



LELAP Update

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Formation of The NELAC Institute (TNI)

- Public and private stakeholders
- Consensus organization
- Implementation of standards voted on by the National Environmental Laboratory Accreditation Program (NELAP) Board

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TNI Programs

- Develop uniform accreditation standards
- Adopt standards for use in accreditation programs
- Develop system for recognition of state agencies (Accreditation Bodies or AB's)
- Implementation of the accreditation program done voluntarily by those states who choose to participate



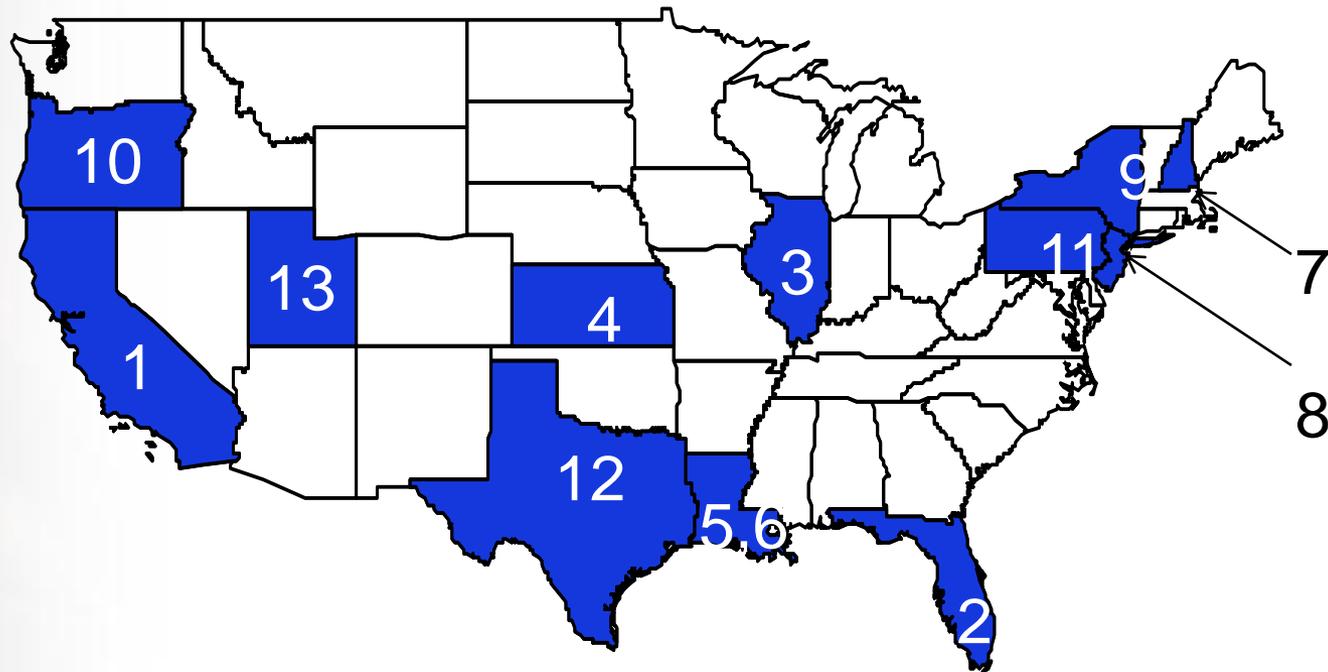
Maturation of TNI Program

- US Environmental Protection Agency (EPA) required changes to National Environmental Laboratory Accreditation Conference (NELAC)
- Institute for National Environmental Laboratory Accreditation (INELA) formed in 2002 to fill gap in standards development effort
- NELAC recognized need for self-support
- EPA provided funding support to assist with transition
- INELA and NELAC merged
- TNI is developing new standards from the 2003 NELAC standard



Current Status

- The national program has achieved the following goals:
 - ✓ 13 AB's
 - ✓ > 2000 accredited laboratories
 - ✓ Recognized competency standard
- The transition continues.....



