



Cleanroom Quality Management: How to Understand and Demonstrate Compliance to International Standards

March 3rd & 5th , 2008

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March 10th, 2008

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Agenda

- Introduction of Hach Ultra Analytics, Cesstech & CT Flow
- International Organization for Standardization
- Overview of Cleanroom Performance Testing (ISO14644)
- Key Requirements Of ISO 14644-2
- Discussions And Interpretations Of The Key Requirements
- Overview of ISO 21501-4 and what does it mean to me?
- Summary : Suggestions on How to Demonstrate Compliance
- Q&A

Who is Hach Ultra? Some of our Product Offerings



EXCELLENCE IN PROCESS ANALYTICS

- Particle Counters

- LPC

- APC

- Vacuum

- Remotes

- Silica analysers

- TOC analysers

- Conductivity & PH

- Sodium

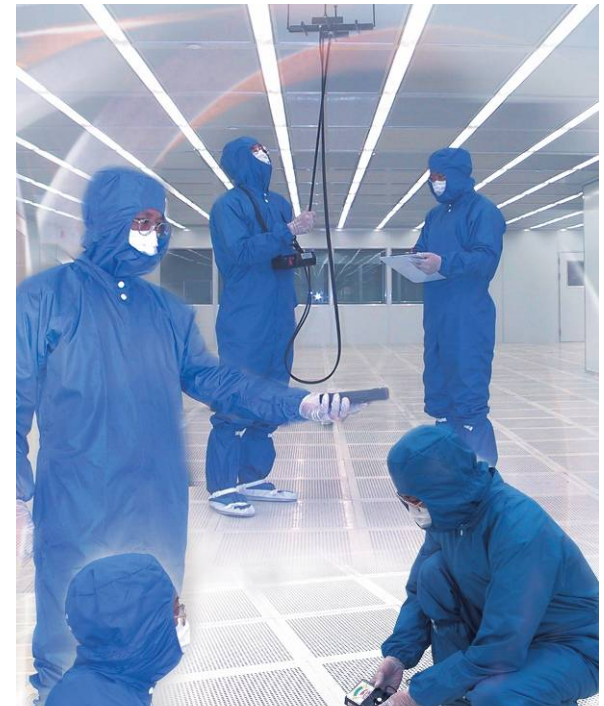
- Dissolved Gases

- Anatel, HYT, Orbisphere, Polymetron



Who is Cesstech / CT Flow?

- Leading supplier of cleanroom equipment, instrumentation and related product lines, backed by our third party Auditing, performance testing, qualification and certification services.
- Recognized provider of ESD and Microcontamination solutions for ultra clean environments and processes
- Long and successful working relationship with many HDD Customers



ISO Standards Cover All Industries

Electronics

- Semiconductor
- Flat Panel
- Circuit Board
- Optical
- HDD
- MEMS/Nanomachines

Life Sciences

- Pharmaceutical
- Biotechnology
- Medical Devices
- Hospitals/Pharmacies

Aerospace

- Launch Vehicles
- Satellites
- Commercial/Military Aircraft

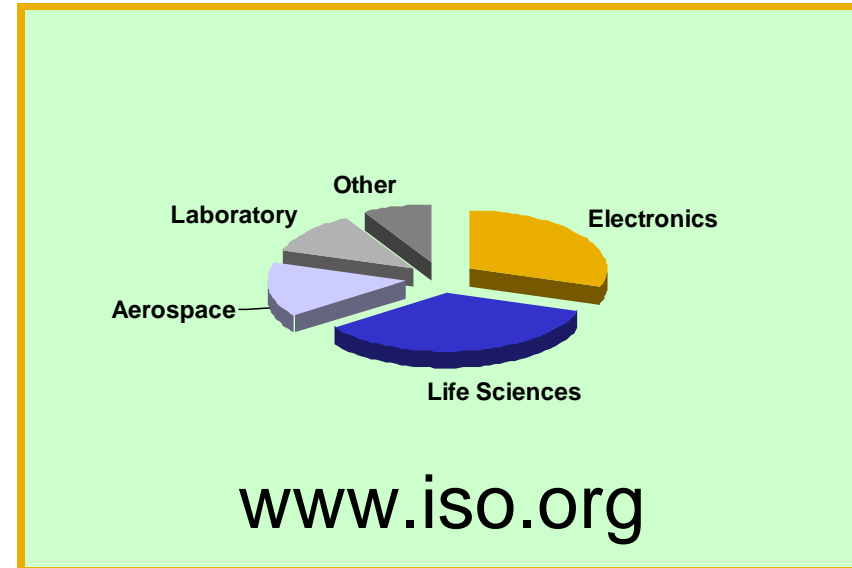
Laboratories

- Analytical Laboratories
- Universities

Other

- Nuclear
- Photographic, X-ray films
- Automobile Painting

Today's Focus : ISO 14644 – Cleanroom Classification and Testing and ISO 21501-4 – Determination of Particle Size Distribution



Overview of Cleanroom Performance Testing and Certification

- Specifications
- Measurement & Testing Methods
 - Test Procedures
 - Instrumentation
 - Operational Condition of the cleanrooms
- Standards and Reference Documents
 - NEBB Procedural Standards for Certified Testing of Cleanrooms
 - ISO 14644 standard (Part 1 and 3)*
 - IEST RP CC006.3
- Performed by suitably qualified personnel
- Certification Results
 - On the day of test (time of test)
 - Verification & Repeatability

The ISO 14644 Standard

- Part 1: Classification of air cleanliness
- Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
- Part 3: Metrology and Test methods
- Part 4: Design, construction and start-up
- Part 5: Operations
- Part 6: Vocabulary
- Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
- Part 8: Classification of airborne molecular contamination

Overview Of Cleanroom Performance Testing and Certification

Type of Tests...

