Qualification of Installers of High Purity Piping Systems





AN AMERICAN NATIONAL STANDARD

QUALIFICATION OF INSTALLERS OF HIGH PURITY PIPING SYSTEMS

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FOREWORD

The high purity industry has been one of the most dynamic in recent times and will continue to grow as newer technologies emerge. The chemical and gas systems that are the backbone of the high technology industry carry toxic materials, which, until now, were not commonly used in the industrial setting. In addition, the increasingly higher demand for cleaner water, chemicals, and gases requires a greater sensitivity to high purity construction and commissioning techniques. Given these facts, it is one of the most potentially dangerous systems to work on due in part to the toxic liquid and gaseous products used in the piping systems. Accordingly, it is in the interest of public safety and health that those who install these systems are highly qualified and are certified in their abilities.

This Standard recognizes the need to have minimum training and performance criteria, identified by industry consensus requirements for high purity piping installers, to assure compliance with consensus standards developed by the industry. The development of this Standard sets uniform criteria that can be used throughout the world to address these issues. It will be revised and changed as the industry and health and safety needs it presents demand.

Suggestions for improvement of this Standard will be welcomed. They should be sent to The American Society of Mechanical Engineers; Attn: Secretary, A112 Main Committee, Three Park Avenue, New York, NY 10016-5990.

This Standard was approved as an American National Standard on March 18, 2004.

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Subject: Cite the applicable paragraph number(s) and the topic of the inquiry. Edition:

Cite the applicable edition of the Standard for which the interpretation

is being requested.

Question: Phrase the question as a request for an interpretation of a specific

requirement suitable for general understanding and use, not as a request for an approval of a proprietary design or situation. The inquirer may also include any plans or drawings that are necessary to explain the question; however, they should not contain proprietary names or infor-

mation.

Requests that are not in this format will be rewritten in this format by the Committee prior to being answered, which may inadvertently change the intent of the original request.

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QUALIFICATION OF INSTALLERS OF HIGH PURITY PIPING SYSTEMS

1 GENERAL

1.1 Scope

This Standard establishes minimum training and performance criteria, identified by industry consensus, for high purity piping system installers. It applies to any individual who installs high purity piping systems, which are typically specified for critical clean applications in the semiconductor, pharmaceutical, biotechnology, chemical, fiber optics, food, and dairy industries.

1.2 Levels of Qualification

This Standard establishes qualification and certification requirements for Levels 1 through 5 for installers of high purity piping systems for either liquid or gaseous products. The levels are as follows:

- (a) Level 1 qualification shall include a minimum of 10 hr of the most current OSHA General Safety Training Course or equivalent, and 6 hr of high purity safety and protocol.
- (b) Level 2 qualification shall include completion of Level 1 requirements and an additional 8 hr of practical training in material and component awareness, handling, rigging, storage, tools, and equipment specific to the high purity industry.
- (c) Level 3 qualification shall include completion of Level 1 and 2 requirements and an additional 16 hr of training in system installation, material end preparation, purging, slope verification, pipe support, and basic material joining in accordance with requirements in appropriate standards referenced in para. 1.3.
- (d) Level 4 qualification shall include completion of Levels 1, 2, and 3 requirements and a mandatory four years of documented practical experience (recognized by the ANSI accredited third party certifier) in the piping industry and an additional 24 hr of training in system installation, codes and standards awareness, thermal plastic fusion, welding, brazing, and bending in accordance with the requirements in appropriate standards referenced in para. 1.3 and applicable manufacturer specifications. In addition, the Level 4 High Purity Installer shall be a certified metallic and/or nonmetallic welder in accordance with para. 8.
- (e) Level 5 qualification shall include completion of Levels 1, 2, 3, and 4 requirements and an additional mandatory two years of documented practical piping

experience (as recognized by the ANSI accredited third party certifier) in the high purity field plus an additional 16 hr of training on testing and acceptance, pressure piping, codes and standards specific to the high purity industry, specification compliance, and documentation in accordance with the appropriate standards referenced in para. 1.3.

