

# TOC Calibration, System Suitability, and Verification: Ensuring Accuracy and Compliance in Water Quality Analysis

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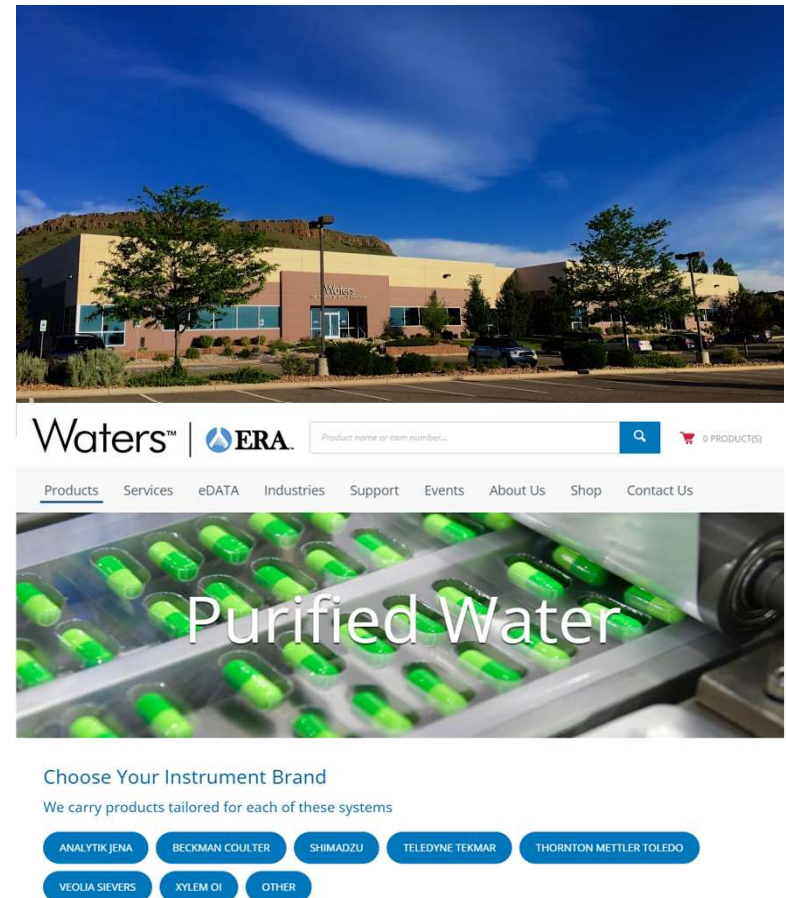
*Sr Product Marketing Manager*

# Waters ERA

## Who we are

- Founded in 1977
- Acquired by Waters Corporation in 2006
- Manufacturing in Golden, CO USA and Wexford, Ireland
- Leading environmental PT and CRM provider
  - 9,000 labs per year, over 80 countries
- Provider of Purified Water Consumables
  - TOC CRMs, turbidity, conductivity supplies
  - <https://www.eraqc.com/purifiedwater-products>

Waters™ | ERA



The screenshot displays the Waters ERA website interface. At the top, there is a navigation bar with the Waters and ERA logos, a search bar with the placeholder text "Product name or item number...", and a shopping cart icon labeled "0 PRODUCTS". Below the navigation bar, there is a main banner image showing a close-up of a water purification tray with green capsules. The text "Purified Water" is overlaid on this image. Underneath the banner, there is a section titled "Choose Your Instrument Brand" with the subtext "We carry products tailored for each of these systems". This section contains several blue buttons with white text: ANALYTIK JENA, BECKMAN COULTER, SHIMADZU, TELEDYNE TEKMAR, THORNTON METTLER TOLEDO, VEOLIA SIEVERS, XYLEM OI, and OTHER.

