



# OPTIMIZING LABORATORY OPERATIONS THROUGH THE USE OF METHOD, REGULATORY, AND STANDARD FLEXIBILITY

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**Flexibility when applied correctly can optimize operations without compromising quality or compliance.**

## Common Challenges In Environmental Labs

Rigid processes causing inefficiencies

Misinterpretation of regulatory and standard constraints

Fear of audits/assessments leading to overly burdensome procedures

## AGENDA

# DISCUSSION POINTS:

1. Understanding Flexibility in Context
2. Method Flexibility: Unlocking Efficiency in Procedures
3. Regulatory Flexibility: Navigating the Gray Areas
4. Standard Flexibility: Making the TNI Standard Work for You
5. Putting it all Together: The Optimization Roadmap
6. Guardrails: Staying Compliant and Defensible
7. Key Takeaways and Call to Action



# What is “flexibility” in the lab?

## Method Flexibility

- Allowed adjustments that do not affect data quality or regulatory acceptability

## Regulatory Flexibility

- Intentional allowances for alternative approaches within federal/state rules

## Standard Flexibility

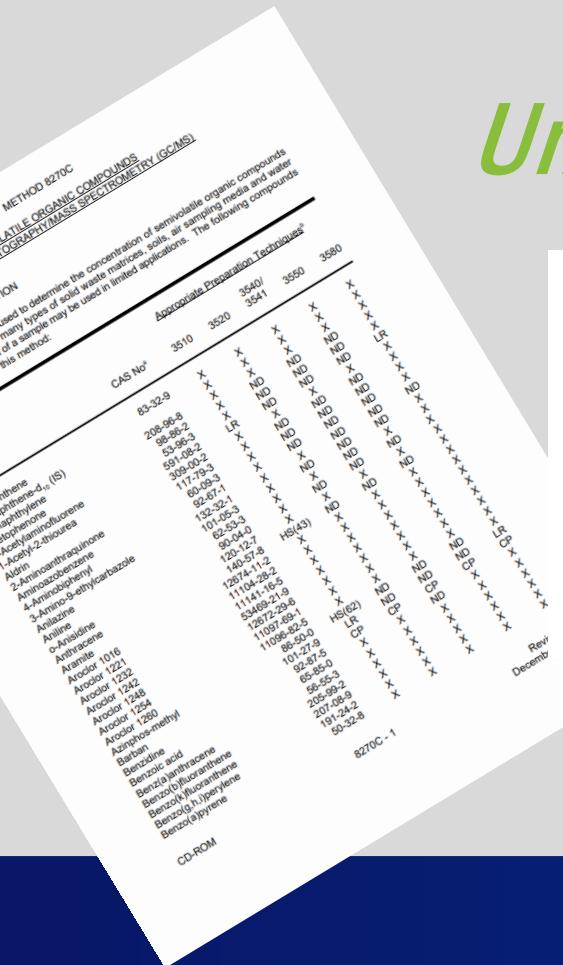
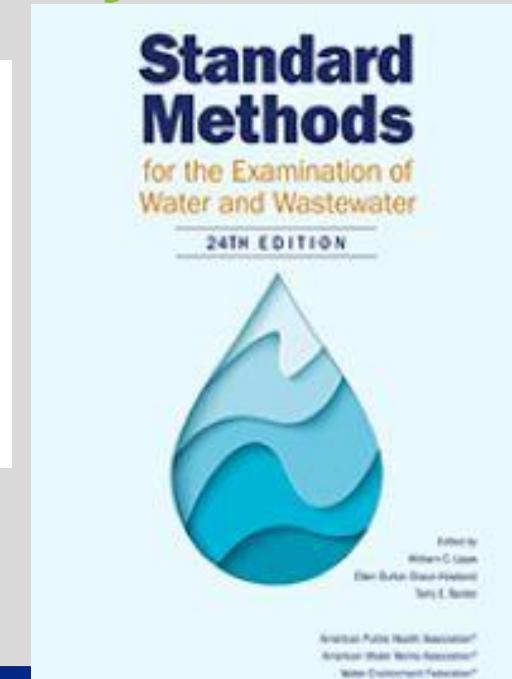
- TNI or similar standards written to cover diverse lab setups

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## Method Flexibility: Unlocking Efficiency in Procedures

# Method Flexibility:

## *Unlocking Efficiency in Procedures*





### **Allowed Flexibility**

- Permitted within Method/regulatory intent
- Supported by performance based language
- Changes are documented, validated, and defensible
- Maintains or improves precision, accuracy, detection limits

### **Allowed Flexibility** vs. **Prohibited Deviations**

### **Prohibited Deviations**

- Not allowed under method, regulation or standard language
- Alters core chemistry or analytical procedures
- No supporting validation or justification
- Jeopardizes data quality, traceability or defensibility





