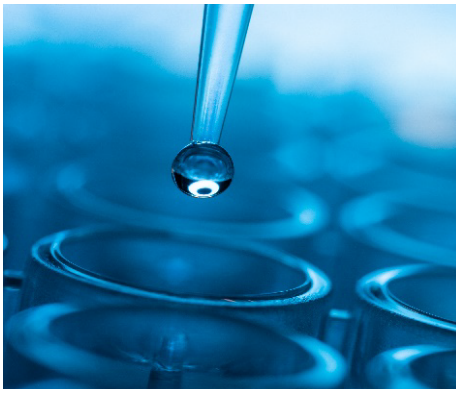
HIGH PURITY WATER BASICS

for Research Laboratories and Facilities

Authored by

Ben Gonzales, PE, CSP
President, Technical Safety Services, LLC

Scott Sturis, Ultrapure Water Specialist
Technical Safety Services, LLC



As a leading expert in high purity water systems, Technical Safety Services has the expertise to provide guidance on the selection of the proper water purification technologies to ensure that the water purification system meets all the end user's needs and complies with the applicable water standard setting organization.

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620 Hearst Avenue, Berkeley, CA 94710 | West Coast: 800.877.7742 | East Coast: 866.536.5656

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Introduction

In a typical research laboratory, researchers and engineering personnel require purified water for a wide range of applications. The quality of the water ranges from general laboratory grade, used for non-critical applications, to ultrapure water which is used for critical analytical research techniques. Pure water plays a pivotal role in almost every life science experiment, diagnostic test or chemical reaction.

However, laboratory water rarely gets the attention it deserves. Without pure water, very few experiments, tests or reactions would be possible. Thanks to its favorable chemical and physical properties, water is often considered the "universal solvent" as it dissolves more substances than any other liquid. Perhaps even more importantly, many biochemical reactions only take place within aqueous solutions. Over the years it has been Technical Safety Services experience that the end user cannot state the level of water purity needed for their research. Typically, their responses are deionized (DI) water, reverse osmosis (RO) water or facilities DI water. Laboratory and research facility personnel need to ensure the appropriate selection of purified water systems for their research laboratories and facilities.

In determining the level of water purity system that may be needed, it is critical to understand and clearly define the needs in the process for the selection of any water purification system. It is highly recommended to consult an in-house water quality expert to assist in defining the water quality required and applicable system needed. The water quality consultant has in-depth working knowledge and experience in water purification, applicable industry standards, including an understanding of water contaminants, water purification technologies, and existing water system/s within your laboratory or facility.

Industry Standards

It is essential for users to familiarize themselves with the applicable industry standards to determine the quality types. These standard-setting organizations are listed in Table 1 below. These organizations classify water purity levels as Type I, Type II, and Type III, with Type I being the purest. However, each purity level is slightly different across the different published standards. Table 2 harmonizes these standards and includes USP purified water quality levels for comparison. End users typically follow the standards closely tied to their industry. For example, hospital, medical, and clinical laboratories tend to follow CLSI or CAP standards. University researchers and industrial laboratory technicians follow ASTM.

In some cases, end users may specify a variation of the water quality standards to meet a sensitive application requirement. For example, a scientist using gas chromatography-mass spectrometry (GCMS) for trace organic analysis may require total oxidizable carbon (TOC) levels controlled lower than specified by the Type I standard. Table 3 lists the typical applications and required water purity. It is essential for users to define the required water quality at each point of use in as much detail as possible.

