THE NELAC INSTITUTE

Accreditation Body Task Force: Findings and Draft Recommendations

Judy Duncan, Chair

Accreditation Body Task Force Mission

- **To identify means for TNI to assist ABs to eliminate bottlenecks and to deal with financial and personnel strains while promoting continuation of nationally recognized full accreditation services to laboratories.**

Members

Steve Arms (ex officio)	NELAP AB
Susan Boutros	Small lab
Lynn Bradley	Other
Bob DiRienzo	Lab
Judy Duncan, Chair	State non-NELAP AB
Jack Farrell	Other
John Gumpper	Other
Judy Morgan	Lab
Matt Sica	State non-NELAP AB
Alfredo Sotomayor	State non-NELAP AB
Dave Speis	Lab
Carol Batterton	TNI staff support
Jerry Parr	TNI staff supoort

Preliminary Observations

- **ABs are facing financial stress, budget cutbacks, and significant financial scrutiny of operations.**
- **State AB staffs are shrinking, their travel is being restricted, and their support functions being reduced or disappearing.**
- **Some ABs are not able to keep up with obligations such as review of PT data, approval of secondary (reciprocal) accreditations, scope expansions, and even timely renewal assessments and delivery of assessment reports.**

Preliminary Observations

- **Some ABs are being forced to restrict or eliminate their program's power to grant primary accreditation to laboratories outside their state boundaries.**
- **Possible impacts of these problems upon laboratories led the TNI Board to charter a task force to investigate what assistance TNI might provide.**

Task Force Activities

- Conference call with ABs
- Meeting with NFSTC to explore third party AB process
- Review of survey data provided by Judy Morgan
- Two surveys soliciting information regarding ability to process out of state primary applications, timeliness of assessments, timeliness of review of PT data, and training needs.

Conference Call with ABs

- Two areas of concern highlighted:
  - Completion of the national accreditation database
  - Accurate information on which ABs are doing out of primary state accreditations
- Mixed response to query about TNI becoming an AB or making contract services available

Ideas from Meeting with NFSTC

- Focus was to determine how TNI could best provide services to the ABs
- One option is a fee for service model selecting two or three of the most critical services needed by the ABs. Additional services could be phased in as we determined need.
- Setting up the service as a separate business unit to account for revenue and expenditures separately is preferable. Easy to see if the venture was fiscally sustainable or not.

Ideas from Meeting with NFSTC

- Having the service partially underwritten by a grant could also help to launch the program.
- Set up a sister organization to provide the services. This approach would be preferable if TNI were offering some high risk services and needed to be insulated. At this point, TNI is only interested in offering pre-decisional activities as services.
- Seek the advice of an attorney on whether or not to set up a separate or subordinate organization. TNI could also partner with another existing organization to provide services.