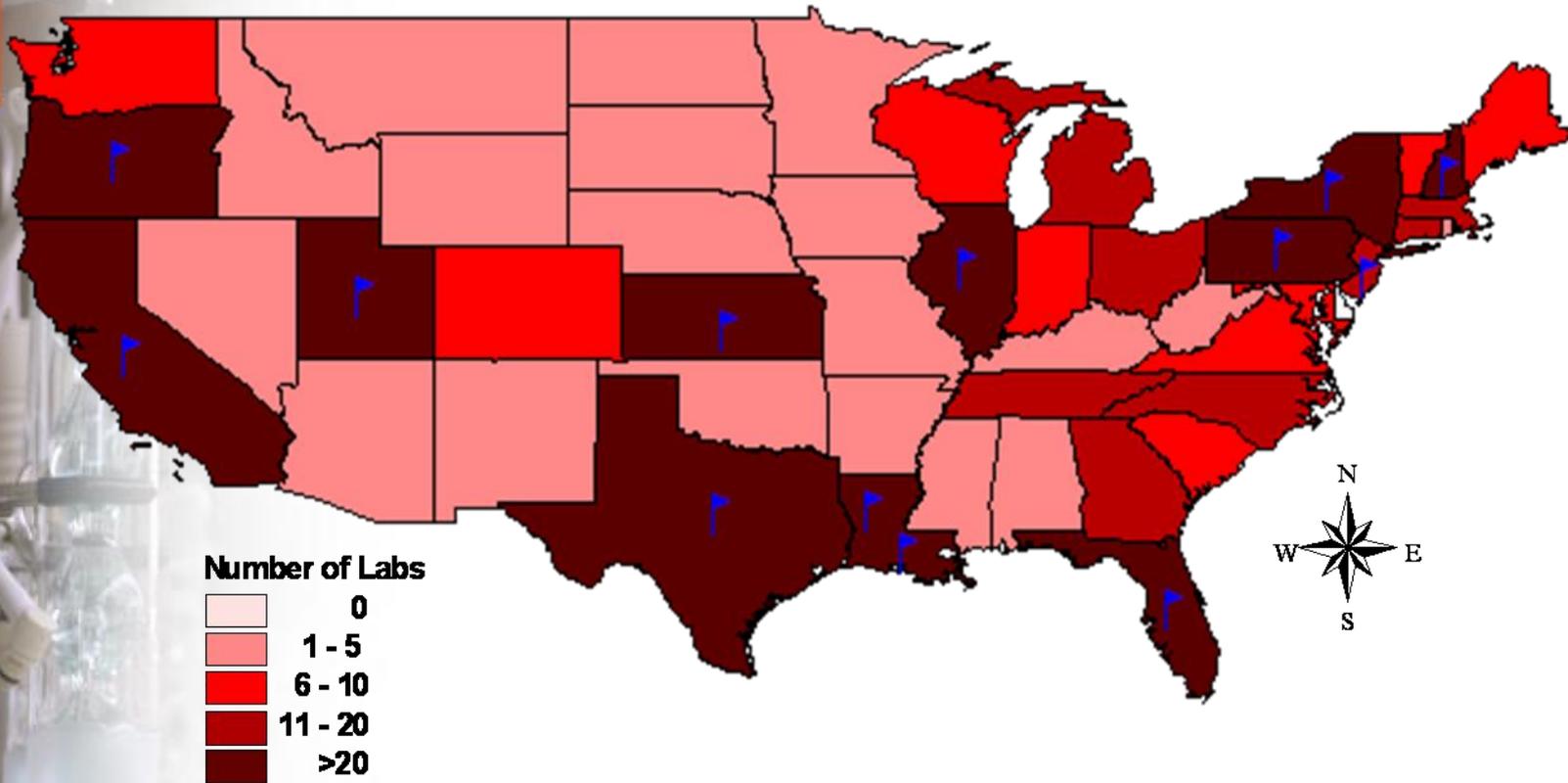
The NELAC Institute (TNI) NELAP Accreditation Bodies

- 1 CA Environmental Laboratory Accreditation Program
- 2 FL Dept. of Health, Bureau of Laboratories
- 3 ILEPA, Div. of Lab., QA Section
- 4 KS Dept. of Health and Environment
- 5 LA Dept. of Health and Hospitals
- 6 LA Dept. of Environmental Quality
- 7 NH Environmental Lab Accreditation Program

- 8 NJ Dept. of Environmental Protection
- 9 NY State Dept. of Health
- 10 OR Health Division
- 11 PA Bureau of Labs., Dept. of Environmental Protection
- 12 TX Commission on Environmental on Environmental Quality
- 13 UT Department of Health



NUMBER OF NELAP-ACCREDITED LABORATORIES BY STATE



There are over 2000 laboratories in the continental US, Alaska, Hawaii, Iceland, Canada, and Europe participating in NELAP.