## TOC background

- Importance
- Compliance
- Fundamentals

## TOC calibration, system suitability, and verification

- Overview of TOC analytical control elements
- Purpose of each
- Regulatory vs quality-driven requirements
- Common challenges labs experience

# Importance of TOC

## TOC Overview

- Indirect indicator of water quality
  - Measures CO<sub>2</sub> from oxidation rather than organic carbon directly
- Non-specific
  - Does not identify individual organic compounds

## Common Uses

- Pharmaceutical-grade water
- Semiconductor manufacturing
- Drinking water monitoring
- Wastewater treatment

## Why it Matters

- High TOC can disrupt ecosystems
- Affects processes requiring ultra-clean water
- Impacts water treatment efficiency

# Compliance and industry

## FDA

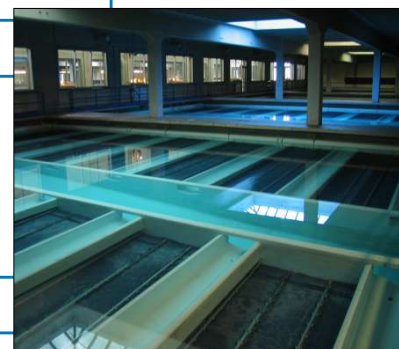
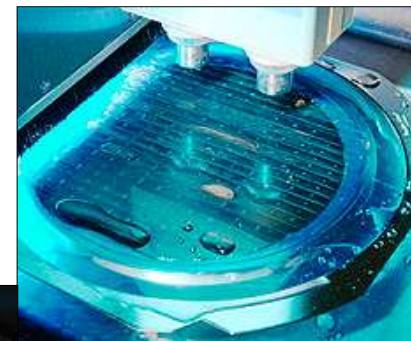
- Bottled Water
- Pharmaceutical
  - USP <643>, EP 2.2.44, JP 2.59
- Cleaning Validation

## Process Monitoring

- Semi-Conductor
- Power
- Pharmaceutical (water system)

## Wastewater and Drinking Water Compliance

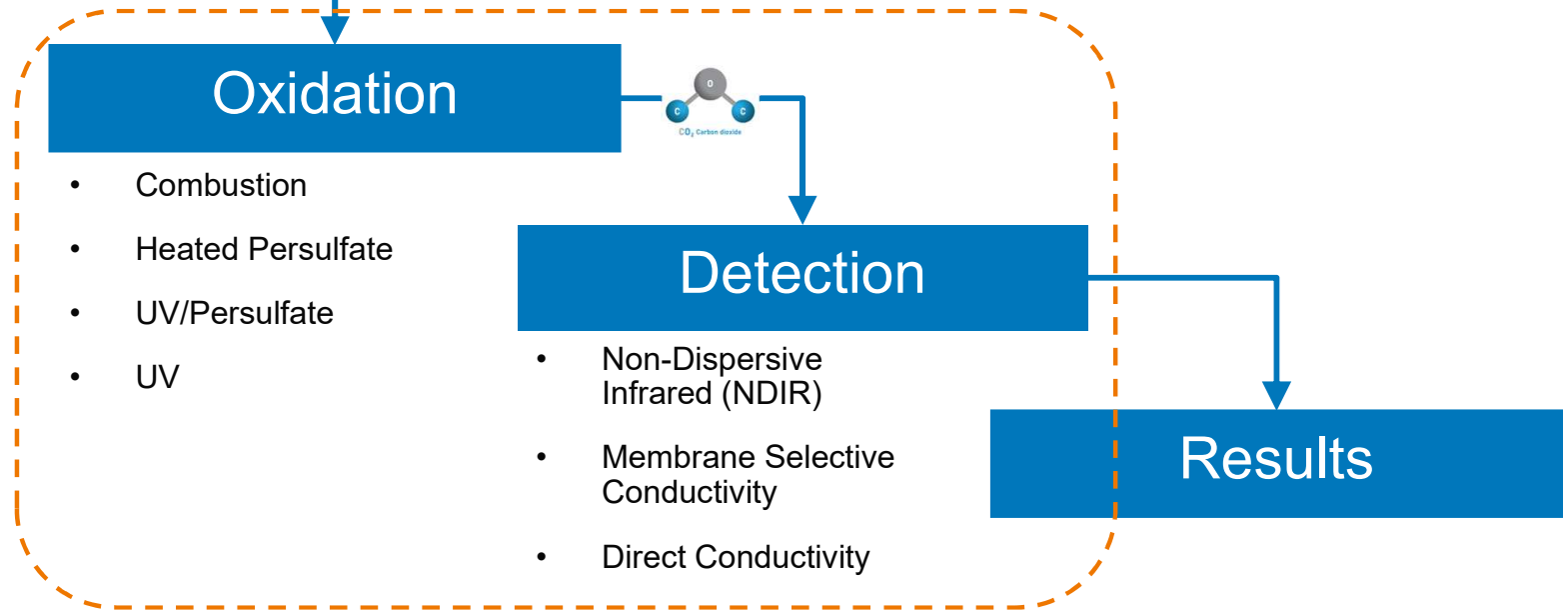
- Environmental (EPA)
  - 40 CFR Parts 141 and 142
- Safe Drinking Water Act (SDWA) – Disinfection Byproducts Rule