AB Survey #1

Status of out of state primary accreditations and timeliness

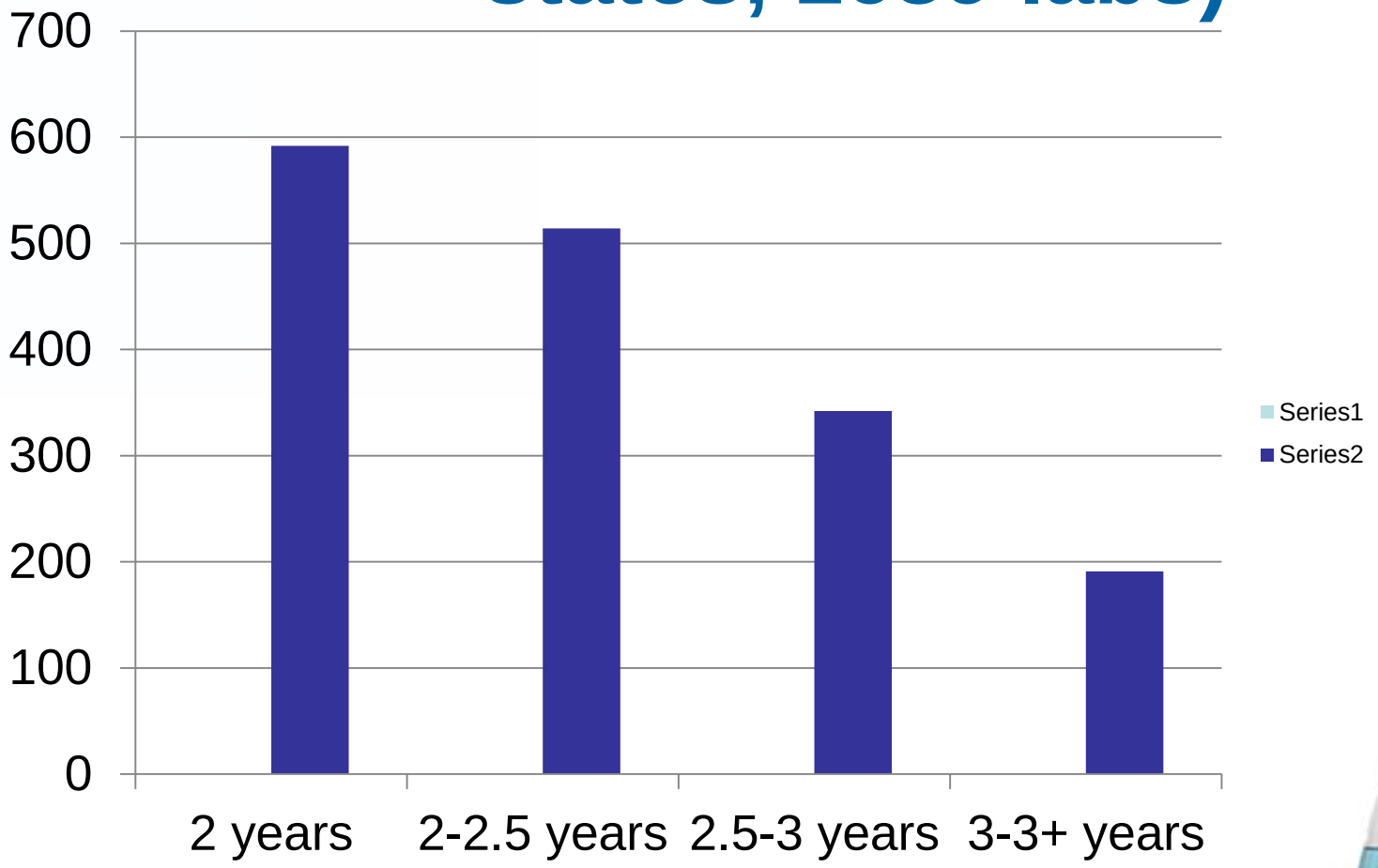
- **Only 5 ABs indicated that they have issues with either accepting primary applications from out of state or timeliness of processing of applications for accreditation.**
- **IL no longer accepting out of state primaries. Existing IL OOS primaries will have to find another AB.**
- **There *could be* issues with available scope of accreditation if more states are restricted from doing out of state primaries.**