 **State with NELAP Accreditation Body**



TNI Partnership

- EPA Regional Offices support TNI.
- NELAC and INELA combined to become TNI on November 6, 2006.
- All key functions of both organizations were continued.



The NELAC Institute

- 501(c)3 non-profit organization with members, managed by a Board of Directors
- Organized into Programs that focus on the mission and vision of the organization



Who Are Our TNI Members?

- Organizations that accredit laboratories
 - Accreditation Bodies
 - States that are not Accreditation Bodies
 - Federal Agencies that operate Accreditation Programs
- Accredited laboratories
 - Commercial, Municipal, University, State, Federal, etc.
- Others
 - State and Federal Agencies that do not operate accreditation programs
 - Data users, consultants, PT providers, vendors, etc.
 - Anyone interested in laboratory accreditation



TNI Board of Directors

- 10 -18 Directors
- Balanced Stakeholder representation
 - ❑ At least 3 Accreditation Bodies
 - ❑ At least 3 Accredited Laboratories
 - ❑ Others
- Election for three vacancies was held in February 2008



What is the NELAP Board?

- Representatives (and alternates) of the AB's who are appointed by their respective state agencies
- Tasked with 3 objectives:
 - Adopting an accreditation system
 - Adopting acceptance limits for PTs
 - Recognizing other accreditation bodies
- Board is governed by a chair and assisted by a TNI program administrator



Governing Principles

- Consensus standards process used for the development of accreditation standards (Expert Committees)
- Implementation of the program will continue to be voluntary by states
- The concept of “balance” used where possible



Programs of TNI

- Core Programs
 - Consensus Standards Development
 - Laboratory Accreditation System
 - National Environmental Laboratory Accreditation
 - Proficiency Testing
- Program Support
 - Administration
 - Policy Development
 - Advocacy
 - Technical Assistance



Consensus Standards Development Program

Coordination Committee

- Works with expert committees
- Develop standards for the accreditation of environmental laboratories
- Assist the Laboratory Accreditation System committee with guidance



Technical Assistance Program

Technical Assistance Committee

- Develops tools and templates to assist laboratories and accreditation bodies with implementing accreditation programs
- Ensures that training programs relevant to the needs of the stakeholder community are provided
- Ensures that laboratory assessors have a forum to discuss common issues
- Develops a mentoring program to assist both laboratories and accreditation bodies with implementing accreditation programs



NELAC/NELAP Operations

- All NELAC operations were migrated into TNI.
- The NELAC dissolved January 16, 2008—"NELAC" is only a word.
- The 2003 NELAC Standard is a public record and is in effect.
- The process of recognition of AB's by TNI is underway.



