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Cesstech is a leading supplier of premium brands of contamination control and ESD products and services for ultra clean environments and processes. Being ISO 9001:2000 certified, Cesstech is engaged in the sales, services, installation and maintenance of these premium brand of products :

- Particle Counting Instrumentation & Systems from PSI (Met One & HYT)
- Air Ionization Products, Systems and Electrostatic Management Solutions from Ion Systems Inc
- ESD/EMI Management & Monitoring Tools from Credence Technologies
- Oxygen Analysis Solutions from Neutronics Inc
- Gas Chromatography Instrumentation & detectors from Gow Mac Inc

Additionally, Cesstech also offers the most comprehensive checklist of third party audits, tests and certification services available :

- Cleanroom, Clean-air device & Minienvironment Performance testing and Certification (Cesstech is NEBB certified, Reg No : CR 152)
- ESDC Testing and audits by NARTE ESD certified staff
- Indoor Air Quality (IAQ) testing supervised by a certified IAQ specialist

Microcontamination & ESD Solutions for Ultra Clean Environments & Processes

## Environment



# A proposed monitoring/written plan based on the ISO 14644-2 Cleanroom Standard

by Mr Inderjit Singh

This article, by **Inderjit Singh**, Director of Singapore-based **Cesstech**, gives an insight to the new **ISO 14644-2 Cleanroom Standard** that provides specifications for testing and monitoring to prove continued compliance with **ISO 14644-1**. It covers the recommended frequency of re-certification and highlights the author's views on a recommended format of a monitoring/written plan to prove continued compliance.

This standard was formulated to specify requirements for the periodic testing of a cleanroom and/or a clean zone, in the *Operational* or *At-Rest* states, as there were several questions raised over the years that addressed the need for a re-certification protocol after initial commissioning of a cleanroom or clean zone. This testing and monitoring requirement is something new altogether and has not been attempted to be defined in any prior standard or recommended practice previously.

### Frequency of re-testing

The ISO 14644-2 standard establishes the schedule for re-testing of the airborne particle count, the airflow volume or velocity test and the air pressure difference tests – all these tests being normative in the standard. The maximum time interval for the airborne particle count to demonstrate compliance can range from between 6 to 12 months, depending on the cleanliness classification – see **Table 1** below. As for the airflow volume or velocity and the air pressure difference tests, these are based on a standard 12 months interval – see **Table 2**.

Classification	Maximum Time Interval	Test Method
≤ ISO Class 5	6 months	Annex B in ISO 14644-1:1999
> ISO Class 5	12 months	Annex B in ISO 14644-1:1999

NOTE : Particle count tests will normally be performed in the operational state, but may also be performed in the at-rest state in accordance with the designated ISO classification

Table 1: Schedule of testing to demonstrate compliance with particle concentration limits (Extracted from Table 1 in ISO 14644-2)

Test Parameter	Maximum Time Interval	Test Method
Airflow Volume <sup>a</sup> or velocity test	12 months	ISO 14644-3:-, clause B.4
Air pressure difference <sup>b</sup>	12 months	ISO 14644-3:-, clause B.5

**NOTE :** These tests may normally be performed in either the operational or at-rest state in accordance with the designated ISO classification

<sup>a</sup> Airflow volume may be determined by either velocity or volume measurement

<sup>b</sup> This test will not apply to clean zones which are not totally enclosed

Table 2: Schedule of additional tests for all classes (Extracted from Table 2 in ISO 14644-2)

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In addition to these normative tests, other tests may also be optionally included and the suggested maximum time interval for these tests to demonstrate continued compliance should be no longer than 24 months.

### Exception to suggested time interval before re-testing

If the cleanroom or clean zone is equipped with instrumentation for continuous or frequent monitoring of the airborne concentration and air pressure differential, the maximum time interval could possibly be extended, provided that the results of the continuous or frequent monitoring remain within the specified limit(s). This is especially significant to users who have sophisticated monitoring systems in place throughout their cleanroom facility.

### Key elements of a proposed monitoring/written plan

The ISO 14644-2 standard proposes that every cleanroom facility has a monitoring / written plan in place irrespective of whether there is a continuous or frequent monitoring system installed. Though specifics of a monitoring or written plan are not spelled out in detail in the standard, there are several key indicators or specifics that need to be included in such a plan to make it feasible and practical:

#### Technical elements

The technical elements part should encompass the key parameters that need to be monitored as part of the plan, the acceptance limits involved and the justification for including these parameters based on product / process requirements, with each based on a risk assessment analysis.

##### i) Parameters

The key parameters that need to be monitored like airborne particle count, temperature, RH, air velocity, room pressure differential, ESC, ESD events need to be specified and included in the plan. The justification and basis for including these parameters need to be detailed in the plan as well.

