

**SUMMARY OF THE
TNI ACCREDITATION BODIES
COMMITTEE MEETING**

JUNE 19, 2007

The Accreditation Body (AB) Committee of The NELAC Institute met at 12:00PM on Wednesday, June 19, 2007. Chairperson Dr. Jefferson Flowers, of Flowers Chemical Laboratories, led the meeting. A list of participants is given in Attachment A.

REVIEW OF NELAC CHAPTER 6

- Review of the NELAC Chapter six occupied the full meeting. The sections that the members determined to be missing from the existing V2M1 were copied into a spreadsheet prepared by Steve Stubbs, see enclosed sheet. The lengthy discussion enabled review of section 6.3.

FUTURE GOALS

This committee will continue discussion and identify the parts of the un-reviewed sections that are not currently dealt with in the existing module. Once complete the committee will identify the sections as to final disposition, e.g. section to be employed as Policy, SOP or other.

ADJOURNMENT

The Chair adjourned the meeting at 1:09 PM on Tuesday , June 19, 2007.

Attachment A

Member	Affiliation	Contact Information
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Lynn Bradley	USEPA OEI Quality Staff	202-565-2575 bradley.lynn@epa.gov
Dan Dickinson	New York State DOH	518-485-5570 dmd15@health.state.ny.us
Jeff Flowers, Chair	Flowers Chemical Laboratories, Inc.	407-339-5984 x219 jeff@flowerslabs.com
Linda Geddes	MWH Laboratories	626-386-1170 linda.geddes@mwhglobal.com
Jeff Goodwin	Manatee County Utility Operations	941-792-8811 jeff.goodwin@co.manatee.fl.us
Steve Stubbs	Texas Comm. On Environmental Quality	sstubbs@tceq.state.tx.us

Attachment B

6.2 GENERAL PROVISIONS

4.2.6-4.2.7

f) If the NELAP insignia is used on general literature such as brochures, letterheads and business cards, a NELAP-recognized accrediting authority shall accompany the display of the NELAP insignia with at least the phrase "NELAP-recognized."

g) Accrediting authorities, within the scope and applicability of their prevailing rules and regulations, shall establish one or more technical committees for assistance in interpretation of requirements and for advising the accrediting authority on the technical matters relating to the operation of its environmental laboratory accreditation program. When such committees are established, the accrediting authority shall have

- 1) formal rules and structures for the appointment and operation of committees involved in the accreditation process and such committees shall be free from any commercial, financial, and other pressures that might influence decisions, or
- 2) a structure where committee members are chosen to provide relevant competent technical support and impartiality through a balance of interests where no single interest predominates, and
- 3) a mechanism for publishing interpretations and recommendations made by these committees.

i) Time lines stated in Chapter 6 can only be extended by official permission from the NELAP Director upon receipt of written justification. The record of any such extension shall detail the rationale for the extension and is to be maintained as part of the NELAP official record.

j) Extension of NELAP Recognition of a NELAP Accrediting Authority can be granted by the NELAP Director with written justification. The record of any such extension is to detail the rationale for the extension and is to be maintained as part of the NELAP official record.

a) Except for NELAP-recognized federal accrediting authorities (see 6.2.1 (h) and (i) below), NELAP-recognized secondary accrediting authorities shall grant accreditation to laboratories accredited by any other NELAP-recognized primary accrediting authority. Such reciprocal NELAP accreditation shall be granted on a laboratory-by-laboratory basis. The NELAP recognized secondary accrediting authority shall consider only the current certificate of accreditation issued by the NELAP-recognized primary accrediting authority.

b) When granting reciprocal accreditation to a laboratory, the NELAP-recognized secondary accrediting authority shall:

- 1) grant reciprocal accreditation for only the fields of accreditation, methods and analytes for which the laboratory holds current primary NELAP accreditation, and
- 2) grant reciprocal accreditation and issue certificates, as required in NELAC, Chapter 4, to an applicant laboratory within 30 calendar days of receipt of the laboratory's application.

c) All fees shall be paid by laboratories as required by the NELAP-recognized secondary accrediting authority.

d) Laboratories seeking NELAP accreditation by a NELAP-recognized secondary accrediting authority shall not be required to meet any additional proficiency testing, quality assurance, or

onsite assessment requirements for the fields of accreditation for which the laboratory holds primary NELAP accreditation.

e) If a NELAP-recognized secondary accrediting authority notes any potential nonconformance with the NELAC standards by a laboratory during the initial application process for reciprocal accreditation, or for a laboratory that already has been granted NELAP accreditation through reciprocity, the NELAP-recognized secondary accrediting authority shall immediately notify, in writing, the applicable NELAP-recognized primary accrediting authority and the laboratory. However, the laboratory is to be notified only in situations where no administrative or judicial prosecution is contemplated. The notification must cite the applicable sections within the NELAC standards for which nonconformance by the laboratory has been noted.