The NELAC Institute

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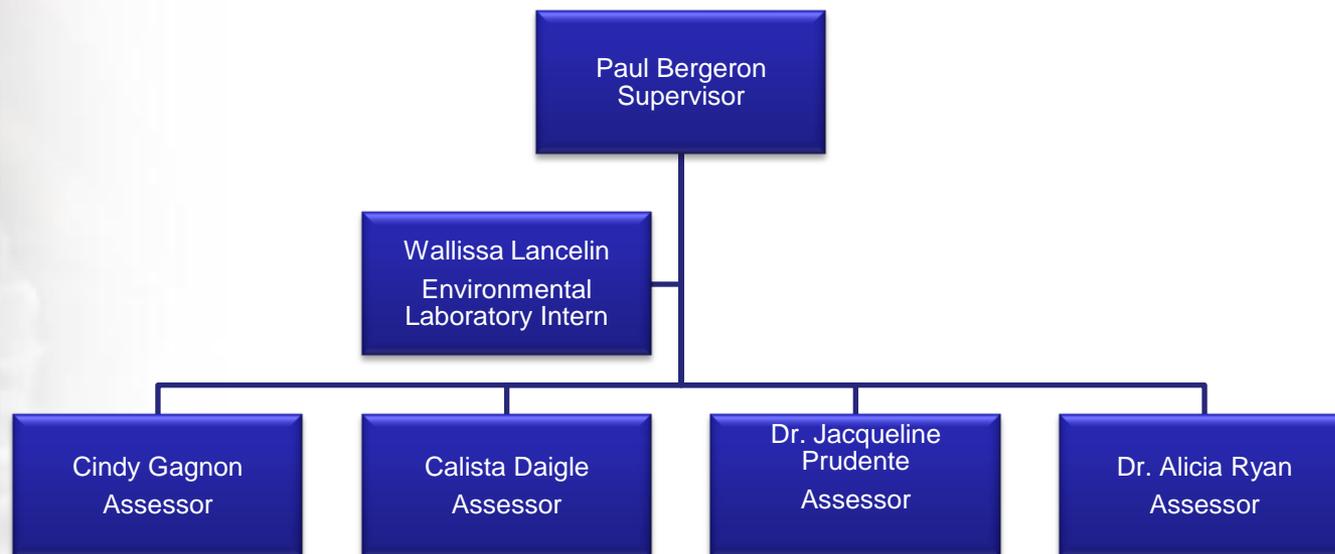
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LELAP





Renewal vs. Annual Fees

- All fees are non-refundable
- 3 year application renewal fees-- \$660 submitted with the renewal application
- Annual Membership Fees--\$594 to \$1980/Major or Minor Test Category dependent



Test Categories

- Metals
- Microbiology
- Biomonitoring
- Classical Wet Chemistry (nutrients, minerals, ions, demands, and coliforms)
- Minor conventional parameters
- Organics (semi-volatiles, volatiles, pesticides, herbicides, and PCB's)
- Dioxins and Furans
- Radiochemistry
- Asbestos
- Geotechnical Soil Testing
- Air Pollutants



Minor Conventional Parameters

- BOD₅, Hexane-Extractable Material, TSS, Fecal & Total Coliform, and Residual Chlorine **ONLY**
- Cost--\$264



Schedules

- Renewal Application—every 3 years
- Annual Fees—every year
- Assessments—every two years
 - Stack tester assessments include home base and field assessments
 - Field assessments may be static (demonstration only) and combined with home base. Assessment possible @ LDEQ Laboratory
- Proficiency Tests and Analytical Data Packages—Twice a year~6 months apart



ASSESSMENT TEAMS

- Assessment teams are comprised of assessors from LELAP and/or contract companies.
- Third party assessments will be assigned at random.
- Most assessments require at least two assessors.

LELAP STANDARD OPERATING PROCEDURES (SOP's)

- LELAP staff meet with contractors to ensure consistency in assessments.
- Upon recommendations from the meetings, LELAP revises its SOP's.
- Changes are made based on issues discussed during the meetings.



Method Update Rule (MUR)

- Promulgated on March 12, 2007 by EPA
- Took effect April 12, 2007
- Published in the 40 CFR 136.
- Removed approximately 200 old EPA methods from the list of approved methods for the Clean Water Act and Safe Drinking Water Act.
- Approved the use of Standard Methods 18th, 19th and 20th editions and Standard Methods online.
- Addendum to rule recognized equivalency of selected Standard Methods from 21st edition and Standard Methods online.



MUR (cont.)

- LELAP as Primary AB—
accreditation will be granted if the new method requires the same technology, matrix, and analytes
- LELAP as Secondary AB—
accreditation will be granted via recognition of the Primary AB's accreditation



MUR (cont.)

- LELAP has sent correspondence to the laboratories notifying them of the MUR and requirement to request scope amendment.
- Permittees may continue to use previously approved methods until the permit is updated.
- The Department initiated action to address permits that specify analytical methods that are no longer approved.



