In-situ Efficiency Measurement for HEPA-Filters

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HEPA filter housings are mandatory in bio-safety laboratories class BSL3 (exhaust air) and BSL4 (supply and exhaust air). HEPA filter elements have to meet requirements of EN 1822 after manufacturing process. But additionally operators of bio-safety laboratories are asking the question more often whether the installed HEPA filter elements are still meeting the quality requirements after delivery and installation as well as later during operation. It would be ideal if the operator would have a compact measuring equipment available to check both efficiency ratio and integrity of the HEPA filter elements without de-installation.

1. Abstract

European standard EN 1822 "High Efficiency Air Filters (EPA, HEPA and ULPA)" and cleanroom standard ISO 14 644-3 "Metrology & Test Methods" are the base thinking about development, design, manufacturing and operation of a measuring equipment for HEPA filter elements as installed in a safe change HEPA filter housing. Both standards are describing the feeding and uniform distribution of test aerosol into the filter housing, and the number and size of the test particles. Further the standards concentrate on upstream raw air measurement resp. particle count, leakage tests and downstream scanning procedures in order to calculate the efficiency ratio of the filter element.

EN 1822 describes also the setup of the test rack for test aerosol feeding and scanning. Although it is impossible to copy that exactly for an in-situ measurement in an installed HEPA filter housing, the principles of EN 1822 have been complied with when designing a compact measurement device. The final setup of the measurement device, including aerosol generator, mixing box, optical particle counters, dilution stages, control, is described in detail.

Most important is the validation process of the measuring system in combination with the relevant filter housing. The parameters for aerosol feeding and uniform aerosol distribution are a result of the validation process and will allow the exact equal setting and result without opening of the filter housing or de-installation of the HEPA filter element later during operation. Both is mandatory in bio-safety laboratories, not only in regard of safety aspects. Cost – effectiveness and also time – saving procedures are important for the operators of such laboratories.

Although the responsibility for the safety and the procedures in a bio-safety laboratory can't be transferred to a third party, a third party expertise on the in-situ efficiency measurement process is an additional advantage. The paper describes the single steps of such a third party expertise shortly.

Finally the other periodic qualifications/procedures of a HEPA filter element installed in a HEPA filter housing for bio-safety laboratories will be highlighted, such as leakage tests for the filter element gasket seat, the disinfection of the filter element and filter housing and the safe change procedure.

2. HEPA filter housings in bio-safety laboratories

HEPA filter housings (Fig. 1) have to be used in bio-safety laboratories class 3 and 4 (BSL3 – BSL4) according to international standards for both supply and exhaust air. Depending on the country and region as well as the users and authorities requirements different standards may apply:

a. American BMBL (Biosafety in Microbiological and Biomedical Laboratories) of Centers of Disease Control and Prevention (CDC) & National Institutes of Health (NIH), 5th Edition 2007.
b. Canadian Biosafety Standards and Guidelines, 1st Edition, 2013.
c. European standards EN 12 128 Laboratories for Research, Development and Analysis, EN 1620 Large scale manufacturing and production processes and EN 1822 HEPA and ULPA filters.

Besides that a lot of local rules and guidelines have to be taken into consideration.

For bio-safety level BSL3 filtration of exhaust air by means of H14 HEPA filters is mandatory while for bio-safety level BSL4 filtration of supply air and double filtration of exhaust air is the requirement. According to the a. m. standards the filter housings have to provide following features at least:

1. HEPA filters have to undergo a leakage and seating inspection after installation.
2. It must be possible to inspect HEPA filters as installed. This applies also for series-installed HEPA filters which have to be inspected individually. Inspection includes measurement of separation efficiency as well as determination of possible leaks.
3. A fumigation of the filter housing and the HEPA filters with formalin or hydrogen peroxide must be possible.
4. It must be possible to exchange HEPA filters with low contamination.

HEPA filter housings for biosafety laboratories fulfill all these requirements.