- Are Not all inclusive
- Is Not necessary to include all

Recommended Tests

Table 1 — Recommended tests for the installation

Recommended test items	Clause for procedure (14644-3)	Clause for apparatus (14644-3)	Referenced in ISO Standard
Airborne particle count for classification and test measurement of cleanrooms and clean air devices	B.1	C.1	14644-1 and 14644-2
Airborne particle count for ultrafine particles	B.2	C.2	14644-1
Airborne particle count for macroparticles	B.3	C.3	14644-1
Airflow test	B.4	C.4	14644-1 and 14644-2
Air pressure difference test	B.5	C.5	14644-1 and 14644-2
Installed filter system leakage test	B.6	C.6	14644-2
Airflow visualization	B.7	C.7	14644-2
Airflow direction test	B.8	C.8	
Temperature test	B.9	C.9	
Humidity test	B.10	C.10	
Electrostatic and ion generator test	B.11	C.11	
Particle deposition test	B.12	C.12	
Recovery test	B.13	C.13	14644-2
Containment leak test	B.14	C.14	14644-1 and 14644-2

NOTE Recommended tests are not presented in order of importance. The order in which tests should be performed may be based upon the requirements of a specific document or after agreement between the customer and supplier.

Types of Tests

Table 1—Index of tests by cleanroom (or clean zone) airflow type

Section	Tests	Unidirectional	Nonunidirectional
6.1	Airflow Volume and Uniformity	1,2,3	1,2,3
	Airflow Velocity and Uniformity	1,2,3	OPT
6.2	Filter Installation Leak	1,2	1,2
6.3	Airborne Particle Count	1,2,3	1,2,3
6.4	Room Pressurization	1,2,3	1,2,3
6.5	Visual Airflow Characterization	1,2,3	N/A
6.6	Lighting Level and Uniformity	1, OPT (2,3)	1, OPT (2,3)
6.7	Noise Level	1,2,3	1,2,3
6.8–6.10	Temperature Uniformity	1,2,3	1,2,3
	Moisture Uniformity	OPT	OPT
6.11	Vibration	OPT	OPT
<p>N/A: Not applicable to this situation 1: Test is suited to as-built phase 2: Test is suited to at-rest phase 3: Test is suited to operational phase OPT: Test is optional, depending on process requirements</p>			
<p>Although the order in which the tests are performed is optional, certain tests should be performed in a preferred sequence, such as the following order for unidirectional cleanrooms: Airflow volume or airflow velocity (section 6.1) Visual airflow characterization (section 6.5) Room pressurization (section 6.4)</p>			

Particle Counts per Cleanroom Classes

Table 1 — Selected airborne particulate cleanliness classes for cleanrooms and clean zones

ISO classification number (M)	Maximum concentration limits (particles/m ³ of air) for particles equal to and larger than the considered sizes shown below (concentration limits are calculated in accordance with equation (1) in 3.2)					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

NOTE Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining the classification level

... in summary...

- Many elements to consider
- Wording is sometimes difficult to understand
- Makes my head hurt
- But what is really important?



ISO 14644-2:2000(E)

- Specifications for testing and monitoring to prove continued compliance to ISO 14644-1
- Specifies requirements for periodic testing of a cleanroom or cleanzone to prove continued compliance...
- Specifies requirements for monitoring of a cleanroom or cleanzone to provide evidence of its continued compliance...

- **Note**
 - Primarily focus on airborne particulate cleanliness
 - Additional (optional tests) are also specified
 - Normative reference to ISO14644-1 & ISO14644-3

Key Requirements Of ISO 14644-2

Table 1 — Schedule of testing to demonstrate compliance with particle concentration limits

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.		

4.2.2 Where the application requires them, tests as given in Table 2 shall be carried out to demonstrate compliance. The requirement for each of these tests shall be determined by agreement between the customer and supplier.

Table 2 — Schedule of additional tests for all classes

Test parameter	Maximum time interval	Test procedure
Airflow volume ^a or airflow velocity	12 months	ISO 14644-3:—, clause B.4
Air pressure difference ^b	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.		
^a Airflow volume may be determined by either velocity or volume measurement techniques.		
^b This test will not apply to clean zones which are not totally enclosed.		

Key Requirements Of ISO 14644-2

Annex A (informative)

Optional tests

In addition to the normative tests specified in Tables 1 and 2, optional tests, such as those listed in Table A.1, may be included within the testing plan.