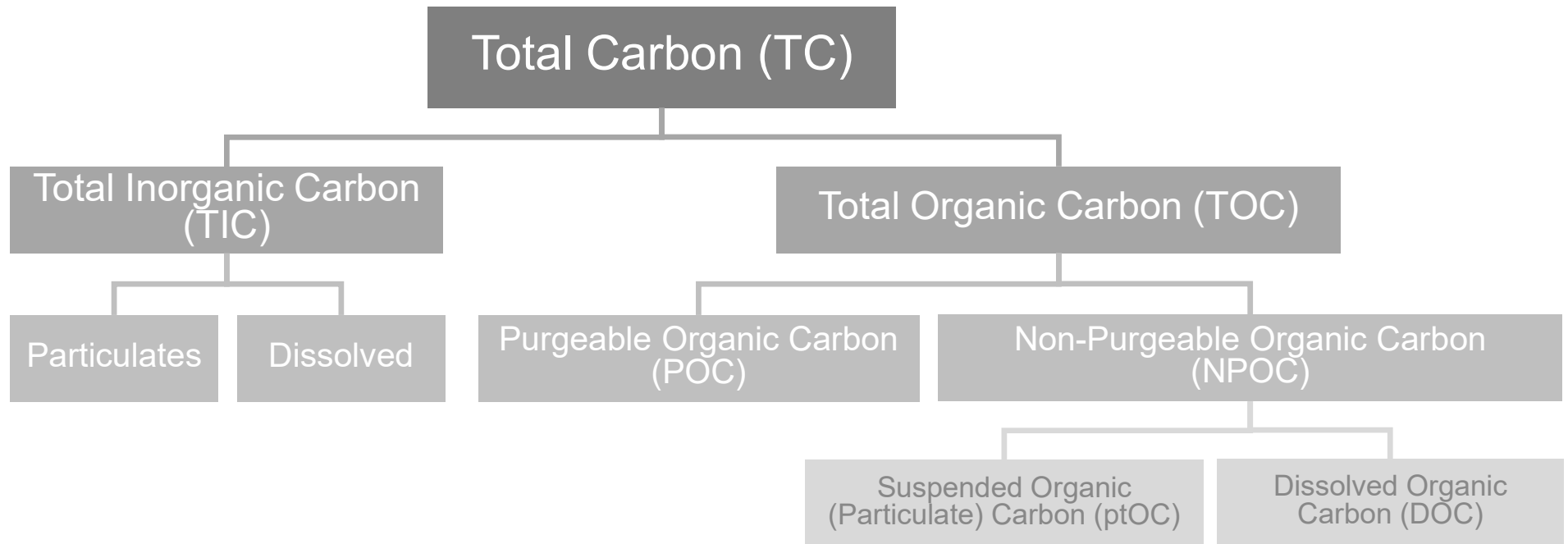
# Fundamentals of TOC analysis

## Sample Introduction

- Autosampler
- Vials/Bottles
- On-Line



# Fundamentals of TOC analysis



# Purpose and role of TOC calibration, system suitability, and verification

## Calibration in TOC Testing

Calibration links instrument signal to known TOC concentrations, ensuring accurate numeric results and traceability