AB Survey # 2

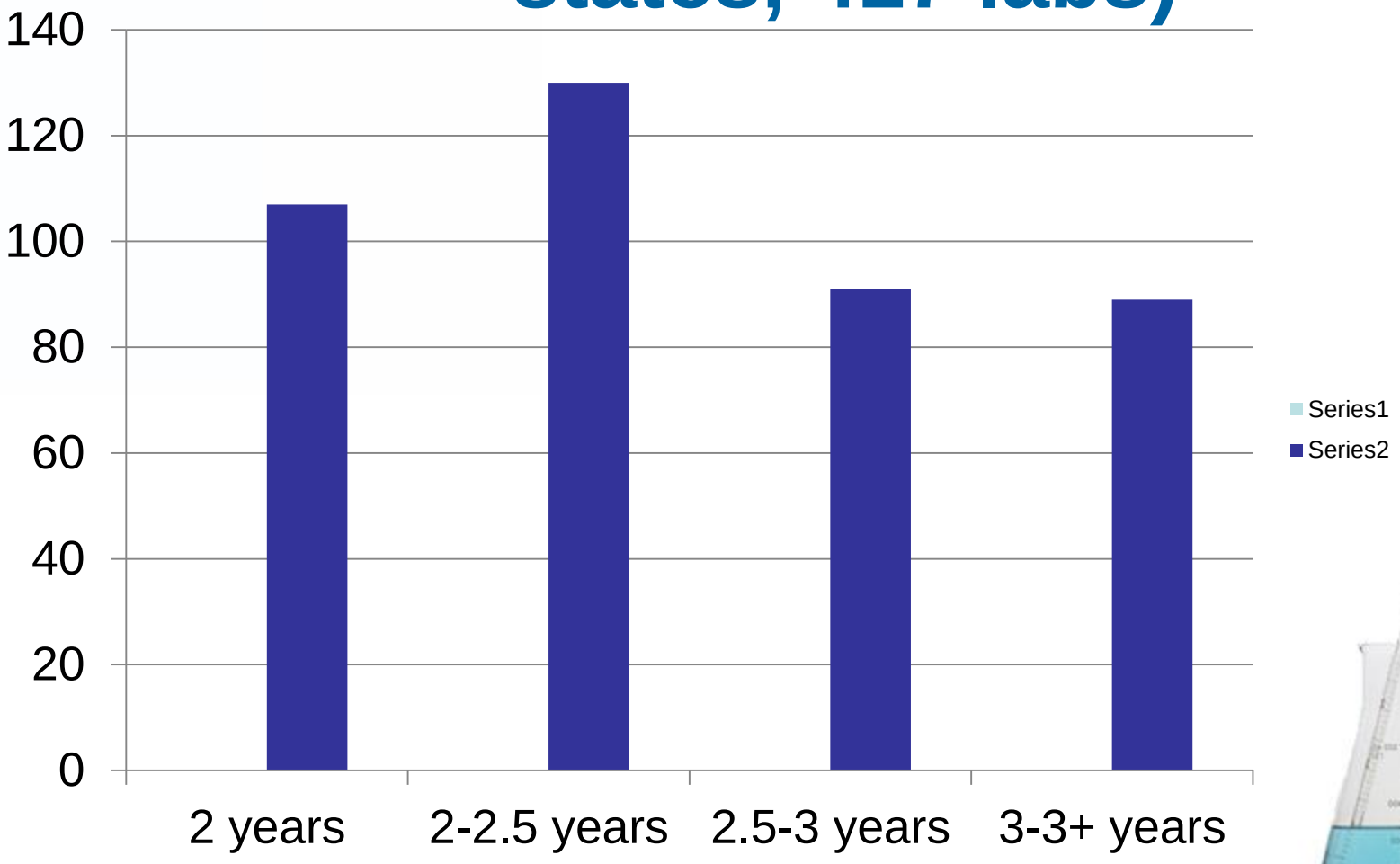
Timeliness and training

- Timeliness of primary instate assessments
- Timeliness of out of state assessments
- Timeliness of review of PT data
- Compliance with training requirements of new standards
- 12 of 15 ABs responded to survey

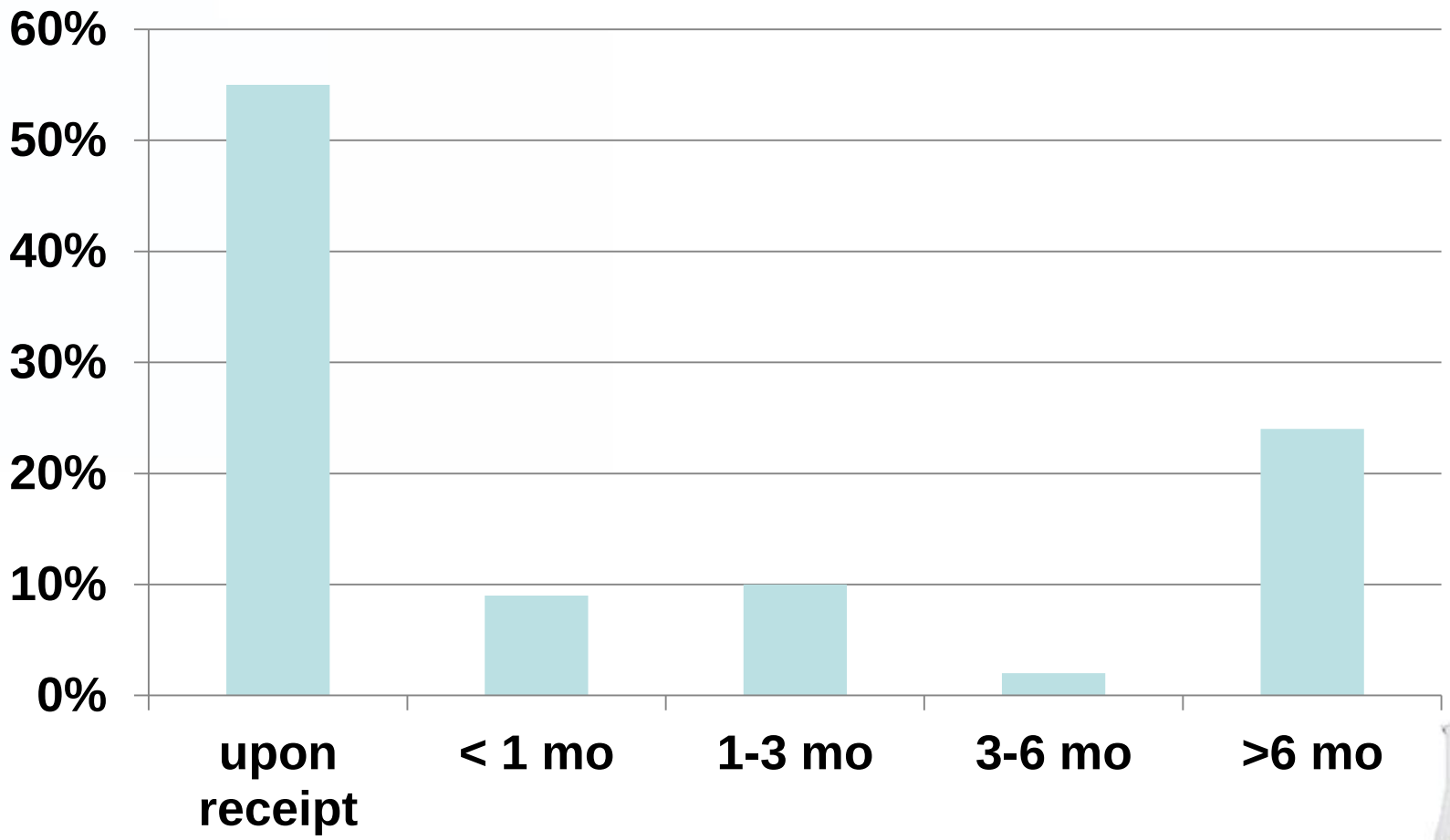
Timeline for instate lab assessments (data from 12 states, 1639 labs)