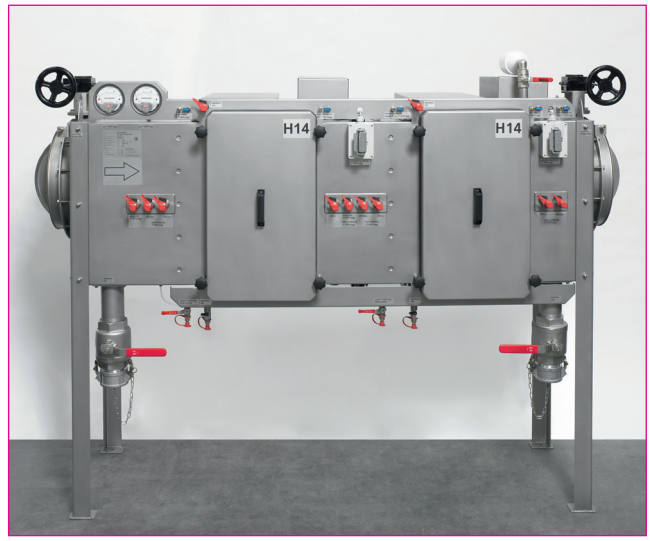

Fig. 1: HEPA filter housing for bio-safety laboratory

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3. EN 1822 and ISO 14 644-3

Inspection of installed HEPA filters may be based on two different standards, EN 1822 and ISO 14 644-3. While the European standard EN 1822 deals with inspection of HEPA filters after manufacturing by means of particle measurement, ISO standard 14 644-3 deals with test procedures of cleanrooms and clean areas. Different procedures are described in this standard relating leak tests and particle measurement. Regarding the tests ISO 14 644-3 requires:

1. Artificial generated polydisperse or atmospheric aerosol, median diameter between 0.1 µm and 0.5 µm
2. The detection limit of the optical particle counter (OPC) should be the same as the median aerosol diameter or even lower
3. If the OPC provides more than one channel between detection limit and 0.5 µ, a channel should be used where the highest number of particles will be shown downstream
4. The aerosol concentration should be high enough upstream, use of a dilution system could be necessary
5. If the aerosol concentration is not stable, particle counting should be done upstream and downstream at the same time
6. Aerosol concentration and uniform distribution has to be checked
7. Scanning of filter element downstream and comparison of particle counts with upstream particle concentration

Fig. 2: In-situ test setup

On the contrary EN 1822 determines the procedure of HEPA filter tests in more detail. Although it applies for HEPA filter testing after production normally, it makes sense to follow its procedures as far as possible for in-situ efficiency measurement and leak testing, too.

4. Description of the validation process

Testing according EN 1822 has to be done with test aerosols at MPPS size, which is most penetrating particle size. This depends on the air velocity through the filter element, but can be determined between 0.15 µm and 0,2 µm. DEHS (=Di-2-Ethylhexyl-Sebacat) – test aerosol complies with this requirement and delivers a particle concentration of $>10^8$ particles/cm^3. This allows a reliable calculation even at high separation ratio (filter class H14 = separation ratio > 99,995%).

The biggest challenge in complying with EN 1822 during in-situ efficiency measurement in a filter housing is the uniform distribution of aerosol. The standard allows a deviation of not more than 10% from the average aerosol concentration at 9 representative points of the filter sur-