## Verification for Accuracy

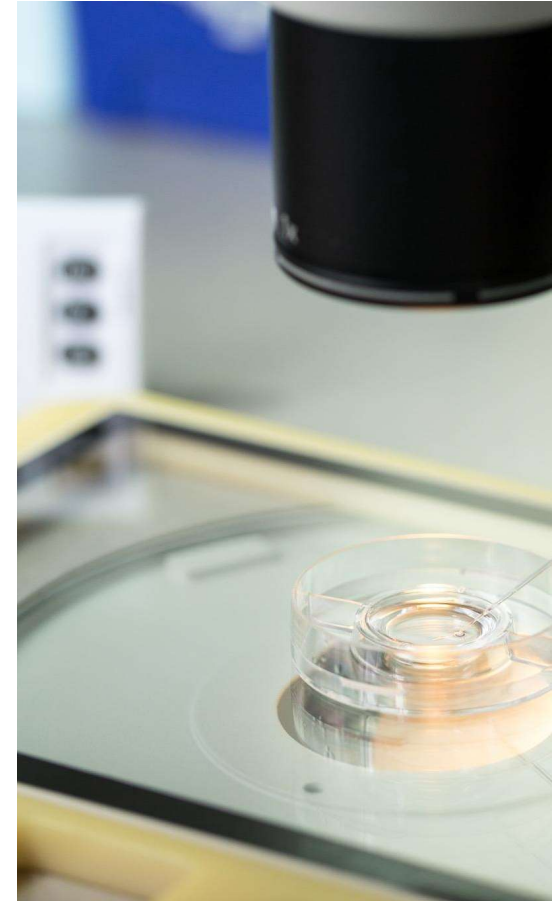
Verification independently confirms calibration validity over time by checking recovery with different standards.

## System Suitability Testing

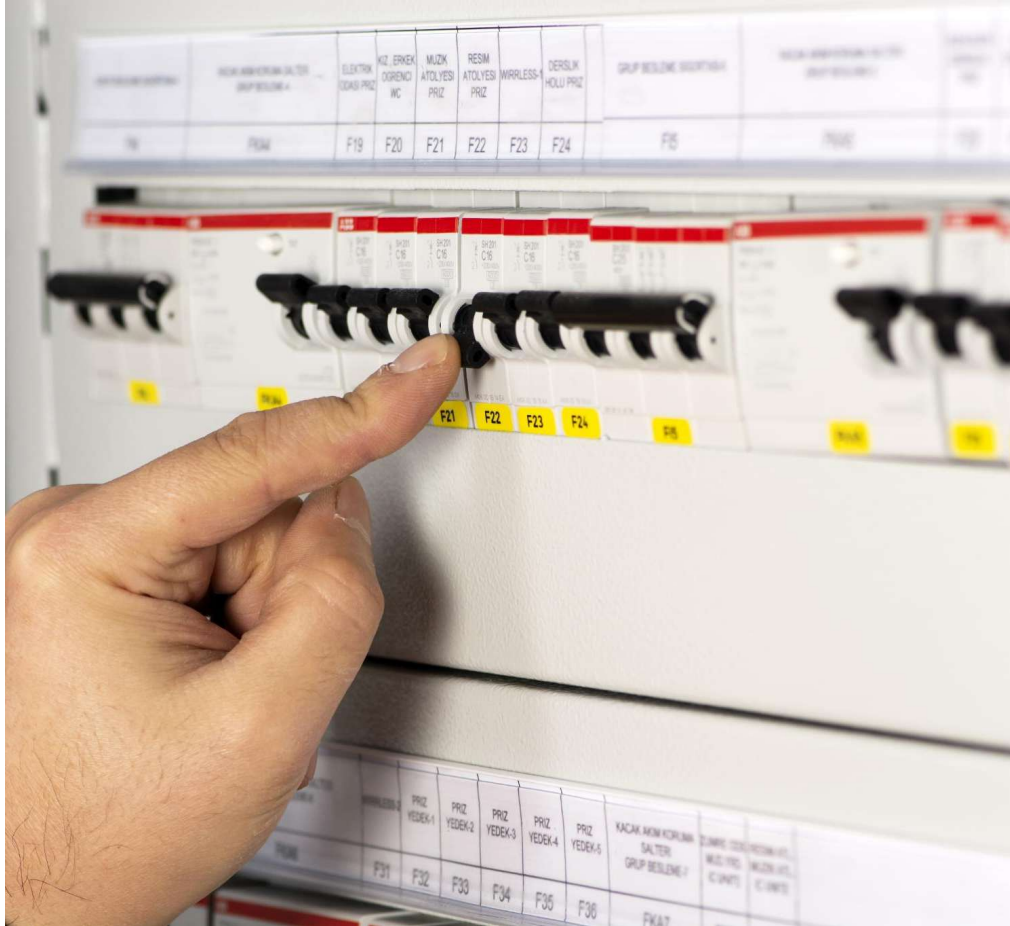
System suitability ensures the analyzer can oxidize both simple and complex organics, meeting regulatory requirements.