MUR (cont.)

- LELAP as Secondary AB—if primary AB has not granted accreditation for the new method, LELAP will offer interim “state” accreditation.
- Interim “state” accreditation will expire June 30, 2008.



Update—Discreet Analyzers

40 CFR 136.6 now allows laboratories to use discrete analyzers without receiving ATP approval from EPA prior to using the new analyzers.



Laboratory Services Division Webpage

- The Laboratory Services Division webpage has information on news, resources, regulations, the Environmental Laboratory Intern Program, student work, and contacts
- Go to <http://www.deq.louisiana.gov/portal/tabid/72/Default.aspx>



Extras

- LELAP posts a quarterly newsletter with topics of interest to accredited laboratories and clients of the LDEQ laboratory
- “Accreditation 101” is accepting reservations—please contact LELAP



Questions?



Preparing for and Responding to Accreditation Audits & Recurring Findings of Accreditation Audits

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April 23, 2008

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Common Findings

- Failure to have correct and up-to-date standard operating procedures (SOPs)
- Failure to document required information in Quality Assurance Manual (QAM)



Common Findings (cont)

- Failure to demonstrate method proficiency by the analyst
- Failure to establish quality control acceptance criteria



Common Findings (cont.)

- Failure to notify the Department of modifications to methods
- Failure to maintain training records



Common Findings (cont.)

- Failure to conduct annual management reviews and internal audits
- Improper error correction technique



Common Findings (cont.)

- Failure to submit analytical data packages in lieu of proficiency test results when proficiency tests are not available
- Failure to implement corrective action plan



Corrective Action Process

Resolving findings and non-compliance the first time and eliminating recurring findings



Recurring Findings

- Assessments are a snapshot of the laboratory operation--They are not intended to find everything
- Recurring findings are a big problem
- Accreditation Bodies (AB's) do not take kindly to laboratories not taking comprehensive corrective actions
- The Quality Systems (QS) approach to corrective actions requires that findings be addressed in all areas of the laboratory



Recurring Findings (cont.)

- It is management's responsibility to address each finding and make sure that it is not occurring in any other area of the laboratory.
- Corrective action must address the problems in all areas and for all staff.



Recurring Findings (cont.)

- Standard Operating Procedures (SOPs) are technically incorrect, do not follow the reference method, or are not implemented.
- Lack of training of management and staff to
 - The 2003 NELAC standard
 - The Louisiana Administrative Code (LAC)
 - The laboratory quality system documentation



Recurring Findings (cont.)

- Lack of documentation of
 - Training
 - Demonstrations of Capability
 - Corrective Actions
 - Internal Audits
 - Annual Reviews by Management
- Lack of implementation of corrective action and occurrence of recurring findings.



Assessment Sequence

- 1) Quality System
- 2) SOPs and Methods
- 3) Review of 1) and 2)
- 4) Compliance



Quality System Tools

- Include
 - Annual Management Review
 - Internal Audits
 - Proficiency Testing
 - Training
 - Corrective Action

- Internal audits are one of the most important tools that management has to determine how the operation is functioning.



QS Tools (cont.)

- Corrective actions are the best mechanism for
 - Continuous improvement
 - Assuring that you are not fixing the same problems time after time after time—re-inventing the wheel
 - Spotting trends and establishing a preventative action process
 - Maintaining accreditation requirements
- Using the corrective action plan (format provided in assessment report) is **mandatory**—it is not optional



Corrective Action Process

The problems with most corrective action processes are

- only address the short term—the quick fix
- these “solutions” don’t last (Recurring Findings)
- process is not used for all corrections—lacks a comprehensive approach
- only used by select management—not a “grass roots” program
- does not address the root cause
- all staff are not trained and encouraged to use the process
- no follow through and monitoring



Closing Corrective Actions

- Analyze—identify the root cause: people
- Update the QS document
- Train
- Implement Corrective Action (CA)
- Verify compliance



Symptoms vs. Root Cause

Symptoms

- Facility has not performed proficiency tests
- Non-compliant data set is missing data qualifiers

Root Cause

- Management and staff are not familiar with standards or regulations
- Analysts are not trained to QS documents



Root Cause Analysis

Clearly define the non-conformance. Refer to the Standard.