Table A.1 — Schedule of optional tests

Test parameter	Class	Suggested maximum time interval	Test procedure
Installed filter leakage	All classes	24 months	ISO 14644-3:—, clause B.6
Airflow visualization	All classes	24 months	ISO 14644-3:—, clause B.7
Recovery	All classes	24 months	ISO 14644-3:—, clause B.13
Containment leakage	All classes	24 months	ISO 14644-3:—, clause B.14

Key Requirements Of ISO 14644-2

- Para 4.2.2 & 4.2.3 - referring to the tests requirement and appropriateness in table 2 and A.1
 - *...by agreement between customer and supplier...*
 - Who is the customer and who is the supplier?
 - Who should dictate the requirement?

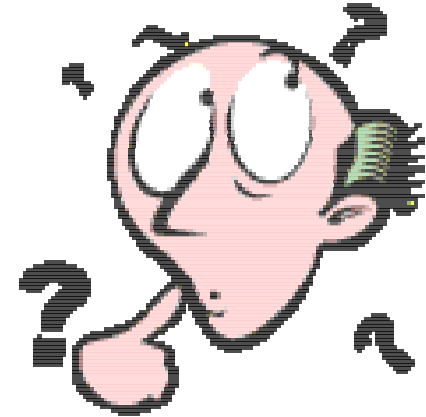


Key Requirements Of ISO 14644-2

- Para 4.2.4 ..
 - Where the installation is equipped with instrumentation for continuous or frequent monitoring for airborne particle concentration,, the maximum time interval in table 2 maybe be extended....., provided that the results of continuous or frequent monitoring remain within the specified limits?
- Para 4.2.5 .. .
 - those installation that require additional tests, and are equipped with instrumentation for continuous or frequent monitoring..., the maximum time interval stated in Table 2 may be extended....
- How to interpret this?

Key Requirements Of ISO 14644-2

- Para 4.2.4...
 - Monitoring locations
 - Where?
 - How many?...
 - Maybe extended to when?
 - Frequent monitoring..
 - Manual sampling acceptable?
 - ... remain within the specified limits.
 - Tolerance?



Key Requirements Of ISO 14644-2

- Re-qualification shall be undertaken, if..
 - Completion of remedial action..
 - **Significant** * change from the current performance specification..
 - **Significant** * interruption of air movement which affects the operation..
 - Special maintenance which **significantly** * affects the operation..

(* determined by agreement between the customer and the supplier)

Clarification:

- scope of the re-qualification?
- Definition of customer and supplier, again, who's who?

Key Requirements Of ISO 14644-2

ISO 14644-2:2000(E)

Annex B (informative)

Guidance on the influence of risk assessment on cleanroom or clean zone tests and monitoring

The risk assessment pertaining to a particular cleanroom or clean zone application will affect the following:

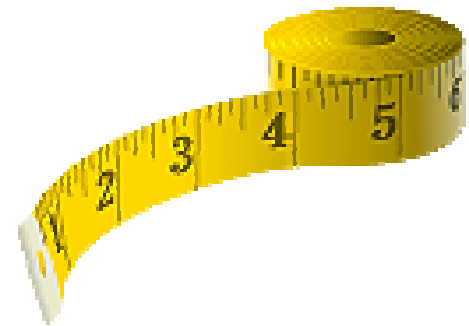
- a) monitoring plan;
- b) interpretation of monitoring data;
- c) actions to be taken as a result of the monitoring data obtained;
- d) selection of parameters to be measured from Table 2;
- e) selection of parameters to be measured from Table A.1.

ISO 21501 – 4

- **Full Title: Determination of particle size distribution – Single particle light interaction methods** Part 4: Light scattering airborne particle counter for clean spaces. Implemented in July of 2007
- Purpose : To provide a calibration procedure and verification method for particle counters, so as to minimize the inaccuracy in the measurement result by the counter, as well as the differences in the results measured by different instruments.
- All instruments used for Audit, Compliance and Classification of air cleanliness in cleanrooms and associated controlled environments per ISO 14644 should conform to this new calibration standard.
- **A realization that the testing required by ISO14644 is only as good as the tools you use to perform the tests!**

What tests does ISO 21501 cover?

- Size calibration
- Verification of size setting
- Counting efficiency
- Size resolution
- False count rate
- Maximum particle number concentration
- Sampling flow rate
- Sampling time
- Sampling volume
- Calibration interval
- Test report (format)



What does it cover in the Annex's

- Uncertainty of particle size calibration
- Counting efficiency (how to configure the test)
- Size resolution (how to calculate)
- False count rate (how to calculate)
- Response rate (from clean air to high particle concentration and back)



What does this mean for me?

- If units used in ISO14644 testing have been calibrated to this new standard, I can have confidence in the results! (Measurement uncertainty is greatly reduced)
- A unit calibrated to this standard, should perform at the highest performance level possible, given it's design.
- If two similar units are calibrated to this standard, I have the highest possible level of repeatability and reproducibility, between those units.
- If two dissimilar units (with the same measuring range) are calibrated to this standard, I have minimized as much as possible, measurement uncertainty within my control.

Summary : Suggestions on How to Demonstrate Compliance

- Will be provided during the sessions...

Questions ?