1.3 References

The following documents form a part of this Standard to the extent specified herein. The latest edition shall apply.

ASME BPE, Bioprocessing Equipment

ASME BPVC, Section IX, Welding and Brazing Qualifications

ASME B31.1, Power Piping

ASME B31.3, Process Piping

Publisher: The American Society of Mechanical Engineers (ASME International), Three Park Avenue, New York, NY 10016-5990; Order Department: 22 Law Drive, Box 2300, Fairfield, NJ 07007-2300

ASTM Volume 14.0, Terminology

Publisher: The American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959

AWS A30, Terms and Definitions

AWS B2.1, Specification and Qualification of Welding Procedures and Welding for Piping and Tubing

AWS D18.1: Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications

AWS Z49.1, Safety in Welding & Cutting and Associated Processes

Publisher: The American Welding Society (AWS), 550 NW LeJeune Road, Miami, FL 33126

Current Good Manufacturing Practice (CGMP) Regulations of the Food and Drug Administration, chapter 1 of CFR 21, part 210 & 211

Publisher: Occupational Safety and Health Administration (OSHA)¹, 200 Constitution Avenue, NW, Washington, DC 20210

¹ CCOHS (Canadian Centre for Occupational Health and Safety) and Provincial amendments may be equivalent to OSHA.

ISO/IEC 17024 Personal Certification Bodies²

Publisher: International Organization for Standardization (ISO), 1 rue de Varembé, Case Postale 56 CH-1211, Genève 20, Switzerland/Suisse

SEMI E52-0703, Practice for Referencing Gases and Gas Mixtures Used in Digital Mass Flow Controllers

SEMI F78-0703, Practice for Gas Tungsten Arc (GTA) Welding of Fluid Distribution Systems in Semiconductor Manufacturing Applications

SEMI F79-0703, Guideline for Gas Compatibility with Silicon Used in Gas Distribution Components

Publisher: Semiconductor Equipment and Materials International (SEMI), 3081 Zanker Road, San Jose, CA 95134

1.4 Examiners of High Purity Piping System Welding

Nonmandatory Appendix A provides suggested guidelines for examiners of high purity piping system welding.

2 GENERAL KNOWLEDGE

2.1 Terms and Definitions

The high purity piping system installer shall demonstrate a basic working knowledge of the appropriate and pertinent terms contained in the standards referenced in para. 1.3 and this Standard.

2.2 Laws, Codes, Rules, Listing Agencies, and Regulations

The high purity piping systems installer shall be able to identify and demonstrate knowledge of the applicable laws, codes, rules, listing agencies, and regulations from the federal, state, provincial, and local levels recognized by the Authority Having Jurisdiction relating to high purity piping installations.

3 PRODUCT PERFORMANCE KNOWLEDGE

3.1 Major Components

The high purity system installer shall be able to list the parts and identify the major components of high purity piping systems and equipment.

3.2 Application and Testing

The high purity piping system installer shall be able to identify and describe the proper application and testing procedures of high purity piping systems.

4 PRODUCT INSTALLATION KNOWLEDGE

4.1 Installation Requirements

The high purity system installer shall be able to understand and recognize the proper installation requirements

for the high purity systems pertaining to

- (a) high purity system component manufacturer recommendations
- (b) ventilation and accessibility requirements for nonmetallic welding procedures
 - (c) Code requirements
- (*d*) cleanliness in handling high purity piping components and system cleanliness
 - (e) safety

4.2 Improper Installations

The high purity piping systems installer shall be able to recognize and identify improprieties in high purity piping systems installation.

5 SYSTEM AND SYSTEM COMPONENT ACCEPTANCE TESTING KNOWLEDGE

5.1 Test Procedures

The high purity system installer shall demonstrate a knowledge of acceptable systems and approved materials, proper material handling, proper flushing, cleaning and neutralizing of piping systems, system installation and certification procedures, installer-performed testing, and verification test in accordance with ASME BPE, Bioprocessing Equipment.

