THE RS REVIEW

2025 Q3 | THE TOTAL SOLUTIONS PROVIDER FOR REGULATED ENVIRONMENTS

EQUIPPED FOR TODAY, READY FOR TOMORROW

As the needs of regulated environments grow more complex, staying prepared is not just a best practice, it is a necessity. At Rees, we continually work to support your operations with services and insights that meet today's standards while anticipating what's next.

This quarter, we've doubled down on the areas that matter most to our customers: compliance readiness, audit preparation, ISO-accredited calibration, and enhanced validation services. Whether it's understanding what 21 CFR Part 11 means for your facility, staying ahead of new inspection protocols, or making sure your systems are always performing at their best, our team is here to help you operate with confidence.

We're also sharing new resources, from blog content to checklists, to make sure you have the tools and information you need right at your fingertips. And with more customers joining the Rees community each quarter, we remain committed to delivering support that's not only reliable but personalized to your environment.

As always, thank you for the trust you place in us. We're proud to be your partner in maintaining compliance, protecting your operations, and planning for what's next.

THE RS BLOG

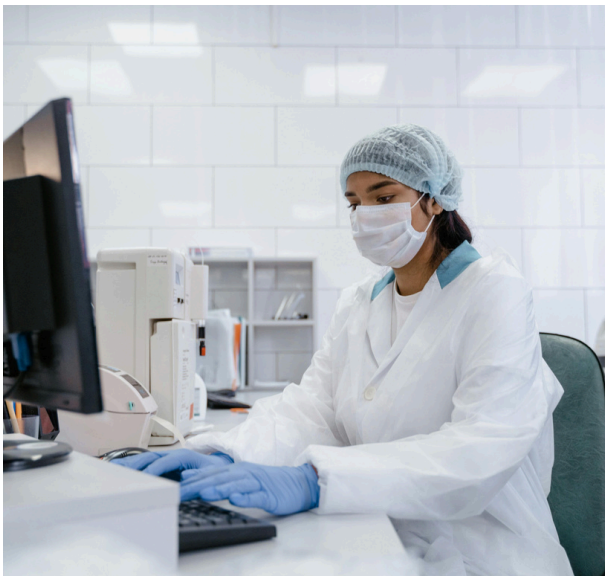
Our blog consists of a variety of topics related to our industry, our products, and our customers. Visit our website and check out our latest posts today!

New Blog Posts:

- 21 CFR Part 11 in Life Sciences: Core Requirements and Industry Best Practices
- Why ISO/IEC 17025 Accreditation Matters in Today's Regulated Industries
- Seasonal Mapping: Why It Matters for Compliance and Quality
- ISO Compliance: The Role of Calibration & Validation in Quality Assurance
- Choosing a Temperature Probe: What Regulated Facilities Need to Know
- Building Automation Systems vs. Environmental Monitoring Systems: Understanding the Difference and Why it Matters
- EMS Readiness for CAP and TJC Inspections: 14-Day Prep Checklist

LET'S GO

ENSURING COMPLIANCE WITH 21 CFR PART 11: WHY IT MATTERS AND HOW REES CAN HELP



In today's digital life sciences landscape, regulatory compliance isn't just a box to check. It's the foundation for trust, product quality, and operational integrity. One of the most critical regulations for organizations operating in FDA-regulated environments is 21 CFR Part 11, which governs how electronic records and signatures are used. At Rees, we're committed to helping our customers stay ahead of these requirements with solutions built for compliance.

What Is 21 CFR Part 11?

This regulation from the U.S. FDA ensures that electronic records are just as trustworthy and legally binding as traditional paper documents. It's applicable to pharmaceutical manufacturers, biotechnology firms, medical device companies, research labs, and any organization that handles data tied to FDA regulations.

Key Requirements Simplified

Staying compliant means your systems must include:

- **Secure Electronic Signatures:** Tied to individual users, with multiple authentication factors.
- **Comprehensive Audit Trails:** Automatically record who did what, when, and why, with no room for tampering.
- **Access Controls:** Limit system functions based on user roles and enforce strict password protocols.
- **Validated Systems:** Software must be proven to work as intended, with documented testing and approvals.
- **Reliable Record Retention:** Ensure data is readable, secure, and retrievable for the full retention period.

How Industry Leaders Stay Compliant

Across the life sciences sector, leading organizations follow best practices like:

- **Risk-Based Planning:** Focus on validating systems that impact product quality.
- **Defined SOPs:** Standard operating procedures for user access, backup, and system use.
- **Tailored Training:** Make sure every user understands their role and responsibilities.
- **Routine Audits:** Catch potential gaps before inspections do.
- **Cross-Team Collaboration:** Quality and IT must be aligned from the start of any system deployment.

A Real-World Scenario with Rees

Consider this scene: A pharma company using the Rees Monitoring System experiences a temperature spike in a critical storage unit. The system triggers an alert in real time. An authorized user responds, documents the event, and signs off electronically.

During an FDA inspection, the quality team instantly retrieves the full audit trail: when the issue occurred, who acted, and how it was resolved, all supported by secure, traceable electronic records. The result? A smooth inspection, zero findings related to data integrity, and peace of mind for the team.