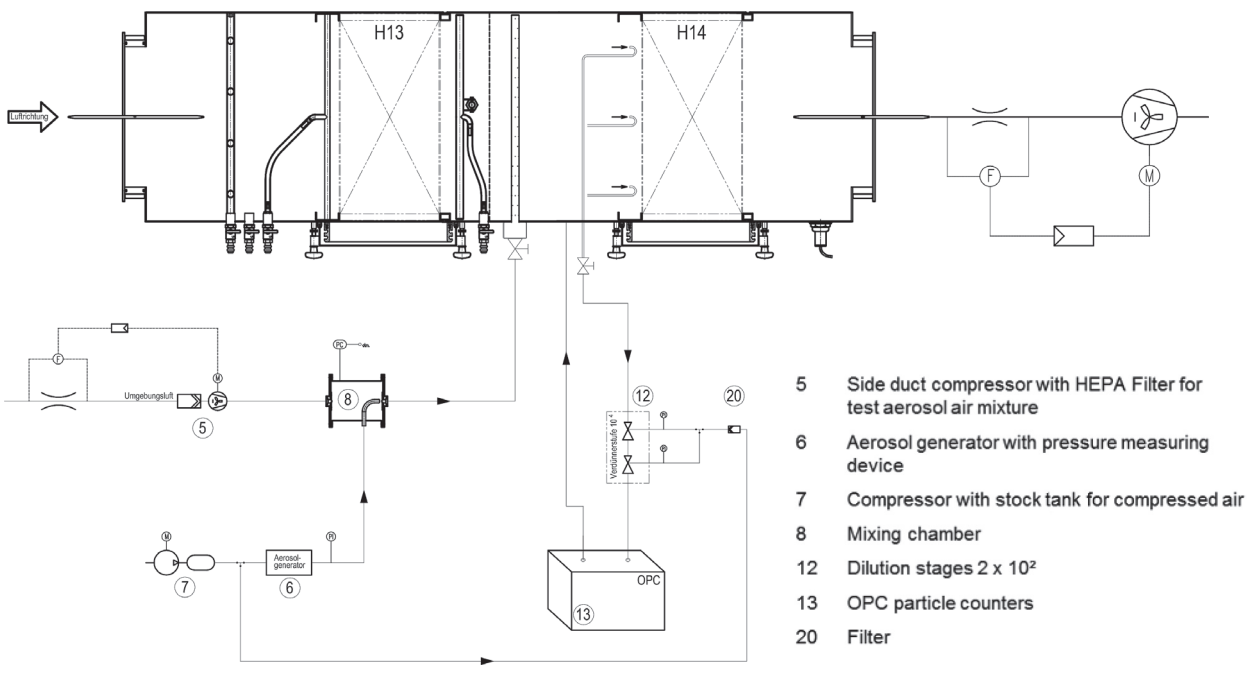

Fig. 3: Aerosol dispersion setup

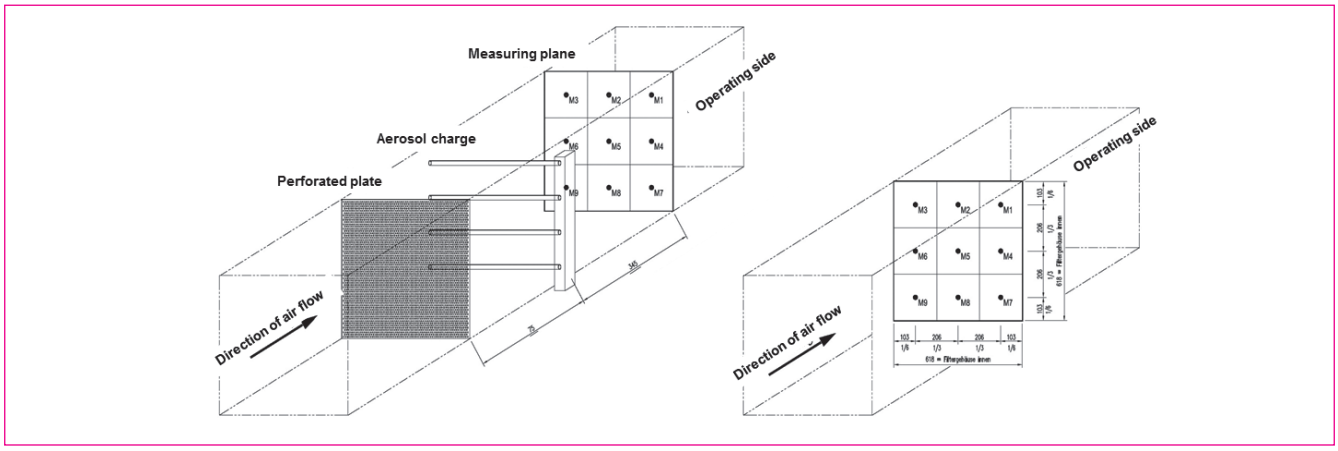

Fig. 4: Aerosol dispersal measuring points

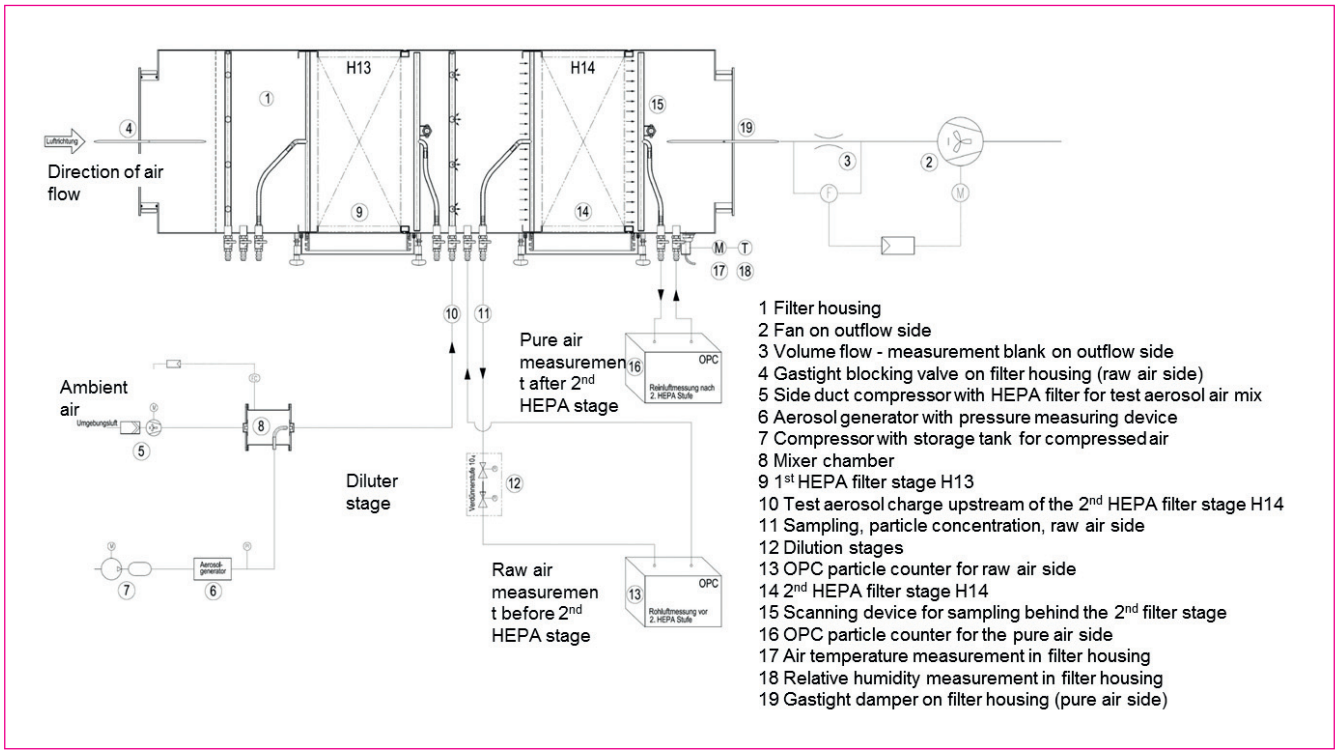

Fig. 5: Efficiency measurement setup

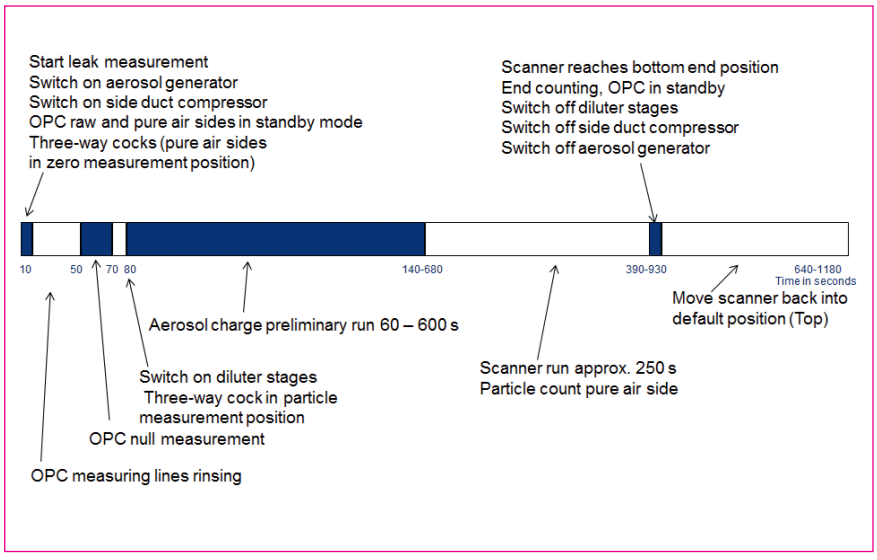

Fig. 6: Efficiency measurement sequence

Fig. 7: Third-party certificate

face. In a test set-up of a production environment aerosols can be fed upstream in a distance of tenfold diameter of the duct system which allows a good mixture of aerosol and airflow. In a filter housing, especially for the second HEPA filter stage, there are 450 mm only for uniform distribution of aerosols. The solution and invention is a pre-mixing box where test aerosol and addition air are mixed and then fed together with high pressure by means of a special distribution device into the filter housing and the airflow in front of the filter element.

With this arrangement and setup the uniform aerosol distribution according EN 1822 could be demonstrated also in the limited space of a HEPA filter housing.

The efficiency measurement setup is arranged accordingly (Fig. 2 to Fig. 6). Aerosol feeding is done as described before. Particle counting is done both upstream and downstream at the same time in order to eliminate deviations and problems by volatile feeding of aerosols.