5.2 Precautions and Safe Practices

The high purity piping system installer shall be able to describe the precautions and safe practices during acceptance tests in accordance with OSHA (Occupational Safety and Health Administration) related to

- (a) confined spaces safety
- (b) site notification
- (c) shutdown notification
- (d) electricity and safety
- (e) tool utilization
- (f) lockout/tagout of equipment, systems, and components
 - (g) hazard communication standards (hazcom)
 - (h) applicable permits

6 ADDITIONAL HIGH PURITY SYSTEMS AND MATERIAL KNOWLEDGE REQUIRED

6.1 High Purity Gases

The high purity piping system installer shall understand the following terms, common gases, and requirements contained in SEMI F79, SEMI F78, and SEMI E52:

- (a) Terms
 - (1) ceiling limit
 - (2) control area
 - (3) controls
 - (4) cryogenic liquid
 - (5) density

² May also be obtained from the American National Standards Institute, Inc., 25 West 43rd Street, New York, NY 10036.

- (6) dewpoint
- (7) fluorides
- (8) halogens
- (9) hydrides
- (10) hydrocarbons
- (11) IDLH (Immediately Dangerous to Life and Health)
 - (12) inert
 - (13) LCLo (Lethal Concentration Low)
 - (14) LC50 (Lethal Concentration 50%)
 - (15) LDLo (Lethal Dose Low)
 - (16) LD50 (Lethal Dose 50%)
 - (17) maximum release rate
 - (18) minimum threshold quantities
 - (19) sulfides
 - (20) Common Gases (non-toxic)
 - (a) silane
 - (b) nitrous oxide
 - (c) sulfur hexafluoride
 - (d) hydrogen
 - (e) oxygen
 - (f) nitrogen
 - (g) helium
 - (h) argon
 - (i) freon
 - (21) Common Gases (toxic/corrosive)
 - (a) ammonia
 - (b) arsine
 - (c) carbon monoxide
 - (d) chlorine
 - (e) diborane
 - (f) dichlorosilane
 - (g) fluorine
 - (h) germane
 - (i) hydrogen chloride
 - (j) hydrogen fluoride
 - (k) hydrogen sulfide
 - (l) methyl bromide
 - (m) nitric oxide
 - (n) nitrogen dioxide
 - (o) phosgene
 - (p) phosphine
 - (q) phosphorus trichloride
 - (r) silicon tetrafluoride
 - (s) sulfur dioxide
 - (t) tungsten hexafluoride
 - (b) Requirements for
 - (1) Class I, II, and III hazardous materials
 - (2) Class I, II, and III piping requirements
 - (3) exterior storage
 - (4) piping controls and gas detection
 - (5) inert materials
 - (6) incompatible materials
 - (7) seismic protection
 - (8) secondary containment

- (9) portable tanks and cylinders
- (10) inert gas purge systems

6.2 High Purity Water

The high purity piping system installer shall understand the following terms in accordance with codes and standards referenced in para. 1.3:

- (a) Total Dissolved Solids (TDS)
- (b) conductivity
- (c) resistivity
- (*d*) Total Organic Content/total oxidization carbon (TOC)
 - (e) Reverse Osmosis (RO)
 - (f) Reversed Osmosis/De-Ionized (RODI)
 - (g) High Purity Water (HPW)
 - (h) Ultra Pure Water (UPW)
 - (i) United States Pharmacopoeia (USP)
 - (j) Water For Injection (WFI)
 - (k) dead leg
 - (1) turbulent flow
 - (m) laminar flow
 - (n) thermal expansion of plastics
 - (o) valves

6.3 Plastics Terminology

The high purity installer shall understand the appropriate terms commonly used to describe aspects of the use of plastics in high purity systems as defined in ASTM 14.02.

