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Air Handling Systems: GMP Compliant Monitoring and Energy-Saving Operation

by Thomas Peither

Standards and Data Types

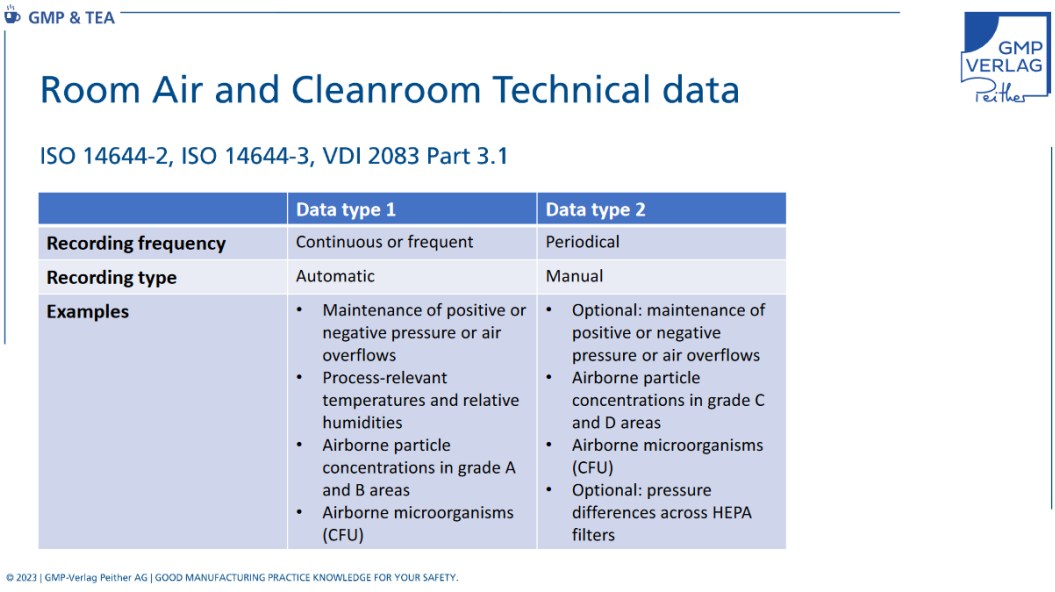
The following standards can be used as a basis for cleanroom monitoring plans:

- ISO 14644-2 Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concen-tration
- ISO 14644-3 Test methods (for metrology)
- VDI 2083 Part 3.1 Metrology in cleanroom air – Monitoring

There are two types of data to be documented for the monitoring of a ventilation and air-conditioning system:

- depending on the frequency of recording, i.e. whether the data is recorded con-tinuously or frequently, or periodically, and
- depending on the type of recording, i.e. automatically or manually.

Figure 1 shows examples of the two data types.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Room Air and Cleanroom Technical data

ISO 14644-2, ISO 14644-3, VDI 2083 Part 3.1

	Data type 1	Data type 2
Recording frequency	Continuous or frequent	Periodical
Recording type	Automatic	Manual
Examples	• Maintenance of positive or negative pressure or air overflows • Process-relevant temperatures and relative humidities • Airborne particle concentrations in grade A and B areas • Airborne microorganisms (CFU)	• Optional: maintenance of positive or negative pressure or air overflows • Airborne particle concentrations in grade C and D areas • Airborne microorganisms (CFU) • Optional: pressure differences across HEPA filters

Figure 1 Room air and cleanroom technical data

In any case, it makes sense to also consider, for example, the opening times of airlock doors and, in particular, associated alarms in the pharma monitoring system.

If an **active room pressure control** is installed and the pressure dif-ference between the clean room and the airlock is monitored, then the room pressure control and also the

room pressure alarm must be suspended when a relevant door is open. It has a very small influence on the air flow between cleanroom and airlock, but a great influence on the differential pressure. It balances out and indicates a value of "0". The situation is different with hinged doors. When opened, they create a suction/push effect of the air and thus cause uncontrolled flows.

The **frequency of** data collection is determined on the basis of risk. It is important to balance efficient use of resources with a meaningful overall data picture. A **higher frequency** is usually useful for areas with a high probability of contamination, such as

- near critical, "cleaner" activities,
- with greater personnel activity,
- with greater material flows,
- longer lasting activities,
- exposed product,
- for the final formulation,
- the filling or,
- where trend analysis shows an increase in particle concentration.