The efficiency measurement is done fully automatically by the Krantz in-situ efficiency measurement system. The system, which consists of two trolleys, will be connected with the aerosol feeding device, the upstream and downstream measuring ports and the scanner of the filter housing. Filter housing and HEPA filter element data will be transferred to the systems via read-in of QR – codes. Afterwards the process is fully automatic according the following sequence.

The result of the efficiency measurement process can be displayed and printed as a test report according EN 1822, as a graph or can be send to a BMS systems for documentation.

Evidence of validation was done by testing the uniform distribution, the efficiency of an unloaded filter element, the efficiency of a loaded filter element and a leak test of a damaged filter element three times each.

5. Third-party approval

An expert report of the validation process and the efficiency measurement process (Fig. 7) was made by TÜV SÜD Industrie Service GmbH. The expertise consists of the following details.

1. Review of the relevant HEPA filter class H14 regarding the requirements of EN 1822-4 and EN 1822-5.
2. Inspection of test setup.
3. Function test of the particle filter housing and the a. m. scan procedure at manufacturer plant, based on EN 1822-4 and EN 1822-5, too.
4. Inspection of functional tests of the particle filter housing according the determinations of EN 1822-4 (leakage test) and EN 1822-5 (efficiency measurement).
5. Documentation of results (qualification report).
6. Audit of work environment.
7. A certificate is issued as evidence of the procedure.

6. Periodic qualification of the HEPA filter

Based on the requirements of the standards for bio-safety laboratories as mentioned above in chapter 1, other periodic qualifications of the HEPA filter have to be done besides the efficiency measurement and the leak testing of the filter element.

1. HEPA filters have to undergo a seating inspection after installation.

To check the tight seat of a HEPA filter element, a leak test device (Fig. 8) can be connected to the filter seat test groove from outside the filter housing. The tightness will be measured according the constant pressure method, which allows a quick and easy read off of the leakage airflow.

2. A fumigation of the filter housing and the HEPA filters with formalin or hydrogen peroxide must be possible.

Filter housings and HEPA filters must be decontaminated periodically. This is done by means of disinfection with either formalin or hydrogen peroxide. Disregarding the disinfection media the procedure of disinfection must be validated by means of bio-indicators. The disinfection parameters like duration and concentration have to be developed for each single design of filter housing. It is essential for the positive result of the process that a so-called "octopus" is used to bring disinfection media to each connection of the filter housing (with its hoses and pipes behind) and also to "dead" areas e.g. of the filter element clamping device (Fig. 9).

Furthermore the filter elements and the gaskets have to be resistant against the disinfection media to avoid changing the filter elements after each disinfection cycle.

3. It must be possible to exchange HEPA filters under conditions of low contamination.

Changing filter elements requires a bag-in / bag-out (BIBO) procedure using plastic bags and heat seal devises to avoid any contamination. This is a required method also if the filter housing was decontaminated previously and it will ensure additional safety both to personnel and environment. Different methods of sealing and cutting the changing bags are available including sealing documentation.

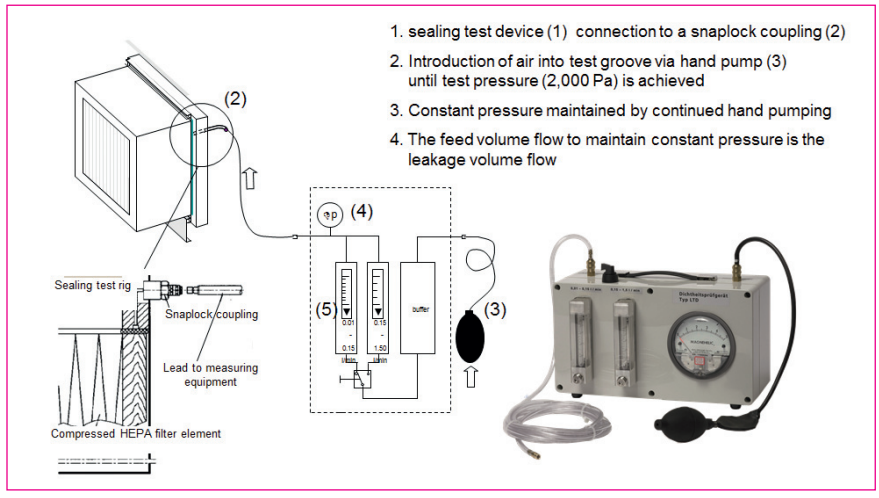

Fig. 8: Leak test device

Fig. 9: Disinfection setup

Fig. 10: Sealing and cutting during safe change with HSD classic device

Fig. 11: Sealing and cutting during safe change with HSD hightec device