### ***Allowed Flexibility***

Substituting Equivalent Reagents

Shortening purge/extraction time with supporting data

Reduced Volume(s)

Updating instrument or adding automation

## Examples



### ***Prohibited Deviations***

Skipping required QC

Modifying HT or preservation

Changes to method defined parameters

Changes in detection technology where specified

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## Method Flexibility: Unlocking Efficiency in Procedures

### EPA 350.1(Ammonia, Automated Phenate Method)

Aspect of Method	Allowed Flexibility	Example Modification	Required Justification/Validation	Operational Benefit
Sample Preservation & Holding Time	Sample preservation method may vary if equivalent results are demonstrated	Using acidified sample vials prepped in advance vs. adding acid at receipt	Demonstrate equivalency of preservation effectiveness	Saves analyst time during sample receipt
Reagents & Standards	Reagents may be prepared in different volumes or stabilized forms if equivalent	Preparing larger batches of phenate reagent with extended shelf life	Show reagent stability over the new timeframe	Reduces reagent prep frequency, lowers workload
Instrument Configuration	Automated analyzers may be substituted if they meet required detection limits	Switching from a segmented flow analyzer to a discrete analyzer	Document calibration, MDL, LCS recovery comparability	Allows newer technology with less maintenance
Calibration Frequency	Daily calibration not always required if continuing calibration verification (CCV) meets criteria	Using a weekly calibration with daily CCVs instead of full recalibration	Demonstrate stability of calibration curve	Reduces daily setup time, fewer standards used
QC Acceptance Criteria	Method allows performance-based QC within specified limits	Adjusting matrix spike recovery range based on historical performance data	Statistical justification with historical QC data	Avoids unnecessary rework of compliant samples
Detection Limit Study	Method allows lab-specific MDL determination	Performing MDL studies using site-specific matrices	Documentation of MDL study procedure & results	More realistic MDL for your lab's workflow
Glassware & Sample Prep	Substitution of equivalent containers acceptable	Using disposable polypropylene tubes instead of glass	Show no adsorption or contamination difference	Saves time on washing glassware, reduces breakage
Data Processing & Reporting	Alternative software acceptable if it meets audit requirements	Using LIMS-integrated calculations instead of manual spreadsheets	Show validation of software calculations	Reduces transcription errors, improves efficiency

# Regulatory Flexibility:

## *Navigating the Gray Areas*

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## Regulatory Flexibility: Navigating the Gray Areas



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## Regulatory Flexibility: Navigating the Gray Areas

Regulation	Applies To	Where Flexibility Exists	Examples of Flexibility	Non-Negotiable Areas
40 CFR Part 136	Clean Water Act (wastewater, NPDES)	Alternate Test Procedures (ATPs); performance-based method modifications called out in 40CFR	Use of modified digestion techniques for metals if validated; alternate calibration curve model	Holding times for VOCs; omission of required QC (blanks, LCS, MDL); preservation requirements
40 CFR Part 141	Safe Drinking Water Act (drinking water compliance)	Minor modifications allowed if equivalent performance is demonstrated and approved by the state or EPA	Switching to more sensitive detectors; changing sample volumes for low-concentration analytes (with approval)	MCLs; approved methods list; reporting outside calibration range
40 CFR Part 260–265 (RCRA)	Hazardous waste analysis	Broad flexibility via SW-846 Performance-Based Measurement System (PBMS)	Substituting instruments; adjusting purge parameters in VOCs; non-standard surrogates	Failure to meet QC objectives (e.g., surrogate recovery); reporting unvalidated data