Table 1: *Standards setting organizations*

ASTM	American Society for Testing and Materials
CLSI	Clinical and Laboratory Standards Institute
CLSI / CAP	College of American Pathologists
ISO	International Standards Organization (ISO 3696)
USP	United States Pharmacopeia, USP28
EU	European Pharmacopeia, EU4

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Table 2: *Comparison of water purity standards vs. USP specifications*

Contaminate	Parameter (units)	Type I	Type II	Type III	USP Purified*
Ions	Resistivity (MO-cm)	> 18.0	> 1.0	> 0.05	1.0
	Silica (ppb)	<10	< 100	< 1000	NA
Organics	TOC (ppb)	< 20	< 50	< 200	< 500
Particles	Particles > 0.2 µm (number/ ml)	< 1	NA	NA	NA
Bacteria	Bacteria (cfu/ml)	< 1	< 100	< 1000	< 100
	Endotoxins (EU/ml)	< 0.001	NA	NA	NA

Increasingly, laboratories, pharmacies, and the life sciences industry are more aware of regulations such as cGMP (current good manufacturing practices) and GLP (good laboratory practices). These regulations aim at improving the quality and reliability of products processed by their respective equipment (including water purification equipment) and ensuring they are installed, maintained, calibrated, and performing correctly. In these environments, the ability to validate water purification equipment is a critical consideration.

Validation services, including IQ and OQ protocol, an outline of PQ protocol, calibrated test equipment, certificates of conformity and quality, and trained personnel, need to be available. In the selection of a purified water systems vendor, the technical and field service support capabilities should be evaluated in the selection of a high purity water system. The performance of any water purification system can be compromised due to improper installation, troubleshooting, repair, or maintenance.

Table 3: *Overview of common pure water applications and required water quality*

Water Quality Required	Operation/Application	Supply/Make-up Water
Type lll Water	**General and Non-Critical Applications** • Washing machine feed for final rinsing of glassware, heating baths, autoclaves, and other non-critical applications.	Reverse osmosis
Type ll Water	**Standard Applications** • Buffer preparation • pH solution preparation • Microbiological media preparation • Feed for clinical analyzers, washing machines, and SST autoclaves • Reagent preparation for chemical analysis or synthesis • Feed for Type l ultrapure water systems	Reverse osmosis followed by deionization – electro-DI or ion exchange
Type l Water	**Critical Applications** • HPLC mobile phase preparation • Blank preparation • Sample dilution in GC, HPLC, AA, ICP-MS & other sensitive analytical techniques • Preparation of buffers and culture media for mammalian cell cultures • Reagent preparation for molecular biology	Type I, Ultra-Pure Polishing

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About the Authors

Ben Gonzales
beng@techsafety.com

Ben A. Gonzales, PE, CSP is President of Technical Safety Services and has over 40 years' experience in Occupational and Environmental Health. Ben worked at the Lawrence Livermore National Laboratory in the Industrial Hygiene Department for 15 years before taking a position at the University of California, Berkeley as Associate Director of EH&S. He has extensive experience in the collection of environmental samples and chemical analysis.

Scott Sturis
ssturis@techsafety.com

Scott Sturis is Technical Safety Services' manager of the Ultrapure Water Systems Engineering Services program. Scott has over 20 years of professional experience in the design, validation and servicing of Type I, II and III high purity water systems and has worked for some of the major manufacturers of high purity water systems in the USA.

Summary

No matter the level of purified water that is needed for laboratory environments, it is beneficial that the user and facilities engineering personnel have a thorough understanding and working knowledge of contaminants, purification technologies, applications, and applicable industry standards. It is critical to select a vendor of purified water systems that can provide full support through the complete process, from assisting the user with the selection of the appropriate purified water system, to design, installation, commissioning, validation, and long-term maintenance. The selection of an experienced vendor and purified water consultant can help ensure that the total water purification system meets all of the end user's needs. Once a purified water system is selected and installed, it is essential that detailed validation documentation is prepared (user requirement, specifications, and total system design), and SOPs are specific to the system. However, no matter the level of water purity that is required for your respective process, it is essential to monitor water quality at critical stages throughout the system. The monitoring of the water quality on a scheduled basis helps to confirm and document that the system is functioning correctly, and final water quality is acceptable.

"For almost 50 years, our goal has always been to take the best possible care of the people who depend on us — and to meet or exceed our client's expectations. We are uniquely positioned at TSS to ensure your operation remains productive and in compliance with regulatory standards. We can assist in the selection of the appropriate purified water system, the design, installation, commissioning, validation and long-term maintenance."

— ***Ben Gonzales PE, CSP, Founder and President*** *of Technical Safety Services*