



# Compliance Guide: Computrac® Vapor Pro XL, VPXL

## Introduction

The Computrac® VPXL is engineered to meet the highest standards of regulatory compliance for moisture analysis in laboratory and production environments. This guide outlines how VPXL supports compliance with key regulations, including **21 CFR Part 11**, **ASTM standards**, and **environmental health and safety protocols**.

## Regulatory Standards Supported

- **21 CFR Part 11:** Secure electronic data storage, audit trails, and user login ensure data integrity and traceability. Every action, result, and calibration is logged for full traceability. Password-protected access, user-level permissions, and encrypted data storage safeguard your data.
- **ASTM Standards:** Accepted by numerous ASTM methods for moisture analysis, ensuring results are recognized and trusted across industries. Manual calibration using **NIST-traceable capillary tubes** meets ASTM and ISO requirements for accuracy and repeatability.

## Data Integrity & Management

- **Secure Data Storage:** Store up to **250 test programs**, **1,000 results**, and **100 graphs** for complete traceability.
- **Report Generation:** Easily print reports for audits and regulatory submissions.
- **Remote Monitoring:** Optional **VPXL Connect Web Server** enables remote access, report downloads, and method transfer between instruments. (Note: This feature does not meet 21 CFR Part 11 compliance requirements.)

## Instrument Validation

- **IQ/OQ/PQ Packages:** Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) packages are available to document and validate instrument performance.
- **Temperature Calibration Kit:** Ensures accurate temperature control and documentation for regulatory audits.
- **Technology Transfer Package:** Expert-led implementation and validation protocols for seamless transition from Karl Fischer or other methods.

AMETEK Brookfield  
11 Commerce Blvd. Middleboro, MA 02346 USA  
1-508-946-6200 or 1-800-628-8139 | [www.brookfieldengineering.com](http://www.brookfieldengineering.com)



## Environmental, Health & Safety Compliance

- **Chemical-Free Operation:** Eliminates hazardous reagents, reducing regulatory burdens for chemical handling, storage, and disposal.
- **Safer for Operators:** Minimizes exposure risks and the need for specialized safety equipment.
- **Eco-Friendly:** Supports compliance with environmental regulations by reducing hazardous waste generation.

## Compliance Documentation & Support

- **Comprehensive Documentation:** VPXL provides detailed user manuals, validation protocols, and compliance certificates.
- **Audit Support:** Dedicated support team available to assist with audits, inspections, and regulatory submissions.
- **Continuous Updates:** VPXL software and documentation are regularly updated to reflect the latest regulatory requirements.

## Best Practices for Maintaining Compliance

- Perform regular calibration with **NIST-traceable standards** and document calibration events.
- Ensure all operators are trained on VPXL's compliance features and data management protocols.
- Conduct IQ/OQ/PQ at installation and after major updates or repairs.
- Regularly back up electronic records and audit logs

## Summary

The Computrac® VPXL is designed to **simplify and strengthen your lab's compliance** with regulatory standards. With robust data integrity, secure reporting, and chemical-free operation, VPXL helps you meet the demands of **21 CFR Part 11, ASTM, and environmental health and safety regulations** – while delivering world-class analytical performance.

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