

The background of the slide is a light gray gradient with several realistic water droplets of various sizes scattered across it. The droplets have highlights and shadows, giving them a three-dimensional appearance. The text is centered on the slide.

STATE AGENCY PARTNER RECOMMENDATIONS FOR LABORATORY ACCREDITATION STANDARDS

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REGULATORY AGENCY PARTNERS

- State Water Resources Control Board
- Department of Toxic Substances Control
- Department of Pesticides Regulation
- Department of Public Health
- Department of Fish and Wildlife
- Federal Food and Drug Administration
- Regional Water Quality Control Boards

STATE REGULATORY AGENCY PARTNERS (SAP)

- **ELAP invited agencies to be partners**
 - Workgroup, ongoing dialog
 - Good customer focus!
- **What State agencies Need**
- **Recommendations**
 - Technical Standards
 - Proficiency Testing
 - Quality Management System



CONFIDENCE IN THE QUALITY OF LABORATORY DATA

- **Accurate**
 - **Consistent**
 - **Quality Assurance**
 - **Legally Defensible**
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ACCURATE

- **Accuracy/Precision**
 - Believable Reporting Limits
 - Repeatability Among Replicates
 - Acceptable Spike Recovery
- **Proficiency Testing (PT) Results**

CONSISTENT

- **Within a Lab - Across staff and time**
 - Training
 - Documentation
 - Internal auditing
- **Between Labs**
 - Performance Testing (PT) Samples
 - Reports - Formats and terminology
- **Between Methods**
 - Non-Standard and Modified Methods

QUALITY ASSURANCE

- **Processes and activities necessary to assure quality of the results**
 - Staff Qualifications
 - Procedures
 - Methods
 - Method validation

LEGALLY DEFENSIBLE

Be able to demonstrate accurate, consistent, quality assured results

- **Documentation**

- **Procedures** - everything that could affect the quality of the results
- **Records** - what they actually did

SAP MADE RECOMMENDATIONS ON:

- **Technical Standards**
- **Proficiency Testing**
- **Quality Management System**

TECHNICAL STANDARDS

- Methods that meet agency needs
- Add alternative methods where appropriate
- Update “Fields of Testing” regularly
- Consult SAP, ELTAC, stakeholders on changes

PROFICIENCY TESTING SAMPLES

- **Consistency Between Labs**
- **Low Opinion of Current PT System**
 - Labs game the system
 - Snapshot in time
- **Long Term - Improve PT System**
 - Meantime – not high value in multiple samples per year

QUALITY MANAGEMENT SYSTEM

- **How an organization makes sure they do things right**
- **Must be present to ensure lab meets agency needs**
- **Lack of Confidence in Other Two Elements Alone:**
 - **Technical standard**
 - Methods may be modified or used incorrectly
 - Annual audit only gives snap shot
 - **Performance Testing**
 - Samples can be gamed and the current system is not robust

WHICH QUALITY MANAGEMENT SYSTEM?

- **Recommendation: The NELAC Institute (TNI) Standard**
 - One Agency felt may be able to use another Standard as a starting point

REASONS FOR TNI

- **Ready for adoption** – writing/modifying another will take too long
- **Clear, consistent, auditable** – no interpretation needed; long history of success
- **Sustainable** – Reviewed/updated regularly by national expert committees
- **Resources Available** - Training and implementation

PHASED IMPLEMENTATION

- Big change
- Work with ELTAC and SAP
- Prioritize Elements to be Implemented Within First Year
- Identify Elements that can have a Multi-Year Phase-in

The image features a light gray background with a subtle gradient. In the top-left and bottom-right corners, there are several realistic water droplets of various sizes, rendered with soft shadows and highlights to give them a three-dimensional appearance. The word "QUESTIONS?" is centered in the middle of the page in a bold, black, sans-serif font.

QUESTIONS?