- (a) plastics
- (b) thermoplastics
- (c) polyolefins
- (d) polymer
- (e) modulus of elasticity
- (f) creep
- (g) yield strength
- (h) ductility
- (i) izod impact
- (j) tensile strength
- (k) stress
- (l) linear expansion
- (m) thermoplastic stress relaxation
- (n) degradation and decomposition of plastics
- (o) PTFE
- (p) PVC
- (q) CPVC
- (*r*) PE
- (s) UHMW PE
- (t) PP
- (u) ECTFE
- (v) ETFE
- (w) PVDF
- (x) CTFE (y) PFA
- (z) FEP

6.4 Nonmetallic Joining Techniques

The high purity piping system installer shall understand the following nonmetallic joining techniques found in standards referenced in para. 1.3 and appropriate manufacturers certification requirements:

- (a) butt fusion
- (b) socket fusion
- (c) IR-fusion-infrared butt fusion
- (d) bead and crevice free fusion process
- (e) mechanical connections
 - (1) flanges
 - (2) threads
 - (3) sanitary fittings
 - (4) unions
 - (5) flair
 - (6) compression
 - (7) metal-to-plastic transition joints

7 CERTIFICATION OF HIGH PURITY SYSTEM INSTALLERS

7.1 Overview

Certification to this Standard shall be through an ISO/IEC 17024 ANSI accredited third party certifier. Certification shall include the successful completion of a minimum number of hours of training appropriate for the level of qualification outlined in paras. 1.2 and 7 of this Standard that includes a written and a practical examination covering all facets of this Standard.

7.2 Practical Experience

7.2.1 Level 4. The qualified Level 4 high purity piping system installer shall have a minimum of four years of documented practical experience (recognized by the ANSI third party certifier) in the installation of piping systems.

7.2.2 Level 5. The qualified Level 5 high purity piping system installer shall have an additional two years of documented practical experience (recognized by the ANSI third party certifier) in the high purity field.

7.3 Recertification of High Purity Piping System Installers

All levels of high purity installer certification shall be renewed at a minimum of every five years. Recertification shall include a written and practical examination covering all facets of the latest edition of this Standard.

7.4 Metallic Welding Qualifications

Each welding procedure, welder, or welding operator shall be qualified in accordance with Section IX of the ASME Boiler and Pressure Vessel Code, as specified in ASME B31.1 and ASME B31.3. In addition, each orbital welding operator shall qualify separately on the smallest and largest size to be welded in production, by a visual

examination of exterior and interior surfaces by the QAR (Quality Assurance Representative).

7.5 Nonmetallic Welding Qualifications

7.5.1 Examination Procedure

- **7.5.1.1 Examination.** The qualification examination shall consist of a written, practical, and, when appropriate, oral examination by the QAR.
- **7.5.1.2 Passing Criteria.** The high purity Installer shall have achieved at least an 80% correct score to pass the written qualification examination.
- **7.5.1.3 Continuity.** Continuity requirements shall be the same as those contained in Section IX of the ASME Boiler and Pressure Vessel Code.

7.5.2 Practical Skills and Knowledge

- **7.5.2.1 Methodology.** The nonmetallic welder shall prove his practical skills in accordance with the methodology being employed.
 - **7.5.2.2 Testing.** Testing shall include the following:
 - (a) materials technology (thermoplastics)
 - (b) welding principles and joining methods
 - (c) context between temperature, pressure, and time
 - (d) choice of parameters
- (e) designation and rules for the processing of plastics and filler materials to which the examination is designed to apply
- (f) meaning of standardized welding signs and symbols
 - (g) types and shapes of welds
 - (h) requirements of the welding equipment
 - (i) influences on the weld quality
- **7.5.3 Welding Performance.** The qualified installer shall demonstrate knowledge concerning the following:
 - (a) proper preparation of the work pieces for welding
 - (b) proper operation of the welding equipment
 - (c) preventing and correcting faults when welding
 - (d) prevention of accidents and fire damage
- **7.5.3.1 Test Piece Preparation.** The dimensions of the test pieces are dependent on the process, the material, and the work piece thickness and filler material (when necessary). The candidate shall prepare the test pieces in an approved manner for welding. The fabrication of the test pieces shall be judged according to the following:
- (a) determination and choice of the welding parameters, including the actual measured values
 - (b) preparation of the joint and welding filler
- (c) adjustment and handling of the welding equipment
 - (d) control measures and recording
 - (e) manufacturer's recommendations

