STANDARDS FOR COMPRESSED GAS TESTING

APPLICATION NOTE HPD-002 (US)

Introduction

This publication provides excerpts from some of the many guidelines and standards that pertain to compressed gases in cleanrooms. The intent of the publication is to provide owners, engineers, and consultants an overview of the standards and guidelines that pertain to the design and operation of compressed gases in today's cleanrooms.

The information provided is arranged by topic. Effort has been made to present the statements that best summarize the topics as they pertain to contamination levels and testing.

The excerpts, in most cases, are worded as they appear in the standard or guideline. However, in some instances may be out of context. Please review the actual guideline or standard for more detailed information and to make the best interpretation of each statement.

Topic	Standard
Acceptable Levels of Contamination a	**ISO 8573-1:2010 Compressed air—Part 1: Contaminants and purity classes** **5.2 Particle Classes** **Table 1—Compressed air purity classes for particles** When it is determined that there are particles with a size greater than 5 µm, then the classification of 1 to 5 cannot be applied.

Class[a]	**Maximum number of particles per cubic meter as a function of particle size, d[b]**		
	0.1 < d ≤ 0.5 µm	**0.5 < d ≤ 1.0 µm**	**1.0 < d ≤ 5.0 µm**
0	As specified by the user and more stringent than Class 1		
1	≤ 20,000	≤ 400	≤ 10
2	≤ 400,000	≤ 6,000	≤ 100
3	–	≤ 90,000	≤ 1,000
4	–	–	≤ 10,000
5	–	–	≤ 100,000
Class	**Mass concentration[b]** C_p **Mg/m^3**		
6[c]	$0 < C_p \leq 5$		
7[c]	$5 < C_p \leq 10$		
X	$C_p > 10$		

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Topic	Standard
Acceptable Levels of Contamination *(cont.)*	[a] To qualify for a class designation, each size range and particle number within a class shall be met. [b] At reference conditions; see Clause 4. [c] See A.3.2.2.
	ISO 8573-1:2010. Compressed air—Part 1: Contaminants and purity classes **Annex A** **A.2 Special applications** This part of ISO 8573 might not be suitable to fully define the requirements of special applications. It can be the case that, for applications such as breathing air, medical air, food and beverage, it is required to consider controlling other contaminants not identified in a classification or not included as a contaminant, to fully specify that requirement. It can be necessary to consult other sources of information, such as a pharmacopoeia, breathing air specifications and clean-room standards, before an air purity specification can be established. In addition, national in-use requirements can also stipulate regular testing for applications such as breathing air supplies.
	ISO 8573-1:2010. Compressed air—Part 1: Contaminants and purity classes **Annex A** **A.3.2.2 Particle classes 6 and 7** Industrial tools and pneumatic-fluid power-operated machines have traditionally been supplied by general purpose filters with a notional particle size rating of 5 μm (class 6) and 40 μm (class 7)…
	US Food and Drug Administration Guidance for Industry **Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (2004)** IV. Buildings and facilities D. Air Filtration 1. Membrane A compressed gas should be of appropriate purity (e.g., free from oil) and its microbiological and particle quality after filtration should be equal to or better than that of the air in the environment into which the gas is introduced. Compressed gases such as air, nitrogen, and carbon dioxide are often used in cleanrooms and are frequently employed in purging or overlaying.

<table>
<tr><th>Topic</th><th>Standard</th></tr>
<tr><td>Acceptable Levels of Contamination (cont.)</td><td>
SEMI E49.8-1103:2003
Guide for High Purity and Ultrahigh Purity Gas Distribution Systems in Semiconductor Manufacturing Equipment
Table 2—Summary of Requirements for High Purity and Ultrahigh Purity Components and Sub-Assemblies
<table>
<tr><th>Description</th><th>High Purity Value</th><th>Ultrahigh Purity Value</th><th>Units</th></tr>
<tr><td>Static Flow Particulate Contribution (valves, regulators, flow controllers)—Test procedures per SEMI F70</td><td></td><td></td><td></td></tr>
<tr><td>Particles ≥ 0.1 µm</td><td>≤ 0.7
(≤20)</td><td>≤0.18
(≤5)</td><td>Ptc/L
(ptc/ft^3)</td></tr>
<tr><td>Particles ≥ 0.02 µm</td><td>≤2.6
(≤75)</td><td>≤0.71
(≤20)</td><td>Ptc/L
(ptc/ft^3)</td></tr>
<tr><td>Cycle Life (valves, regulators and MFCs)—sample at least four and no more than 10 components using a 90% confidence interval and exponential hazard function:

Manual valves—MTTF of ≥ 25 K cycles
Pneumatic valves, regulators and MFCs—MTTF of ≥ 500 K cycles</td><td colspan="3">Following cycling, components must meet the particulate contribution requirements of this table and the leak rate requirements in Sections 6.2, 7.2 and 7.3.</td></tr>
</table>
</td></tr>
<tr><td>Designation</td><td>
ISO 8573-1:2010. Compressed air—Part 1: Contaminants and purity classes
6. Designation
6.1 Designation principle
The designation principle of the purity class of compressed air at the specified measuring point shall include the following information in the order given and separated by a colon:
ISO 8573-1:2010 [A:B:C]
Where
A is the purity class for particles; see Table 1
B is the purity class for humidity and liquid water; see Table 2
C is the purity class for oil; see Table 3
6.2 Unspecified designation
When a class for any particular contaminant A, B or C is not specified, the designation shall be replaced by a hyphen. In the example given below, there is no humidity or liquid water classification.
ISO 8573-1:2010:2010 [A:-:C]
6.3 Class X designation
When the contamination level falls within class X, then the highest concentration of the contaminant shall be given in round brackets. In the example given below, the concentration of liquid water, C_w, is 15 g/m^3.
ISO 8573-1:2010:2010 [A:X(15):C]
</td></tr>
</table>