## Layered Assurance Model

Calibration, verification, and system suitability collectively ensure accuracy, stability, and regulatory fitness.



# Calibration frequency, standards, and acceptance criteria



## Calibration Frequency Guidelines

Calibration frequency depends on manufacturer recommendations, usage, and quality system needs, often annually or more.

## Calibration Standards Selection

Calibration standards vary by instrument type, with sucrose and potassium hydrogen phthalate (KHP) commonly used compounds.

## Acceptance Criteria and Verification

Calibration acceptance relies on software criteria like correlation coefficients and independent standard verification.

## Common Calibration Errors

Errors often arise from compromised standards, improper storage, and operator errors.

# Regulatory requirements and interpretation of system suitability results

## Purpose of System Suitability Test

Ensures TOC analyzer oxidizes a range of compounds to confirm balanced oxidation performance within regulatory limits.

## Interpretation of Results

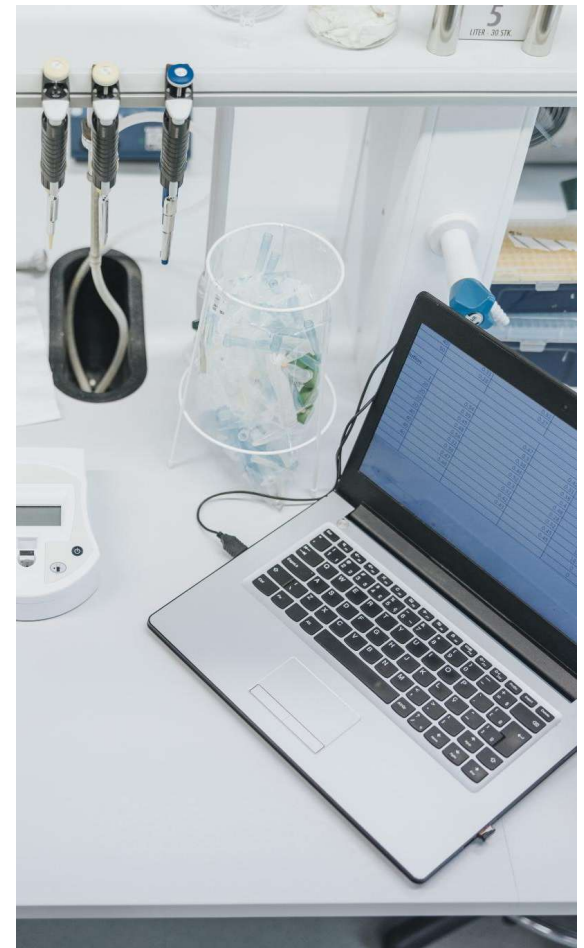
System suitability is assessed as a collective result; failure indicates overall oxidation issues, not just individual compounds.

## Common Causes of Failure

Failures often stem from reagent degradation, UV lamp intensity issues, or improper sample storage conditions.

## Global Regulatory Differences

Different pharmacopeias require different compounds for testing, necessitating global compliance awareness.



## Verification strategies, documentation, and trending



### Verification Testing Importance

Verification testing ensures TOC analyzers remain accurate between calibrations, enhancing quality system robustness.

