ISCC'22
INTERNATIONAL SYMPOSIUM ON CONTAMINATION CONTROL
11-13 OCTOBER 2022
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NEW GUIDELINE ON TESTING OPERATING THEATRES IN THE NETHERLANDS

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19

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New guideline on testing operating theatres in the Netherlands

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Abstract

Operating theatres in the Netherlands are commonly based upon the use of Uni Directional Airflow in the middle of the room, in order to protect the patient, operating staff and the instrument tables.
From the early days on these UDF systems have been qualified on design parameters and were tested only by air cleanliness classification by particles, at rest. As this is method not totally satisfactory, within the VCCN, a project group evaluated various methods of testing and came to a new approach. The test principle based on segregation test is proposed for adoption in the ISO-14644-3. The method has been tested and improved and is proven to be helpful in assessing operating rooms and instrument lay-up rooms.
The ultimate test is the cleanliness during actual surgery. A methodology to monitor is currently under development and practical evaluation is on its way.

Key words: Operating Theatres, Instrument lay-up room, Segregation test, Monitoring.

1. Introduction

As the proper design is aimed to perform 'operational', the VCCN has been looking for an improvement over the current national practice of testing operating theatres 'at rest'. As there is no operational performance specified, in practice only a number of technical design and construction aspects are prescribed. Based on that, for the high grades of protection, operation theatres are equipped with UDF systems, while operations needing normal grades of protection only, can be designed based on the dilution mixing airflow principle. Thus the testing requirements are limited to parameters that are related to the technical design such as; airflow volume, air velocity, installed filter system leakage tests and ,as major contamination control parameter, the cleanliness of air by particles. Furthermore temperature, relative humidity and room overpressure are normally specified and verified.
By this set of tests 'at rest' however, no relevant indication of the performance 'in operation' is provided. There is no relevant challenge in the 'at rest' state apart from the 'recovery test' in the case of a dilution mixing system, while a recovery test is not the right test for an UDF system.

2. Evaluation of available methods

The VCCN projects group 4 set out criteria for a "challenging test" . Criteria were set to:

- Based on challenging the performance and not on testing technical parameters only.
- Testing for proper functioning 'segregation' systems (terminology according to ISO-14644-4 section A5 §A.5.2) [1]
- not to elaborate to execute
- repeatable
- independent of the chosen ventilation concept
- applicable also to instrument lay-up area's

In view of this the VCCN project group investigated several available methods that challenge an UDF system such as: DIN 1946-4 [2], SIS TS39 2012 [3] and HTM-03-01 [4]. Each of the methods have their specifics:
DIN 1946-4 has two options: 1) measuring the degree of protection or 2) measuring turbulence intensity. The latter (2) of these is considered as to far of a challenging method and its relevance is questionable. The first method requires dummies representing the medical staff. The type and shape of the dummies, especially the shape of the head, have been found to have significant impact on the test outcome. Furthermore the DIN test determines the degree of protection by comparing the measured concentration within the UDF protected area to a "calculated background value". This is seen as a drawback as the challenge in the periphery around the UDF is standardized to a specific calibrated output of particles per time, assuming a challenging concentration but the actual concentration is not measured.

SIS TS39 2012 also specifies a degree of protection test comparable to the DIN but without dummies.
Here also the drawback is found that no real background particle concentration is measured to compare the particle concentration within the UDF area to.
HTM-03 relies on another way to challenge by using less filtered air from outside the OR to challenge the UDF zone. As a positive point the challenging concentration is the measured value but the required minimal challenging concentration of 106.000 particles/m3 as well as the maxima for the concentration in the outer zone under the UDF of 10%, in the inner zone of 1% and in the very center of 0,1% are considered inadequate.
Although all considered methods are based on a kind of challenge none of the methods was found to be acceptable.

2. An improved test method

2.1 Principle

The principle of the test is shown in figures 1 and 2.
Emission to reach a challenging concentration C_{ref} of minimal 10^6 particles $\geq 0{,}5\mu m$ in is introduced at a distance of minimal 1,5 meter from $C_{ref.}$.