- Ask some questions...
 - Why did this occur?
 - How did this happen?
 - Has this occurred before?
 - Where did the previous solution fail?
 - Which of the foundation systems is affected?
 - Fix the symptom...or fix the problem?
 - Is the solution documented?
 - Is the change monitored?



Root Cause Analysis

- Error corrections are not performed according to the quality manual and the NELAC Standard in the QA department, metals extractions and sample receiving.
- Two of the four analysts in the volatile organics area do not follow the requirements of the SOP. The analysis does not match the test method requirements.



Management Reviews NELAC Standard Chapter 5



5.4.14 Management Reviews

5.4.14.1 In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically and at least annually conduct a review of the laboratory's quality system and environmental testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.



5.4.14 Management Reviews (cont.)

5.4.14.1...the review shall take account of

- a) the suitability of policies and procedures;
- b) reports from managerial and supervisory personnel;
- c) the outcome of recent internal audits;
- d) corrective and preventative actions;
- e) assessments by external bodies;
- f) the results of proficiency tests;
- g) changes in the volume and type of work;
- h) client feedback;
- i) complaints; and
- j) other relevant factors, such as quality control activities, resources and staff training.



5.4.14 Management Reviews (cont.)

5.4.14.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale. The laboratory shall have a procedure for review by management and maintain records of review findings and actions.



Management Review Elements

Policies and Procedures

- Are our policies up-to-date and relevant to our operations?
 - If not, what needs to be changed?
- Are our procedures up-to-date?
 - Do written procedures accurately reflect what is being done?
 - Do we need to change how things are being done?
- Are changes that were made last year effective? If not, why not?



Management Review Elements (cont.)

Reports from Managerial and Technical Staff

- What issues are identified?
 - Technical
 - Routine Analytical Work
 - Method Development Activities
 - Quality Control and Quality Assessment
 - Administrative
 - Client Requirements
 - Staffing Issues
 - Building Issues
- How can they be resolved?—What actions will be taken?
- Of actions taken in the previous business year, which were effective? If not, why not, and how to improve. 59



Management Review Elements (cont.)

Audits—Current Business Year

- Internal and External Audits
 - What was found?
 - What are the recommended corrective actions?
 - Implementation Recommendations?
 - Available Resources?
- Proficiency Tests
 - How did we do?
 - Reasons for failures and recommended corrective actions
 - Implement Recommendations
 - Available Resources?



Management Review Elements (cont.)

Audits—Previous Business Year

- Internal and External Audits
 - Were Corrective Actions Implemented?
 - If not, why not?
- Proficiency Tests
 - Compared to current year, did we do better/worse?
 - Were Corrective Actions Implemented?
 - If not, why not?



Management Review Elements (cont.)

Client Satisfaction/Feedback

- Complaints
 - Types
 - Resolutions?
 - Comparison with previous year—
did we improve?
- Services--types



Management Review Elements (cont.)

Employee Satisfaction/Feedback

- Turnover
- Work Environment
- Training
- Benefit Packages
- Employee Evaluations
 - Incentives/Recognition Programs
- Ethics
- EEOC Issues
- Health and Safety Plan



Management Review Elements (cont.)

Preventive Measures

- How can we prevent recurrences of problems in audits, client relations or other areas?
- Preventative Measures from the Previous Business Year
 - Were they implemented?
 - Was there improvement?
 - If not, why not?



Management Review Elements (cont.)

Changes from Previous Year

- What has changed over the past year?
 - Client base
 - Work volume
 - Requested analyses
 - Personnel
 - Physical facilities
- Impacts and Effects
 - Do we need change? If so, what?
 - Do we need additional resources?
 - Do we need to cut back on services?



Documenting Management Reviews

- Formal
 - Annual Reports
 - Publish Results of Meetings
 - Document all Reviews
- Informal
 - Meeting Minutes



Preparing for and Responding to Audits & Recurring Findings of Accreditation Audits complete....

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Questions?



Laboratory Issues/Challenges

An Open Forum
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April 23, 2008

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