### Independent Verification Standards

Using independent standards from different suppliers or preparation methods increases verification reliability and validity.

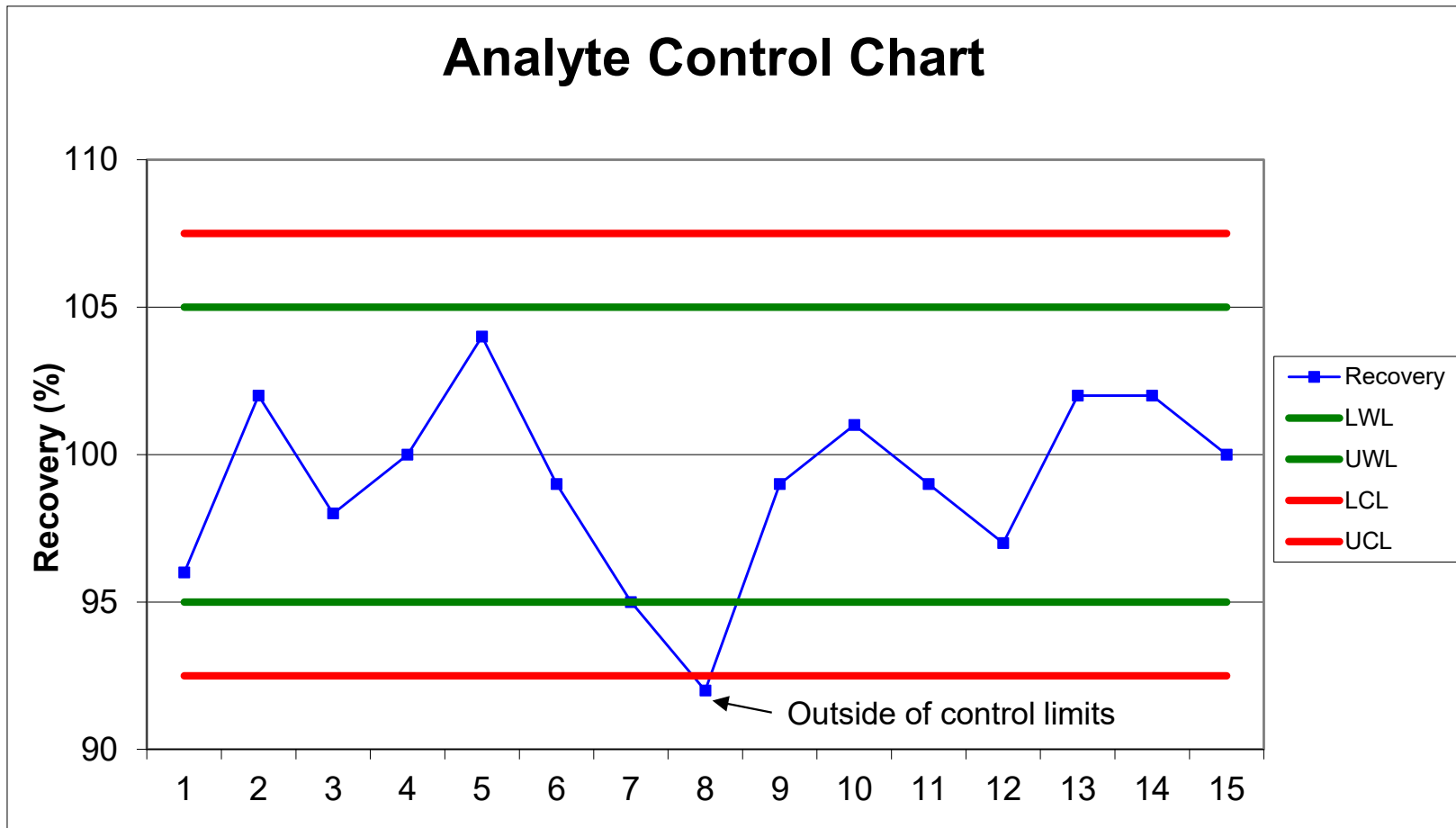
### Documentation and Audit Readiness

Comprehensive, traceable documentation of verification results supports audit readiness and quality compliance.