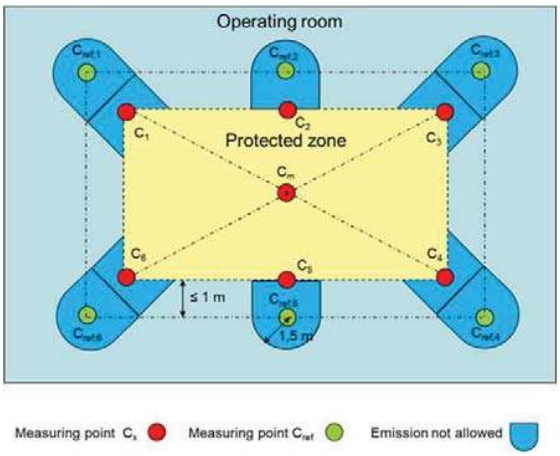

Figure 1. Footprint of the emission and test locations

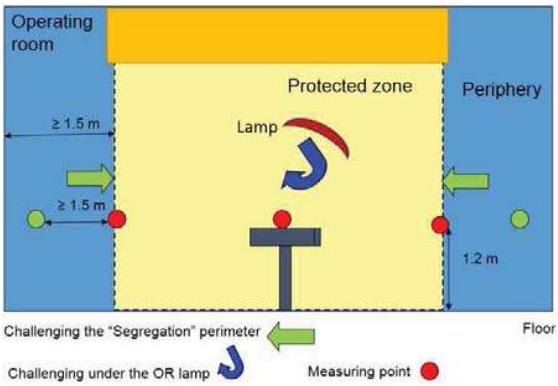

Figure 2. Cross section of the emission and test locations

Emission to reach a challenging concentration C_{ref} of minimal 10^6 particles $\geq 0{,}5\mu m$ is introduced at a distance of minimal 1,5 meter from $C_{ref.}$. The concentration is measured at the perimeter of the protected zone and in the center simultaneously. Working around all positions for each set the degree of protection at the perimeter, DP_x , is found with equation 1:

$$DP_x = -\log\left(\frac{C_x}{C_{ref}}\right) \quad (1)$$

And the degree of protection in the center of the perimeter is found with equation 2:

$$DP_m = -\log\left(\frac{C_m}{C_{ref}}\right) \quad (2)$$

When the DP_x values for all points are larger than 2 and when the DP_m values for all points are larger than 3, the perimeter fulfils the requirement of the protected zone.

An additional test to assess the influence of the lamp is defined as a OR lamp wake recovery test. Although ISO 14644-3 clearly states a recovery test to be not recommended for an UDF system, it was considered to be of use in the case an UDF is compromised, such is the case under an OR lamp. The modified recovery test requires a 100:1 reduction, measured above the operating table, after simulating a particle generating event just below the center of the OR lamp. The recovery should be achieved within 3 minutes.

3. Experiments

During the development the method was assessed by the VCCN project group as well as various testing companies.

Single tests were performed in various hospitals and operating theatres and to collect data on resolution and repeatability test were done in 2 hospitals in 3 identical OR's by different test groups.
During the test the lamps were in the position as described by the DIN 1946-4.
The challenging concentration was generated by evaporating domestic water, leaving sufficient solid particles to the required challenging concentration.

In the test sequence the ISO classification for particles $\geq 0{,}5\mu m$ under the UDF was demonstrated to be under ISO 5 and for the periphery under ISO 7, both in the 'at rest' state.

3. Results and discussion

The results were initially processed based on the statistics of ISO 14644-1 1999 but, as can be seen in figure 4, the full use of the 95% one sided student distribution statistics were found to be better.

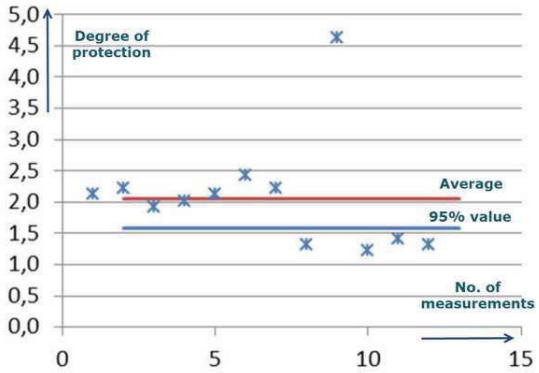

Figure 3. Effect of statistics on Degree of protection

In 2 typical situations independent measurements by 3 different test companies were carried out and compared. Figure 4 shows the boundary of the protected zone to be detected to substantial resolution (± 10-20 cm).

