to inflate.

Changing extract filters containing hazardous substances

- 5.14 Filters handling extract air from an LEV system will obviously present a hazard and should be subject to a safe system of work.
- 5.15 Filters used in an extract system for the containment of hazardous substances or organisms should incorporate design provision for their safe removal when so contaminated. This may be achieved by:
 - a. sealing the hazardous substance into the filter before it is removed;
 - b. a system to fumigate the filter to kill any organisms;
 - c. housing it in a "safe change" unit that permits the filter to be ejected into a bag and sealed without staff having to come into direct contact with it.
- 5.16 The method chosen should reflect the nature of the hazard.
- 5.17 Filters fitted to remove hazardous substances from extract air are classed as hazardous waste and should be handled and disposed of accordingly.

Ventilation system cleaning

- **5.18** The intake section of a ventilation system should be vacuumed-out as necessary to remove visible particles.
- 5.19 AHUs should be vacuumed-out and/or washed down internally as necessary to remove obvious dust and dirt.
- **5.20** Chiller batteries, humidifier units, energy-recovery batteries or plates and their drainage systems should be washed down with hot water annually to remove visible contamination.
- 5.21 Supply air distribution ductwork conveys air that has been filtered. It will require internal cleaning only when it becomes contaminated with visible dirt. The frequency of cleaning will depend on the age of the system and grade of the AHU final filter

but will typically be in excess of ten years. There is no requirement to clean ductwork annually. A rapid build-up of visible dirt within a supply duct is an indication of a failure of the filtration or its housing.

- 5.22 Extract air systems handle unfiltered air. They should be cleaned as frequently as necessary in order to maintain their operating efficiency. Room extract terminals, particularly those sited at low level in critical care areas, will need regular cleaning.
- 5.23 On completion of cleaning, the ductwork should not be "fogged" with chemicals. This treatment has no lasting biocidal effect and is responsible for initiating the breakdown of the galvanised coating of ductwork. This will result in accelerated corrosion of the inside of the duct, with the products of corrosion being shed into the air stream. It will also significantly shorten service life.
- 5.24 Following duct cleaning, all service hatches should be checked to ensure that they have been correctly replaced and do not leak.
- 5.25 Duct-cleaning equipment that uses rotating brushes or a vacuum unit can easily damage flexible sections of ductwork. On completion of cleaning, all flexible duct sections should be checked for rips and tears. The straps that secure them to rigid duct sections and air terminals should also be checked to ensure that there is no air leakage.

Chilled beams

5.26 The efficiency of these units will rapidly decline if they become blocked with fluff/lint. They should be inspected every six months and cleaned as appropriate.

Split and cassette air-conditioning units

5.27 These units incorporate internal recirculation air filters and a drainage system to remove condensate from the cooling coil. The systems should be inspected and cleaned every three months.

Portable room air-conditioning units

5.28 Portable units are sometimes kept in-store or hired-in to cope with temporary local situations giving rise to excessive temperatures. They typically incorporate internal recirculation air filters and a drainage system to remove condensate from the

cooling coil. The infection control team must be consulted before these types of unit are deployed.

- 5.29 The units should be inspected and thoroughly cleaned before being taken into use. Units that are to be used in areas containing immunocompromised patients will, unless new, need to be fumigated before use.
- **5.30** All portable units should be inspected and cleaned every week that they remain in use.
- **5.31** Units that have been used in isolation rooms or areas containing infective patients will need to be fumigated before being used in other locations, or returned to store or to the hirer.
- 5.32 Units employing an internal water reservoir and wick to promote evaporative cooling must not be used in healthcare premises.

Self-contained mobile filter and/or ultraviolet (UV) light units

5.33 The efficacy of these units is directly related to their cleanliness. In this respect, the manufacturer's instructions regarding service/maintenance and lamp and filter replacement should be closely followed.

- **5.34** Units that have been used in isolation rooms or areas containing infective patients will need to be fumigated before being used in other locations, or returned to store.
- 5.35 Filters fitted to remove hazardous substances from the recirculated room air are classed as hazardous waste and should be handled and disposed of accordingly (see also Health Technical Memorandum 07-01 – 'Safe management of healthcare waste').