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ENSURING COMPLIANCE WITH 21 CFR PART 11: WHY IT MATTERS AND HOW REES CAN HELP

Rees Monitoring Solutions: Built for Compliance

Our monitoring systems are fully aligned with 21 CFR Part 11 standards. Whether you're building out a new facility or upgrading legacy systems, Rees provides:

- Secure and traceable electronic records
- Robust audit trail functionality
- Validation support and documentation
- Role-based access and system security

Ready to Evaluate Your Compliance?

Whether you're preparing for an inspection or simply want to enhance your digital readiness, our experts are here to help. Request an assessment to see how your current system measures up and how Rees can help you stay future-ready.

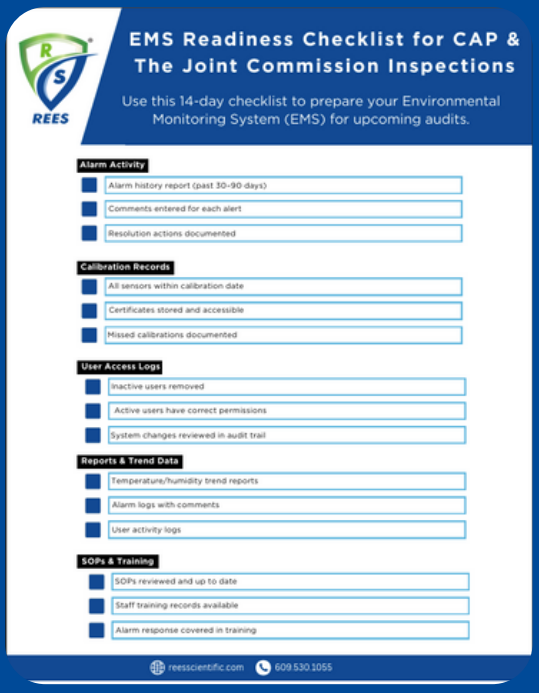
EMS Readiness for CAP and TJC Inspections: 14-Day Prep Checklist

Our latest blog highlights a key update, effective June 4, 2025, TJC accredited hospitals now receive 14 days' notice before routine inspections from the College of American Pathologists (CAP) or The Joint Commission (TJC). While helpful, this short window means your Environmental Monitoring System (EMS) should be inspection-ready at all times.

The blog's 7-step EMS checklist includes:

1. Review alarm activity and responses
2. Audit sensor calibrations
3. Verify user access and activity logs
4. Confirm equipment naming and tagging
5. Prep reports in advance
6. Update SOPs and training records
7. Validation Documentation

It also answers FAQs on record timeframes, EMS validation, handling noncompliance, and using digital vs. printed reports. The message is clear, make EMS readiness a daily practice so you're always prepared when the 14-day clock starts.



WELCOME TO THE REES COMMUNITY

Rees is proud to have partnered with both new and recently expanded customers in 2025 Q2, we look forward to supporting you!

American Red Cross
Columbia, SC

American Red Cross
Douglasville, GA

Alphazyme

Noxy Health Products

AdiraMedica

astoriom

Beth Israel Lahey Health Pharmacy
Burlington, MA

BioRepository Resources

Narcotics Analysis

Cleveland Clinic
Coral Springs, FL

eurofins
Burlingame, CA

Harbor-UCLA Medical Center
Torrance, CA

NIH
Bldg. #10 - SRLM

UAB Microbiome Center
The University of Alabama at Birmingham

Massachusetts Institute of Technology

NOAA Fisheries

Northwestern University
Transplant Immunology Lab

Northwestern Medicine
Central DuPage Hospital Lab

Texas A&M Health Science Center
Institute of Biosciences

University of Wyoming
Veterinary Lab

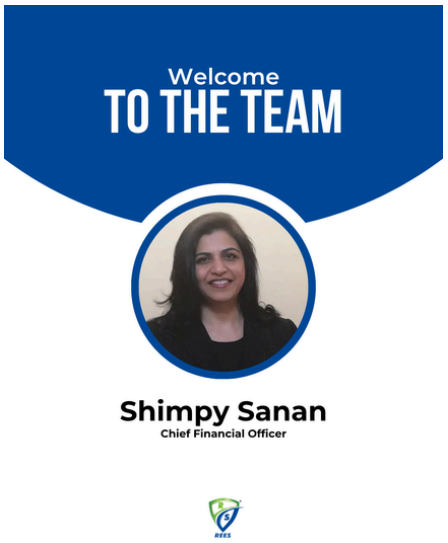
SteriTek

abbvie
North Chicago, IL

NYC Health+ Hospitals
NYC Public Health Lab

WELCOME SHIMPY

We're thrilled to welcome Shimpy Sanan as our new Chief Financial Officer! With over 25 years of financial leadership experience, Shimpy has held senior roles at leading global companies including AmSpec, Hess Corporation, Google/DoubleClick, and MediaMind. She has successfully led strategic financial transformations, implemented enterprise systems, and improved operational efficiency across multiple international markets.