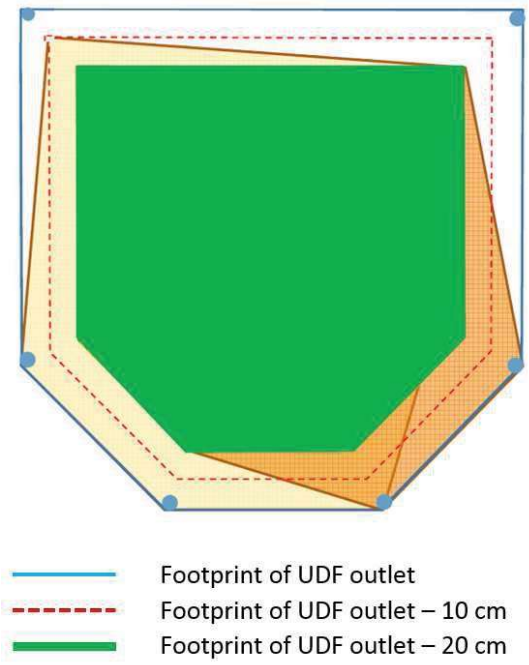

Figure 4. Common protected area based upon independent measurements.

The OR lamp wake recovery test showed the important effect on the UDF, with a down flow velocity of 0,3 m/s any contamination is swept away within 4 seconds over a distance of about 1,2 meter.

Typical values in good functioning operating rooms were found to be in the order of magnitude of 1- 2 minutes.

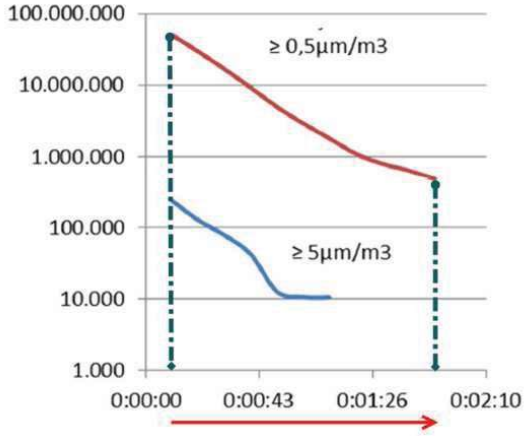

Figure 5. Typical value of OR-Lamp wake recovery test: 1 minute and 57 seconds.

In the project group the results were processed in the draft of the VCCN guideline 7 [5]. The method was found applicable for the instrument lay-up area as well as the hygienic requirements there are found to be equally important. [6]
As the principle is found to be useful for segregation by airflow systems, the principle has been proposed to be included in the revision of ISO-14644-3. The acceptance of this proposal is pending.

4. Recommendations

The testing of operating theaters 'at rest' using a method that includes challenging to assess the potency of the system to handle the 'operational' loads is an important step, but not considered to be the closing stone. What really is important is monitoring the critical conditions 'during operation'. This could include a combination of various parameters: particle concentration in air, viable concentration in air, sedimentation of particles and/or viables, viables being the parameter of interest. Particle monitoring could be used as an early warning because of the ease of monitoring as compared to current methods for cfu measurements. Performance criteria on viables lack a direct scientific relation to post-operative infection rates. Practical values are found to be $\leq$ 10 cfu/m^3 and $\leq$ 1 cfu/Agar Ø90mm 1 hr. during operation for critical surgery and $\leq$ 100-200 cfu/m^3 and $\leq$ 12 cfu/Agar Ø90mm 1 hr. during operation for normal surgery.

5. Conclusions

The proposed test method, based on challenging, proved to be executable with sufficient reproducibility and resolution to assess the protected zone in an operation room.
The method can be used to classify the protected zone or to detect the boundaries when unknown.
As the protected zone is not the projected footprint of the UFD ceiling as commonly employed marking of the real protected zone on the floor is mandatory to make sure the staff, the patients as well as the instrument tables are within the protected zone.

Further guidance on monitoring during operation is needed and will help to improve the understanding how achieved cleanliness benefits infection prevention.

Acknowledgements

Acknowledgements to the members of VCCN Project group 4, the participants to the method evaluation team as well as the experts in CEN TC156 WG18 ventilation in hospitals for their contributions in the discussion.

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