Inspection and maintenance records

5.36 Records of inspection and maintenance activities should be kept for at least five years.

Appendix 1 – Annual inspection of critical ventilation systems – AHU and plantroom equipment

Definition of terms used on survey form

General condition

End of useful life

This should be clear from the condition of the AHU and its associated services and plant. The main indicators will be:

- extensive internal and/or external corrosion of the AHU casing;
- failure of filter housings to prevent air bypass;
- general corrosion of heater and cooling battery fins, attenuator surfaces etc;
- significant failure to meet minimum standards;
- associated plant services and control elements in a poor condition or not able to fulfil their purpose;
- AHU aged 20 years or more.

Action: Urgent replacement indicated.

Poor

Should be fairly apparent but would include an assessment of the degree of corrosion; cleanliness of coils and batteries; quality of filter mountings and their ability to prevent air bypass; fan and drive train condition; the control system elements' ability to fulfil their function; condition of the access doors and inspection covers. The age of the AHU is generally less important.

Action: Extensive refurbishment or programmed replacement indicated.

Average

Some faults but generally free of significant corrosion, clean internally and conforming to minimum standards.

Action: Faults capable of correction at next maintenance period.

Good

Conforming to the minimum standards, obviously cared for and subject to routine maintenance.

Action: Routine maintenance will preserve standard of the equipment.

Compliance with minimum standards (questions 2 to 23, 32 and 33)

Poor

More than three answers are negative.

Action: Management action required by estates/facilities department.

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Average

No more than three answers are negative.

Action: Maintenance action required.

Good

No answers are negative, full compliance.

Action: None.

Maintenance quality (questions 5, 12, 26 to 31 and 34 to 40)

Poor

More than three answers are negative.

Action: Management action required by estates/facilities department.

Average

No more than three answers are negative.

Action: Maintenance action required.

Good

No answers are negative.

Action: None.

Annual inspection of critical ventilation systems – AHU and plantroom equipment

Hospital								
Plant	Plantroom							
Air-h	Air-handling unit Age of unit							
Area	served by unit							
Date	Date of survey Name							
Gene	eneral condition: End useful life Poor Average Good							
	Compliance with minimum standards (Questions 2 to 23; 32 and 33) Poor Average Good				Good			
	itenance quality estions 5, 12, 26 to 31, 34 to 40)		Рос	or	Average	Good		
No	Survey question	Yes	No	Comments				
	Plant running?							
2	Is the unit and its associated plant secure from unauthorised access?							
3	Is the unit safely accessible for inspection and maintenance?							
4	Is the air intake positioned to avoid short circuiting with extract or foul air from other sources such as gas scavenging outlets?							
5	Are all inspection lights operating?							
6	Are motorised dampers fitted to the intake and discharge?							
7	Are fan motor(s) outside of the air stream?							
8	Is the fan drive train visible without removing covers?							
9	Is the cooling coil located on the discharge side of the fan?							
10	Is an energy-recovery system fitted (state type)?							
11	Are condensate drainage systems fitted to all energy recovery systems, cooling coils and humidifiers in accordance with Chapter 3 of Health Technical Memorandum 03-01, Part B?							

12 Arc	rvey question e drainage traps clean and filled	Yes	No	Comments
	th water? (see Table 3 in Health chnical Memorandum 03-01, rt B)			
	the drain trap air break at least mm?			
14 If a typ	a humidifier is fitted, state the be	-	-	
	the humidifier capable of eration?			
	there space to safely change the errs?			
	e there test holes in the principal cts?			
18 Arc	e the test holes capped?			
	hat is the general condition of e exterior of the AHU?	-	-	
20 Are	e the principal ducts lagged?			
the	hat is the general condition of e associated control valves and bework?	-	-	
22 Is t	the pipework adequately lagged?			
23 Is t	the system clearly labelled?			
	cord prefilter differential essure	-	_	
	cord main filter differential essure	-	-	
	Sv	vitch pla	nt off. F	it padlock to isolator
	d the motorised dampers close plant shut-down?			
27 Is t	the vermin/insect screen clean?			
	the intake section including the 5 coil clean?			
	e the prefilters correctly fitted th no air bypass?			
	e all drive belts correctly aligned d tensioned?			
31 Is t	the cooling-coil matrix clean?			
cap	e all drip-trays fully accessible or pable of being removed for aning and have a fall to drain?			
33 Are	e the drainage trays stainless?			
34 Are	e the drainage trays clean?			
	e there any signs of water nding in the AHU?			