### Validate the Change

Calibration Curve

MDLs

RLs

Sample comparisons

### Document and Communicate

Certifying Body or Regulator

SOPs

Method Validation Packet

Train Staff

### Operational Benefits

Increase Efficiency

Reduced Cost

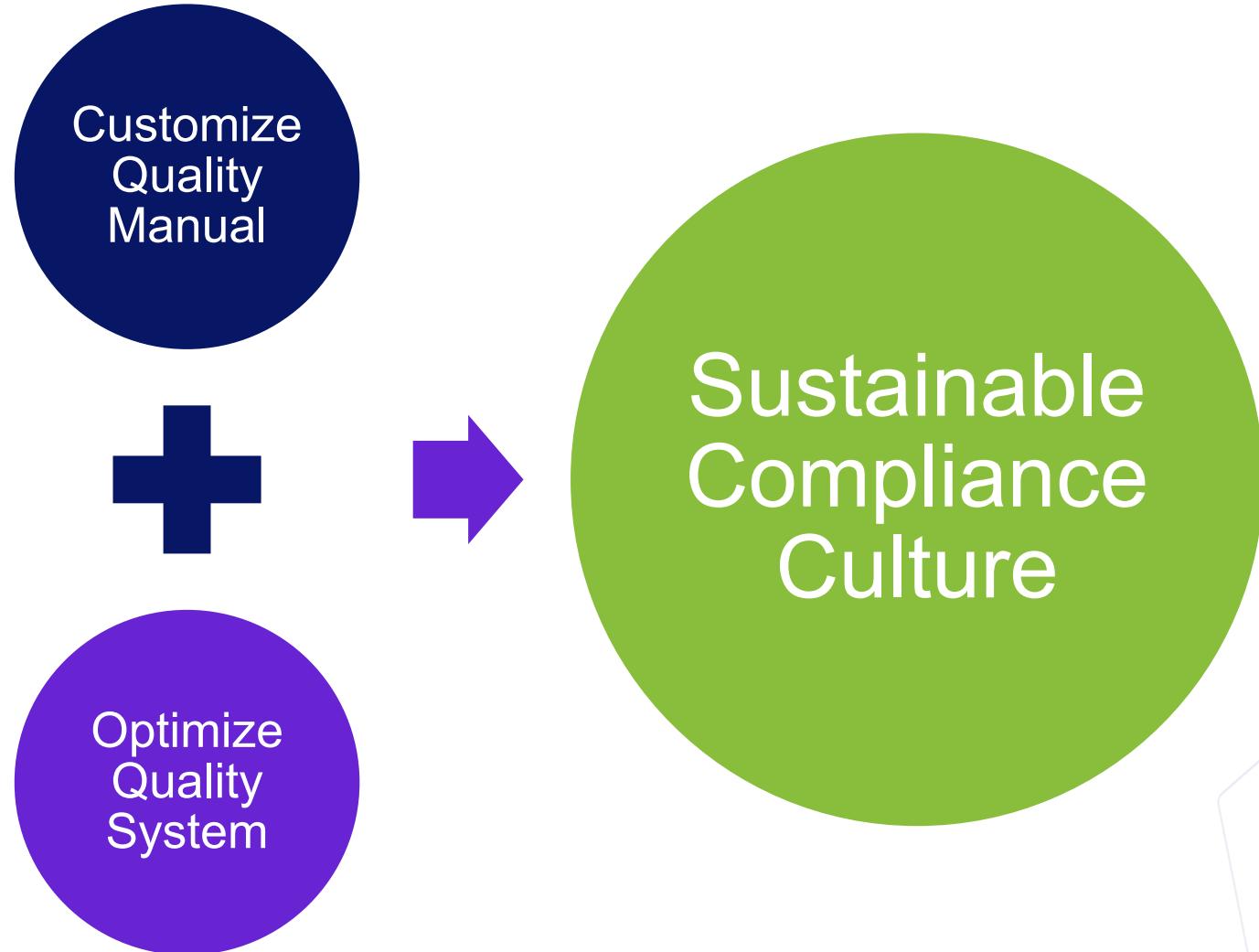
Increased Cross Training

## Standard Flexibility:

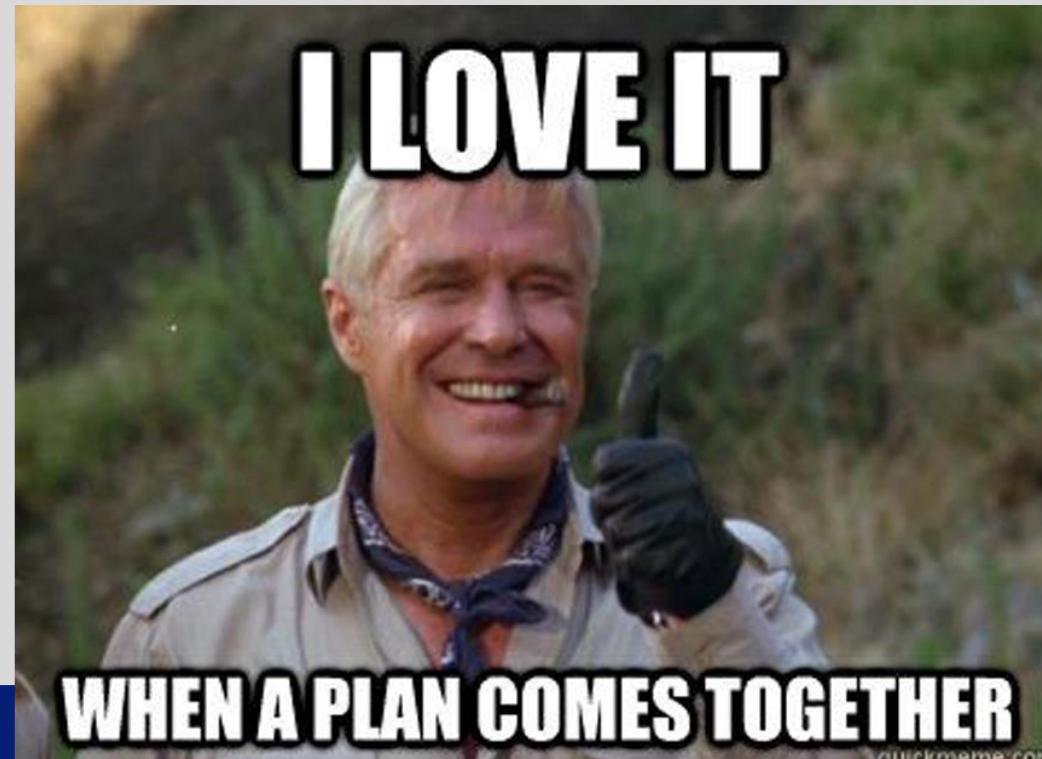
*Making the TNI Standard work for you*

“the TNI Standard is not designed to tell you HOW you must do something. It is designed to tell you WHAT you must do.”



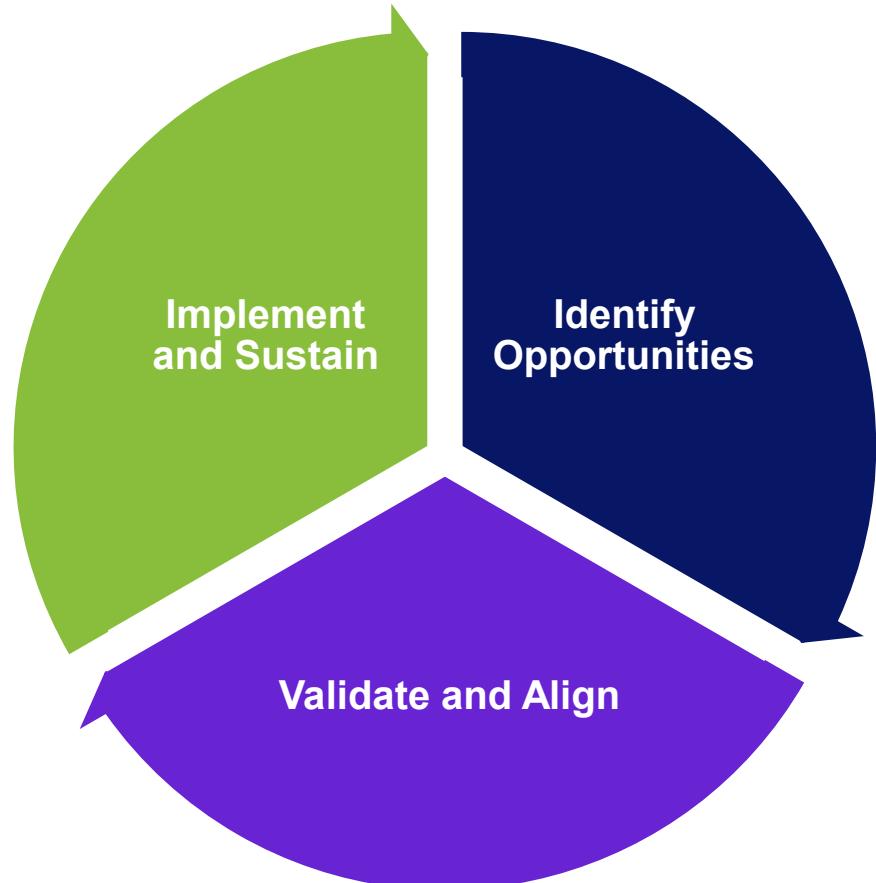


## Putting it All Together: *The Optimization Roadmap*



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## Putting it All Together: The Optimization Roadmap



### Identify Flexibility Opportunities

- Map current workflows and expose pain points
- Review methods and CFRs for allowed optimizations
- Prioritize based on risk, impact and defensibility

### Integrate Flexibility Across the Lab

- Engage QA, Technical Staff and Operations early in the process
- Validate all changes with side-by-side comparisons
- Update SOPs and train all impacted staff

RVT

Triple Quad

EZ Herb

Wet Chem  
Automation

Metals  
Digestions

## Guard Rails:

*Staying Compliant and Defensible*

Flexibility



Cutting  
Corners



## Always maintain defensibility through:

Review of  
Methods,  
Regulations,  
Standards

Validation of  
Changes

Proper  
Documentation

Management  
Approval

Regulator  
Engagement

Auditable proof of method equivalency and quality impact

### Key Takeaways

Flexibility exists in methods, regulations, and standards  
– *if you understand them deeply*

*Smart use of flexibility leads to optimized workflows, reduced burden, and higher productivity*

Always balance efficiency with defensibility

### Call to Action

Re-examine your lab processes through the lens of “Is this required? Or just what we have always done?”



# THANK YOU

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