Lower frequencies are sufficient when the probability of contamination is low, e.g. in areas of

- for "less clean" activities,
- in which short-term openings are made on containers with small openings,
- for closed processes or,
- where trend analysis shows a reduction in particle concentration.

Operation and Maintenance – Reduce CO_2 Emissions!

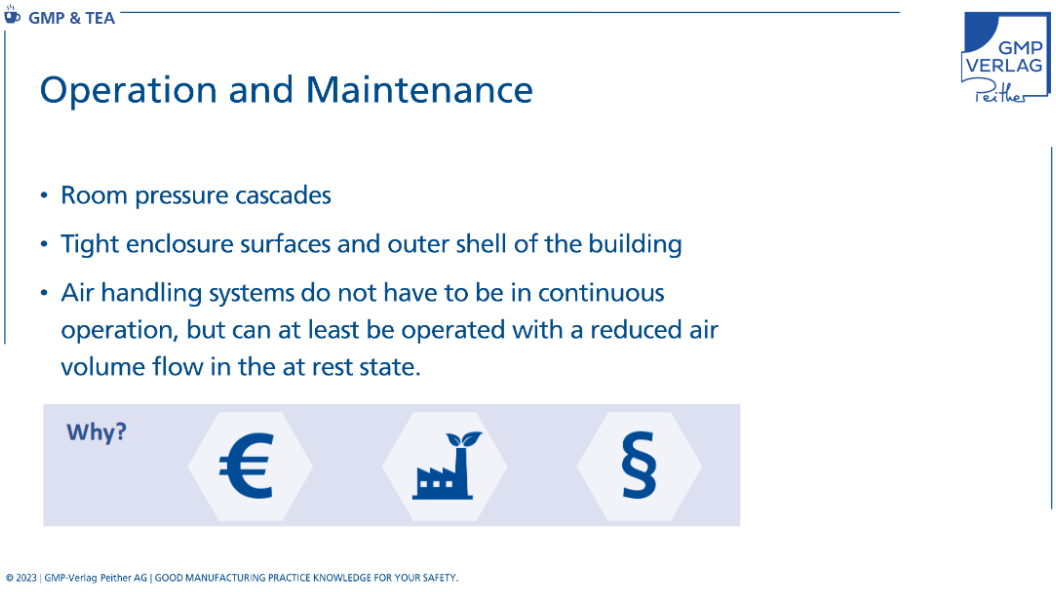

Figure 2 Operation and maintenance

To prevent infiltration of false air during operation and maintenance, one usually relies on so-called **room pressure cascades**. In addition, the enclosing surfaces of the cleanroom and the outer shell of the building should be appropriately tight.

Cleanroom air handling systems do not have to be in continuous operation. If there are no people in the room and no production is taking place, no particles or germs are released and there is no risk of contamination.

For reasons of **energy efficiency**, it therefore makes sense to operate the units during the "at rest" state at least with a reduced air volume flow.

This is where the advantage of **networked, "integrated" building management systems becomes apparent,** as monitoring continues to be active and for the lowered operation different alarm and action limit values apply.

For the operating case with reduced air volume flow, the values for overpressures or underpressures and the air cleanliness classes required for idling must be specified separately. In the reduced ventilation mode, the **target for the temperature** can be set to 25°C in summer and 18°C in winter, for example, with a control tolerance of ±2K.

An alert limit of ±3 K is sensible, an action limit is omitted. The values for humidity can also be adjusted as long as no condensation occurs on the surfaces and the relative humidity at the air-to-surface boundary layer remains below 80%.

And why all this? Quite simply, **energy savings of 50% and more** would be possible.

This is entirely in the interest of the company to save costs; in the interest of everyone to reduce CO_2 emissions, and last but not least, energy efficiency audits are required by law.

More than enough incentive, in my opinion!

A translated and shortened excerpt from episode 33 of the German webcast GMP & TEA 'Monitoring von Reinräumen und reinen Bereichen (Monitoring of Cleanrooms and Clean Areas)'

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