No	Survey question	Yes	No	Comments
36	Is the matrix clean for each heater-battery?			
37	Have the main filters been correctly fitted with no air bypass?			
38	Is AHU and its associated main ductwork clean internally?			
			Energi	ise plant
39	Did unit restart satisfactorily?			
	Test a	utomatio	c fan-mo	tor change-over, if fitted
40	Did automatic change-over operate satisfactorily?			

Additional comments

(For example: air leaks from access doors; control valves leaking or passing; general cleanliness of the area around the unit; or any other items of concern.)

Competent Person/Authorised Person

Appendix 2 – Operating suite annual verification

Definition of terms used on survey form

Assessment of compliance with Health Building Note 26 and Health Technical Memorandum 03-01 (all questions relevant to the type of theatre)

Poor

Air volumes and hence air-change rate is less than 75% of the design; room pressure differentials do not ensure a flow from clean to less clean areas; supply or extract air diffusers are not clean; pressure stabilisers not clean and/or not operating correctly; significant faults or failures of indicators on surgeon's panel; visible faults in the fabric of the suite; doors unable to close completely; general air of neglect.

Action: Urgent management action required.

Average

Air volumes and room pressure differentials approximate to the original design values; supply air diffusers clean but extracts visibly fouled; most pressure stabilisers clean and operating correctly; some of the indicators on the surgeons panel not working; minor faults in the fabric and décor of the suite.

Action: Maintenance action required.

Good

Better than average.

Action: None.

Maintenance quality (all questions relevant to the type of theatre)

Poor

More than three answers are negative.

Action: Management action required by estates/facilities department.

Average

No more than three answers are negative.

Action: Maintenance action required.

Good

No answers are negative. Action: None.

Annual verification of theatre ventilation systems Theatre suite information

Hos	pital					
Thea	tre name/no.] Туре о	f Theatre		
Date of survey			AHU l	ocation &	D	
Name						
Compliance with HBN & HTM			Рос	or 🗌	Average	Good
Maintenance quality			Poo	or 🗌	Average	Good
No	Survey question	Yes	No	Comment	s	
1	Has the annual verification of the AHU been carried out?					
2	Are windows hermetically sealed?					
3	Are the ceilings in the theatre and prep room complete and sealed?					
4	Are there any significant faults in the fabric of the rooms in the suite?					
5	Are room light fittings correctly sealed?					
6	Do all doors close completely and hold against the room pressure?					
7	Are the pressure stabilisers operating correctly and silently?					
8	Are all supply and extract air terminals and pressure stabilisers visibly clean?					
9	Measure and record the operating room temperature		_			
10	Does this accord with that displayed on the surgeon's panel?					
11	Measure and record the operating room relative humidity	-	-			
12	Does this accord with that displayed on the surgeon's panel?					
13	Measure and record the supply and extract air flow in the principle ducts	-	_			
14	Measure and record the air flow at all supply and extract terminals	-	_			
15	Does the derived air-change rate achieve at least 75% of the design?					
16	For UCV units, also measure and record the air velocities within the canopy using the method set out in Chapter 8 of Health Technical Memorandum 03-01 (Part A)	-	_			

No	Survey question	Yes	No	Comments
	Do the air velocities achieve the standard appropriate for the type of canopy?			
18	Measure and record the room differential pressures	-	-	
19	Do the room differential pressures ensure a flow of air from the clean to the less clean areas?			
20	Measure and record the noise levels in the principal rooms of the suite	-	-	
21	Do the noise levels fall below the limits set out in Table 2 of Health Technical Memorandum 03-01, Part B?			
22	Check the operation of all ventilation control functions represented on the surgeon's panel.	-	-	
23	Do the indicators accurately represent the operational state of the ventilation system(s)?			
24	For UCV systems: is the UCV and AHU interlocked to ensure that the AHU runs at full speed when the UCV is at operating speed or at set-back? (see Table 6 in Health Technical Memorandum 03-01, Part A)			
25	With the UCV running at set- back, does the system maintain the standard of a conventional operating room?			
26	For all theatres: with the system running at set-back, does it maintain a flow of air from the clean to the less clean areas?			

Additional comments

(For example: the general décor; are the suite and its ventilation systems suitable for their designated functions?)

Competent Person/Authorised Person

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