Timeline for out of state lab assessments (data from 12 states, 417 labs)



PT Processing



Third Party Assessors

- 7 of 12 ABs responding do not use 3rd party assessors
- 2 ABs use 3rd party assessors for out of state assessments only
- One AB uses 3rd party for radiochemistry assessments

Meeting 2009 Standard Training Requirements

- 4 ABs indicated they would have no problem
- 8 ABs indicated possible problems due to budget constraints, travel constraints, availability of training, and keeping up with new staff training.

AB Plans for Meeting New Training Requirements

- USEPA certification officer training (2 ABs)
- In-house training (7 ABs)
- Arrangements with TNI (3 ABs)

Training Areas Where TNI Can Assist

- **Toxicity: 9 of 12**
- **Radiochemistry: 7 of 12**
- **Asbestos: 6 of 12**
- **Organics: 5 of 12**

Other Concerns from ABs

- TNI needs a mechanism for immediate resolution of issues that arise during implementation of the new standards.
- All required training, including basic assessor training should be available online.
- State budget concerns will impact how ABs manage their programs.
- Out of state travel for training is prohibited. Web-based training is preferable.

Laboratory Needs / Requests

- Access to primary and secondary accreditation
- Timeliness of processing
  - Applications for primary and secondary accreditation
  - Renewals of accreditation
  - Preparation of on-site inspection reports
  - Timely review of corrective actions
- Standardization of program implementation

Where do we go from here?

Come back after the break!

Key Finding

- **One size solutions will not fit for all states. TNI needs to develop a range of solutions to address many concerns.**

Onsite Lab Assessments

- **The most immediate need is to assure that the 27 out of state labs that were previously accredited in Illinois have found a new AB for primary accreditation. TNI is contacting each lab to be sure that they have found an alternative AB for primary accreditation.**

Onsite Lab Assessments: Options for Discussion

- Provide assistance to ABs in securing third party assessors
- Surveillance audits in alternate assessment cycles may be a solution. If a lab is doing a good job, the frequency between assessments can be lengthened. This would allow the AB to better manage their resources.
- Adjustment of frequency of assessments in the standard may be another solution

Assistance with Administrative Review: Draft Recommendations

- **TNI should explore options for assisting with**
  - **Application review**
  - **Follow-up on corrective actions to assure that they are implemented as required**
  - **Assessment tracking tools**

Third Party Assessors: Draft Recommendations

- **Simplification of the contract process for third party assessors would help some states. Possible actions for TNI include -**
  - **Development of a process to pre-qualify third party assessors**
  - **Development of a model solicitation template for third party assessors**
  - **Development of an evaluation process for selection of third party assessors**
  - **TNI could develop a service for a state to contract with TNI to obtain the use of third party assessors**
  - **TNI could explore the use of resource sharing between states and develop model MOUs**

Third Party Assessors:
Draft Recommendations

- **Qualification or credentialing of third party assessors would assist on many levels and should include development of minimum qualifications and verification of training**
- **TNI should not pursue becoming a third party accreditor at this time**

PT Data Review:
Draft Recommendations

- **TNI should consider developing a process for centralized review of PT data for conformance with the standard. Following TNI review, states can take whatever action is warranted under state programs. State responses may be different, but review criteria will be the same. This may help secondary accreditation issues.**
- **TNI is sponsoring a mentoring session at this meeting to explore best practices from states and the commercial sector.**

National Database:
Draft Recommendation

- **TNI should expedite the implementation of the national database to assist ABs with secondary accreditation issues.**

Training of Assessors:
Draft Recommendations

- **TNI needs to have web-based training of assessors up and running in 2011.**
- **The initial focus of the training should be in the technical areas identified.**

Next Steps

- **The AB task force will receive comments and suggestions at this meeting and by email.**
- **Information will be compiled into a report to be presented to the TNI Board with input from the NELAP AC and LASEC for determination of appropriate action.**

Questions, comments?

Additional comments can be emailed to

Judy Duncan judy.duncan@deq.ok.gov

or

Carol Batterton carbat@beecreek.net