### Control Chart Trending

Control charts enable monitoring of verification trends to detect bias or drift before specification failures occur.

# Ongoing performance



## Effective Troubleshooting

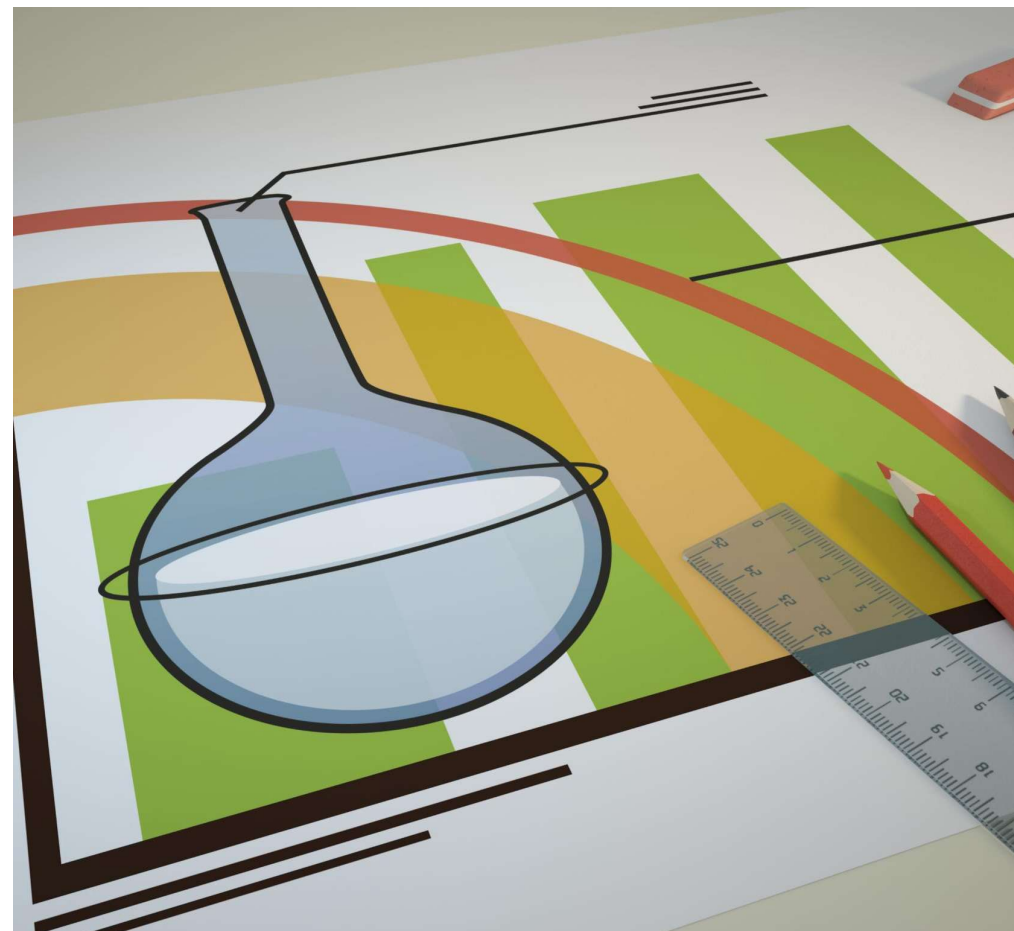
Identify failure modes by prioritizing checks based on sudden or gradual changes in TOC results to avoid unnecessary recalibrations.

## Routine Maintenance Importance

Regular upkeep varies by analyzer type and prevents unexpected failures by replacing worn components and maintaining key parts.

## Performance Monitoring

Use control charting programs to track verification recovery and baseline stability for early detection of performance degradation.



## Summary



TOC is essential for water quality in regulated and high-purity systems



Fundamentals + oxidation + detection = foundation of accurate measurement



Calibration, system suitability, and verification ensure accuracy and compliance



Quality consumables/CRMs support consistent performance across instruments



Trending, maintenance, and troubleshooting sustain long-term reliability



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THANK YOU!