Topic	Standard

Instrumentation

ISO 8573-4:2001 Compressed air—Part 4: Test methods for solid particle content

6 Selection of method

The method to be selected depends on the concentration range and the sizes of particles in the compressed air. For choosing the method most suitable for the concentration range and sizes of particles estimated to be present in the sample, see Table 1.

The applicability of particular measurement equipment to a method should be verified with the equipment manufacturer.

Table 3— Compressed air purity classes for oil

Method	Applicable concentration range particles/m³	Applicable solid particle diameter d µm
		≤ 0,10 0,5 1 ≤5
Laser particle counter	0 to10^5	
Condensation nucleus counter	10^2 to 10^8	
Differential mobility analyzer	Not applicable	
Scanning mobility particle sizer	10^2 to 10^8	
Sampling on membrane surface in conjunction with a microscope	0 to 10^3	

ISO 8573-4:2001 Compressed air—Part 4: Test methods for solid particle content

7 Sampling techniques

7.1 General

Solid particles can be measured at atmospheric pressure or under ambient pressure conditions depending on equipment used. Measurement can be carried out at partial or full flow.

a) Full flow—sampling of total airflow

b) Partial flow—sample taken from a percentage of the airflow

If the particle diameter is greater than 1 µm, then sampling shall be isokinetic.

Full-flow sampling

ISO 8573-4:2001 Compressed air—Part 4: Test methods for solid particle content

7.2 Full-flow sampling

7.2.1 General

For full-flow sampling using physical methods, if the particle diameter is greater than 0.5 µm, a gridded membrane shall be used…

Particular attention shall be paid to the cleanliness of the test equipment, and other precautions shall be taken, e.g. valve purging and stabilization to constant test conditions…

7.2.2 Test Equipment

Full-flow sampling shall be carried out by gridded membrane only.

Topic	Standard
Isokinetic sampling	**ISO 8573-4:2001 Compressed air—Part 4: Test methods for solid particle content** **7.3 Isokinetic sampling** **7.3.1 General** Accurate isokinetic sampling is not critical for small particles (less than 1 μm), although approximate isokinetic conditions are advisable…
High Pressure Diffuser	**ISO 8573-4:2001 Compressed air—Part 4: Test methods for solid particle content** **7.4 Reducing system pressure before measurement** If the system pressure is reduced before the measurement, the reduction method shall not influence the resulting particle count and particle distribution.
Design Qualification	**SEMI 49.6-1103:2003 Guide for Subsystem Assembly and Testing Procedures—Stainless Steel Systems** **9 Assembly Qualification and Quality Assurance** **9.3 Design Qualification** Gas delivery system design performance should be qualified in terms of two parameters: particulate generation and contaminant spike recovery. This testing should be performed on the initial gas delivery system prototype and on any design revision system which significantly impacts the component selection or system configuration. **9.3.1 Particulate Generation** Static and dynamic particle testing should be performed in accordance with SEMI F70 with a flow rate of at least 3 times the maximum process flow rate at the recommended supply pressure, except during mass flow controller testing when test flow rates should be between 0% and 100% of the MFC (Mass Flow Controller) value. Testing should be performed on all flow paths that differ significantly in components or configuration. Dynamic test protocols should be as follows: • Each valve in the test flow path should be cycled individually. • Starting with the valve furthest upstream, cycle each valve once every 20 seconds. • MFC valves should be cycled from 0% to 100%.
Manufacturing Qualification	**SEMI 49.6-1103:2003 Guide for Subsystem Assembly and Testing Procedures—Stainless Steel Systems** **9 Assembly Qualification and Quality Assurance** **9.4 Manufacturing Qualification** Manufacturing qualification tests should be performed to verify the manufacturing and quality control procedures followed in the manufacturing of the gas delivery system. As the configuration of gas systems varies greatly from process to process, no specification should be given here other than to state that static and dynamic particle testing, moisture level, oxygen level and hydrocarbon testing should be performed to show that the gas delivery system will meet the purity levels required. **9.5 Certification** Certification for gas delivery systems should include: leak rate certification, particle counts with specified flow rates at specified pressures and flow schematic indicating which flow paths were tested and which components were cycled…

References

SEMI Standard 49.6-1103:2003 Guide for Subsystem Assembly and Testing Procedures—Stainless Steel Systems. 2003

ISO Standard 8573-1:2010 Compressed air—Part 1: Contaminants and Purity Classes. 2010

ISO Standard 8573-4:2001 Compressed air—Part 4: Test methods for solid particle content. 2001

US Food and Drug Administration Guidance for Industry. Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice. 2004

UNDERSTANDING, ACCELERATED

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