##### ii) Sampling plan

The sampling plan should include the number of points that need to be measured for each parameter, the grid size and a layout showing the plan view of the facility and the sampling grid. For example, for airborne particle count, re-certification of a facility that does not have a monitoring system in place, this is straightforward and should be based on ISO 14644-1 for the minimum number of sample locations. For a facility with a monitoring system in place,

the number of sampling locations should be based on the process requirement. Generally, it will not be necessary to monitor the minimum number of sampling locations as per ISO 14644-1. The number of sampling locations should be based on the cleanroom facility and the number of critical processes involved. Generally, a few points in the general environment and the critical process environment needs to be monitored. But justification needs to be provided on the number of monitoring points selected. This same basis can be used for monitoring of pressure differential, air velocity, Temperature/RH, ESC etc.

##### iii) Acceptance and alarm limits

For all parameters to be monitored or re-certified, the acceptance limits need to be clearly defined. For example, for airborne particle count, the size of the particles to be monitored need to be defined as well as the alert and excursion / alarm limits need to be clearly stated. For example, with a

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**A good written plan based on ISO 14644-2 should include all key technical elements, a remedial action plan, re-certification guidelines & a training plan**

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monitoring system in place, for an ISO Class 4 Cleanroom where particle size of  $0.3\mu\text{m}$  and greater is being monitored, the threshold or alarm set point should be set at not more than  $1020\text{ particles/m}^3$  (or lower) and the alert level could be set to perhaps, 80 percent of this threshold level or some other level that makes sense to your process requirements.

##### iv) Risk assessment

For each of these technical elements, a risk assessment needs to be done prior to the selection of any parameter or data. The impact your selection has on the product and process of your manufacturing clean environment needs to be studied, justified and recorded. For example, if 10 locations are selected for placement of particle sensors connected to a monitoring system, you will have to justify why 10 points are selected and the risk or impact this selection will have on your process and final product quality. The monitoring plan, the selection of parameters, the interpretation of monitoring data (alert / excursion limits) and the actions to be taken as a result of the monitoring data needs to be exposed to a risk assessment analysis prior to selection and implementation.

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### Remedial action plan

The remedial action plan will contain a step by step procedure on actions that have to be taken when the specified alert or excursion limits of the monitored parameters are exceeded and therefore fall into non-compliance. It is recommended that a time limit be set for the excursion levels (say trigger continuously for 5 mins before non-compliance sets in) so that false triggers are not acted upon. It is also recommended that the cleanroom facility be re-certified after completion of remedial action to rectify an out of compliance condition, when there is a significant change in the current performance specification or when there is a significant interruption of air movement which affects the operation of the cleanroom/installation. All remedial actions have to be appropriately recorded and the nature of the occurrence, the action taken, date and time, parties involved (including certifying agency) etc., all needs to be recorded.

### Re-certification

The monitoring plan should also include the frequency of re-certification irrespective of whether there is a monitoring system in place . If there is no monitoring system in place the written plan should indicate the frequency of regular monitoring checks and the recommended time interval to prove continued compliance by a third party certifier where appropriate, based on ISO 14644-2 Tables 1 and 2. Where there is a monitoring system in place, the written plan should also optionally include the time interval before a complete third party re-certification, although this need not be carried out if the facility or cleanroom is in compliance throughout. The re-certification protocol, in case of a non-compliance situation, should also be outlined and listed in this section (with reference to the “Remedial Action Plan”). Therefore, as part of the re-certification protocol, either due to non-compliance or to prove continued compliance, the written plan (under this sub section of “Re-certification”) should address the following:

- Frequency of re-certification (with / without monitoring system in place)
- Tests to be performed, methodology, instruments to be used, acceptance criteria
- Operational condition of test (At rest or Operational)
- Selection criteria of certifying agency (eg: must be NEBB certified, ISO 9000 certified, experienced, good track record etc)
- Format of re-certification report (should state all submission requirements and necessary sub-headings like test

procedures, summary of data, layout & sampling plan, credentials / certificates of certifying agency etc)

### Training outline/plan

The final part of the written or monitoring plan should include a portion on training . The training should encompass basics of cleanroom testing for personnel who would be doing the regular measurements and/or re-certification for facilities without a monitoring system in place. For facilities with a monitoring system in place, the training plan should also include a comprehensive understanding of the monitoring system besides having a fundamental understanding of cleanroom performance testing. To summarize, the training plan should cover the following:

- Frequency of training (Initially and also periodically, e.g: once every six months)
- Conduct of training (In house or by a certified testing agency/monitoring system vendor)
- Types of Training/content (e.g: basics of cleanroom performance testing, fundamentals of a continuous/frequent monitoring system, basics of contamination control and monitoring)
- Records (records have to be maintained of all personnel trained and a review has to be done annually of the training needs and requirements)

### Conclusion

Though, very vague in structure and content, the ISO 14644-2 Standard no doubt attempts to stipulate guidelines on the maximum time interval before re-certification to prove continued compliance with ISO 14644-1. The positive aspect of this standard is that it encourages all cleanroom users to have a written or monitoring plan in place that helps implement protocol on parameters that need to be continuously monitored, a remedial action plan, a re-certification guideline and lastly emphasizes the importance of a proper recording methodology.

*Editor's Note: This article is contributed by Inderjit Singh, Director of Cessstech (S) Pte Ltd, a provider of microcontamination and ESD solutions for ultra clean environments and processes including third party cleanroom performance testing & certification.*

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