Shimpy's areas of expertise include Consolidations and Reporting, GAAP Compliance, Global Taxation, Budgeting and Forecasting, Cash Flow Management, M&A, and Debt Restructuring. She also brings hands-on experience with financial platforms like Hyperion, SAP, Oracle NetSuite, and Microsoft X3, strengthening financial reporting and regulatory compliance.

She holds an MBA from Columbia University, a BBA in Accounting from the Zicklin School of Business, and a BS in Finance from Delhi University. At Rees Scientific, Shimpy oversees accounting, financial strategy, and HR operations, driving growth and internal excellence. Please join us in warmly welcoming her to the Rees Team!

ENSURING QUALITY: HOW CALIBRATION AND VALIDATION DRIVE ISO COMPLIANCE

Calibration and validation are essential pillars of ISO compliance, ensuring the accuracy and reliability of data in laboratories, biotech companies, and regulated manufacturing environments. Calibration verifies that instruments such as temperature or humidity sensors are delivering precise measurements, while validation confirms that systems perform as intended and consistently meet regulatory requirements.

Together, they build trust in your monitoring results, support product quality, and help meet standards like ISO 17025, ISO 9001, and 21 CFR Part 11.
These processes not only strengthen data integrity but also improve audit readiness, enhance operational efficiency, and support market access by demonstrating compliance to partners and regulators.

At Rees Scientific, we offer ISO 17025-accredited calibration services and comprehensive validation protocols tailored to meet both ISO and FDA requirements. Our systems include secure audit trails, access controls, and electronic signature verification to ensure full traceability and accountability.

Whether you're managing an upgrade, preparing for an audit, or strengthening your quality system, our expert team is here to help. Let Rees support your compliance journey with services that reinforce the safety, quality, and performance of your operations.

Read our full blog post, ISO Compliance: The Role of Calibration & Validation in Quality Assurance to how calibration and validation help ensure ISO compliance and reliable system performance.

Ready for the summer heat?

Prepare Your Facility for Summer with Rees Precision Temperature Mapping

LEARN MORE

SOCIAL MEDIA MOMENT

KEY DATES

Sept 29 - Oct 1
Health Connect Partners
Chicago, IL

Oct 1
ISPE
Boston, MA

Oct 12-15
AATB
Atlanta, GA

Oct 26-29
AABB
Charlotte, NC

Resources

Check out the latest Rees guides & case studies

Visit the Resources section of our website to download industry guides, case studies and more!


CASE STUDY

REES

MONITORING SUCCESS: DUKE UNIVERSITY'S EVOLVING PARTNERSHIP WITH REES SCIENTIFIC

A LONG-STANDING PARTNERSHIP

For nearly two decades, Rees Scientific has been a trusted partner of Duke University, supporting departments like the Cord Blood Bank, stem cell research, and cancer research. This long-standing relationship highlights our commitment to delivering reliable, innovative monitoring solutions tailored to each department's unique needs.

In September 2024, the Duke Human Vaccine Institute (DHVI) joined the Rees family, further expanding our presence within Duke University and marking the start of a highly collaborative, dynamic partnership.

CLIENT PROFILE

Client: Duke University
Location: Research Triangle Park (RTP), North Carolina
Industry: Academic Research and Vaccine Development
Departments Served: Cord Blood Bank, Stem Cell Research, Cancer Research, Duke Human Vaccine Institute (DHVI)
Solutions Utilized:

- Environmental Monitoring System (EMS)
- Wireless, hardwired, and hybrid sensor configurations
- Custom PLC design and system integration
- Comprehensive calibration, preventative maintenance, and ongoing technical support
- Customer Since: Early 2000s; Duke Human Vaccine Institute since 2024

INITIAL ENGAGEMENT: A CUSTOM MONITORING SYSTEM

Duke University's initial investment was a testament to the scale and complexity of their research environment. They deployed a 270-input hybrid system that included:

- Wireless Sensors: Covering temperature, humidity, CO_2, power monitoring, and water detection, supporting both room and CTU (Critical Temperature Units) monitoring, as well as life-safety systems for process-gas storage.
- Hardwired Differential Pressure: A high-speed, reliable solution that's among the best in the industry for data transmission and accuracy.

www.reesscientific.com Page 1

JOIN THE REES TEAM

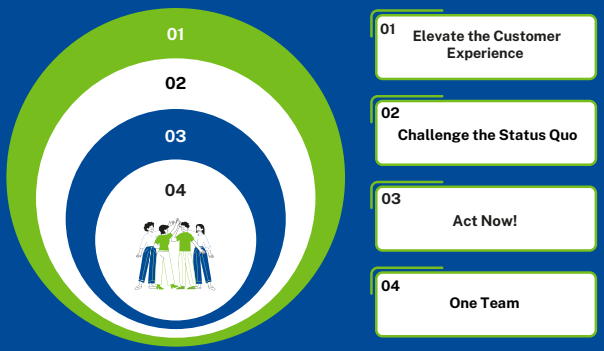
Want to be a part of the Rees team? Visit our website to submit your resume for one of our open positions. We look forward to working with you!

- Field Service Technician II
- Area Sales Representative

JOIN US

OUR MISSION

THE Total Solutions Provider for Regulated Monitoring



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