Validations - 'Compliant design leads to correct delivery'

What is a validation?

A validation is the process that proves a ventilation system is:

- 'Entirely fit for purpose and achieves the operating performance originally specified'.
- The complete installation, from intake to discharge is inspected & assessed that it is fit for purpose as a whole.

ALL new and refurbished units should be compliant with HTM 03-01 2021, these compliance obligations must be accounted for during the design stage. Whilst a validation checks for a systems HTM 03-01 compliance obligations; the goal is to ensure no new units are built to a non-compliant standard, not to highlight or fix existing issues. A validation should function as a pre-emptive measure to stop non-compliant designs reaching the construction or installation phase in the first place.

The validation process itself consists of multiple stages of inspection and review, covering the initial brief, the design specification, the installation itself and the acceptance testing post installation.

According to HTM 03-01 Part A 12.3 validators must also 'be completely independent of the system designers, contractors, suppliers, installers, commissioners and those who will subsequently operate the system'. To ensure the validator's independence, they should be directly employed and paid for by the healthcare provider.

As your validator, AirisQ would act as your representative inspecting the system and checking the performance before recommending to you (the hospital/healthcare provider) whether to accept the system or not.

Validations are all performed to the standards set out in HTM 03-01 Part A 2021 Chapter 12 as current guidance states that any new or refurbished system should achieve the current standards.

When is a validation required?

HTM 03-01 Part A 12.1 states 'All new and refurbished ventilation systems should be independently validated prior to acceptance by the client'.

HTM 03-01 Part A states, a validation must take place:

- When a new AHU system is installed
- When an existing system is refurbished
- When there is a significant change to the system
- Post a ductwork cleaning & re-balancing service.
- Post a mid-life point refurbishment (typically around 10 years after installation)

Why should the validation process be followed & when should it start?

Timeline of a validation

The sooner we are engaged & can begin the validation process; the fewer compliance issues will be noted at the end of the process. Our knowledge, expertise & experience allow us to identify issues early on and provide a detailed summary to ensure they can be rectified before the project continues.

Design Proposal Review

It is **essential the appointed validator is involved in the client's initial brief and design specification**, prior to the project being put out to tender. This allows the validator to be aware of the client's requirements and any limiting factors. (Note: the appointed designer still carries the design 'risk;' advice from the validator will not negate this.)

For example, HTM 03-01 Part A. 11.6 states that the positioning of test holes should be determined during the design stage.

Additionally, it is important the validator understands the complete project not merely the ventilation aspects. Design decisions about the types of ceilings, doors, access hatches, fire compartmentation, floor markings, the room's function, the positioning of equipment and workflow patterns will all directly impact ventilation performance. It is not sufficient to consider the ventilation in isolation.

The contract arrangement should give the validator the right to visit site as often as they deem necessary during the contract period. Remember the validator's role is to ensure the finished system is fit for purpose; **they are an extra set of eyes working directly for you**.

First Fix inspection

The validator should conduct a physical walk around inspection of the installation once the AHU is "on-site" and the main & branch ductwork is for the most part installed, but prior to any ductwork being concealed by wall or ceiling panels.

It would also be beneficial for the following tests to be witnessed by the validator during this stage of the inspection:

- AHU installation leakage (BS EN 1886)
- Supply & extract duct leakage (BESA DW/143)
- Initial permeability test

The quality of the installation, compliance of the AHU, suitability of the basic installation, location & future accessibility of commissioning dampers, location, compliance for testing of the dampers etc can all be assessed during this visit.

On a large-scale project with multiple AHUs being manufactured it may also be beneficial for the validator and the client to visit the manufacturer and inspect a single unit before the others are built and transported to site. At that time, the leakage and deflection tests could be demonstrated by the manufacturer in the factory.

Once the single unit has been delivered to site it is useful to get all mechanical & electrical services connected and the location of all valves, pipework joins, drain points etc, along with the route of cabling/wiring agreed upon. If this can be done and is compliant all other units can be installed in the same fashion and will also be regarded as compliant at the time of the final stage of validation.

On completion of the first fix visit the validator will provide the client with a short report identifying items that are not complaint with the design specification. This allows the client time to have the contractor rectify issues before continuing the project.

Remember a validation is to ensure you the client gets the system you have paid for. ***If the design specification is correct****, any issues with non-compliance are for the contractors to rectify at their expense.*

Follow on Inspections

Depending on the size and complexity of the installation additional inspection visits may be required. The validator should attend site as frequently as necessary to eliminate any installation issues as the project develops, whilst the relevant trades are still in attendance – rather than trying to resolve issues at the time of final acceptance.

Final Acceptance Inspection

This inspection will determine if all the elements work together to achieve the project aim. The commissioning of the AHU should have been carried out by the suppliers of various elements.

The testing of the entire system as part of the validation process should occur after the main contractor has asserted the installation is fully complete, fully commissioned and achieving the specific levels of performance and is therefore ready to be handed over to the client and put into use. This stage of the validation process is to independently check on behalf of the client that the main contractor is correct in that assertation.

If the validator then discovers there are a significant number of snags and non-compliances, the validation should be terminated. It is then the contractor's responsibility to rectify these issues and re-present the system for validation. At this point, the validator must repeat the validation process. The client is entitled to deduct any additional validation fees incurred from the main contractor.

It is vitally important to complete a validation process before the healthcare provider accepts a new system. Due to the nature of the ventilation installation and the intensity of use a system will undergo in a healthcare setting it will NOT BE POSSIBLE TO CORRECT FAULTS AFTER THE SYSTEM HAS BEEN ACCEPTED and taken into use. There are medico-legal issues around putting a non-compliant system into use. Pre-announced handover or occupancy dates are not a reason for a healthcare provider to accept a non-compliant installation.

Following a validation, a full report detailing the findings will be produced and sent to the client's lead Project Manager. The report will conclude with a clear statement on whether the system achieved or did not achieve the standards set out in the agreed design specification.

The validator's report should then be distributed to the head of the user department, Infection Prevention & Control and Estates & Facilities.

What a validation is NOT

A validation is **NOT to discover snags and non-compliance issues with the unit post installation**. Instead, a validation should be used as a way for the client to consult with an independent expert during the design and installation process to help avoid these issues occurring.

It is NOT Commissioning

It is NOT a Verification

It is NOT a Snagging Exercise

REMEMBER: If the validator, discovers there are a significant number of snags and non-compliances the validation should be terminated**. If the design specification has not been met** it is then **the contractor's responsibility** to undertake remedial works to the system and re-present the system for validation. At which point the validator must repeat the validation process. **The client is entitled to deduct any additional validation fees incurred from the main contractor.**

A validation helps ensure the healthcare provider (hospital Trust) is getting what they have paid for and that the contractors have met their contractual obligations by providing a system that is 'fit for purpose' and meets its design requirements.

In Summary

As part of a validation service, AirisQ will:

- Conduct multiple onsite inspections.
- Consult on the ventilation system design.
- Assess the systems 'fitness for purpose' as a whole and ensuring it achieves the operating performance originally specified.
- Provide a recommendation to the client on whether to accept the completed unit.
- Create a comprehensive report on the validation process detailing the units design specification and compliance with HTM 03-01.