- **7.5.3.2 Evaluation.** The evaluation of the test pieces with respect to surfaces and cross-sections shall be by inspection of the sectional view in accordance with manufacturer's weld inspection guidelines and the following:
 - (a) shape/symmetry of beads
 - (b) height of beads
 - (c) surface of beads
 - (d) notch between beads
 - (e) imperfections in cross-section/depth of melt
 - (f) alignment of components
 - (g) contamination
- **7.5.4 Welding Supervision.** In order to ensure proper fabrication of the test pieces, they shall be welded under the supervision of the QCI (Quality Control Inspector) and QAR.
- **7.5.4.1 Practical Examination Contents.** The QC and QAR for plastic welders shall judge and evaluate the test pieces and specimens on the following:
- (a) preparation for welding and the handling of welding machines and equipment
 - (b) fabrication of the test pieces
- (c) visual measurement of the welded joints (surface cross-sections and micro cross-sections)
- **7.5.4.2 Evaluations.** Evaluations made by the QC shall be either acceptable or non-acceptable with the individual evaluations and measured values entered into an Evaluation Record Form.

8 80-HR HIGH PURITY PIPING SYSTEM INSTALLER TRAINING OUTLINE

The 80-hr training requirement described in para. 7 shall include instruction, as a minimum, in the following topics appropriate for the level of qualification/certification:

(a) Session One (10-hr) Level 1. OSHA Safety Training or equivalent

- (b) Session Two (6-hr) Level 1. High Purity Safety and Protocol in accordance with specific industry standards
 - (1) double containment
 - (2) reactive gases
 - (3) EMF
 - (4) clean room protocol
 - (c) Session Three (8-hr) Level 2. Basics
 - (1) material and component awareness
 - (2) handling
 - (3) rigging
 - (4) storage
 - (5) tools and equipment
- (d) Session Four (16-hr) Level 3. General Requirements for High Purity Installation
 - (1) system installation
 - (2) technician labor
 - (3) material end preparation
 - (4) purging
 - (5) slope verification
 - (6) pipe support
 - (7) basic material joining
 - (8) welding terminology (AWS A30)
- (e) Session Five (24-hr) Level 4. Advanced High Purity Installation
 - (1) codes and standards awareness
 - (2) thermal plastic fusion
 - (3) welding (AWS Z49.1, AWS A18.1, AWS B2.9)
 - (4) brazing
 - (5) bending
 - (f) Session Six (16-hr) Level 5
 - (1) testing and acceptance
- (2) pressure piping relevant to appropriate ASTM material standards
 - (3) codes
 - (4) specification compliance (leak testing, integrity)
 - (5) documentation
 - (6) fluid systems (preparation and cleaning)
 - (7) turn over package

NONMANDATORY APPENDIX A EXAMINERS OF HIGH PURITY PIPING SYSTEM WELDING

A1 INSPECTOR QUALIFICATION

These guidelines provide recommended inspector qualifications for inspection to the applicable codes and standards and to ensure that high purity systems are of sufficient quality to provide the required system purity, weld integrity, and weld strength for use in high purity applications.

A2 EXAMINATION METHODS

These guidelines establish the recommended criteria for the qualification and certification of individuals whose job requires appropriate knowledge of the technical principals applicable to the visual examinations they perform and establishes the recommended requirements for training and qualifying NDE personnel to perform examination methods according to the applicable portions of the following reference standards:

- (a) ASME A112.20.1, Level 5
- (b) ASME B31.1 Power Piping Code
- (c) ASME B31.3 Process Piping Code
- (d) AWS-CWI

SNT-TC-1A, American Society for Nondestructive Testing Recommended Practice

Publisher: The American Society for Nondestructive Testing (ASNT), 1711 Arlingate Lane, P.O. Box 28518, Columbus, OH 43228-0518

A3 DEFINITIONS

NDE: nondestructive examination.

QAR (Quality Assurance Representative): designated by the Owner and shall be an employee of the Owner, an employee of an engineering or scientific organization, or of a recognized insurance or inspecting company acting as the Owner's agent. The Owner's Inspector shall not represent nor be an employee of the piping manufacturer, fabricator, or erector unless the Owner is also the manufacturer, fabricator, or erector.

QC (Quality Control Inspector): an individual from a technically competent organization or the representative of the contractor/employer. This individual cannot be the installer.

A4 REQUIREMENTS

Final visual examination shall require 100% examination by QC and 20% inspection by QAR. In delegating the performance of inspections, the Owner is responsible for determining that a person to whom an inspection function is delegated is qualified to perform that function in accordance with ASME B31.3.

A5 QUALIFICATION OF QAR

The QAR shall have not less than 10 year's experience in the design, manufacture, erection, fabrication, or inspection of high purity piping systems. Each year of satisfactorily completed work towards an engineering degree recognized by the Accreditation Board for Engineering and Technology shall be considered equivalent to 1 year of experience (up to 5 years total). These requirements are in accordance with ASME B31.3.

ASME STANDARDS RELATED TO PLUMBING

Air Gaps in Plumbing Systems	A112 1 2-1001(P2002)
Air Gap Fittings for Use With Plumbing Fixtures, Appliances, and Appurtenances	
Performance Standard and Installation Procedures for Stainless Steel Drainage Systems for	A112.1.3-2000
Sanitary, Storm, and Chemical Applications, Above and Below Ground	۸112 3 1-1003
Macerating Toilet Systems and Related Components	
Water Heater Relief Valve Drain Tubes	
Water Closet Personal Hygiene Devices	, ,
Plastic Fittings for Connecting Water Closets to the Sanitary Drainage System	
Point of Use and Branch Water Submetering Systems	
Framing-Affixed Supports for Off-the-Floor Water Closets With Concealed Tanks	
Floor and Trench Drains	
Roof, Deck, and Balcony Drains	
Enameled and Epoxy Coated Cast Iron and PVC Plastic Sanitary Floor Sinks	
Backwater Valves	
Grease Interceptors	
Grease Removal Devices	
Plumbing Fixture Fittings	
Plumbing Fixture Waste Fittings	
Performance Requirements for Backflow Protection Devices and Systems in Plumbing Fixture Fittings	
Flexible Water Connectors	
Deck-Mounted Bath/Shower Transfer Valves With Integral Backflow Protection	
Enameled Cast Iron Plumbing Fixtures	
$\hbox{\it Vitreous China Plumbing Fixtures and Hydraulic Requirements for Water Closets and Urinals}$	
Stainless Steel Plumbing Fixtures (Designed for Residential Use)	
Porcelain Enameled Formed Steel Plumbing Fixtures	
Trim for Water-Closet Bowls, Tanks, and Urinals	
Whirlpool Bathtub Appliances	
Suction Fittings for Use in Swimming Pools, Wading Pools, Spas, Hot Tubs, and Whirlpool Bathtub Appliances	
Non-Vitreous Ceramic Plumbing Fixtures	
Dual Flush Devices for Water Closets	
Wall Mounted and Pedestal Mounted, Adjustable and Pivoting Lavatory and Sink Carrier Systems	A112.19.12-2000
Electrohydraulic Water Closets	A112.19.13-2001
Six-Liter Water Closets Equipped With a Dual Flushing Device	A112.19.14-2001
Bathtub/Whirlpool Bathtubs With Pressure Sealed Doors	A112.19.15-2001
Manufactured Safety Vacuum Release Systems (SVRS) for Residential and Commercial	
Swimming Pool, Spa, Hot Tub, and Wading Pool Suction Systems	
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