1) If the alleged nonconformance is noted during the initial application process for reciprocal NELAP accreditation, final action on the application for reciprocal NELAP accreditation shall not be taken until the alleged nonconformance issue has been resolved, or

2) If the alleged nonconformance is noted after reciprocal NELAP accreditation has been granted, the laboratory shall maintain its current NELAP accreditation status until the alleged nonconformance issue has been resolved.

f) Upon receipt of the subsection 6.2.1 (e) notification, the NELAP-recognized primary accrediting authority shall:

1) review and investigate the alleged nonconformance,

2) take appropriate action on the laboratory as set forth by the NELAC standards, including the addition of any change of accreditation status in the National Environmental Laboratory Accreditation Database. All such actions shall be taken in accordance with the laboratory's right to due process as set forth in the NELAC standards, Chapter 4, Accreditation Process,

3) respond to the NELAP-recognized secondary accrediting authority, in writing, with a copy to the NELAP Director, within 20 calendar days of receipt of the subsection 6.2.1 (e) notification providing:

i) an initial report of the findings;

ii) a description of the actions to be taken; and,

iii) a schedule for implementation of further action on the alleged nonconformance, if necessary.

g) If, in the opinion of the secondary accrediting authority, the primary accrediting authority does not take timely and appropriate action on the complaint, the secondary accrediting authority should notify the NELAP Director of the dispute between the two accrediting authorities regarding proper disposition of the complaint. Within 20 calendar days of receipt of such notification, the NELAP Director shall review the alleged nonconformance and take appropriate action according to the standards set forth in this chapter.

h) Federal accrediting authorities shall serve as the accrediting authority only for governmental laboratories.

i) County, municipal, and non-governmental laboratories shall not claim either primary or secondary accreditation by a federal agency, even if the laboratory is performing analyses under contract to that agency.

6.2.2 Where to Apply for NELAP Accreditation

a) All county, municipal and non-governmental laboratories seeking NELAP accreditation or renewal of NELAP accreditation must apply for such accreditation through their home state (the state in which the laboratory facility is located) accrediting authority.

b) Laboratories located in a territory or state that is not NELAP-recognized may seek NELAP accreditation through any NELAP-recognized state or territorial accrediting authority.

c) Except as noted in subsection 6.2.2 (g) below, state governmental laboratories seeking NELAP accreditation or renewal of NELAP accreditation may apply for such accreditation through their home state, home territory or through a NELAP-recognized federal accrediting authority.

- d) Except as noted in subsection 6.2.2 (g) below, federal governmental laboratories located in a department or agency that is a NELAP-recognized federal accrediting authority shall follow that department or agency's policy regarding NELAP accreditation or renewal of NELAP accreditation.
- e) Federal governmental laboratories located in a federal department or agency that is not a NELAP-recognized accrediting authority may seek NELAP accreditation through any NELAP-recognized federal or state accrediting authority, except where the relationship poses a conflict of interest.
- f) Laboratories that are NELAP accredited by a state accrediting authority that has lost NELAP recognition may seek renewal of NELAP accreditation through any NELAP-recognized state accrediting authority. The laboratory's NELAP accreditation from an accrediting authority that has lost NELAP recognition shall remain valid throughout its current certificate of accreditation.
- g) NELAP accredited laboratories whose home state becomes a recognized NELAP accrediting authority may retain their primary accreditation through the state that holds their current accreditation. The laboratory may retain their existing certificate of accreditation through to the date on the certificate, or until such time that they choose to renew. Depending on the regulations of their home state, the laboratory may still be required to apply for secondary accreditation from their home state until time for renewal for their primary accreditation. At the time of renewal, they must apply for their primary accreditation through their home state accrediting authority as applicable based on requested FOTs.
- h) Governmental laboratories that are organizational units of the same department or agency in which the accrediting authority is located or have other institutional conflicts of interest shall:
- 1) demonstrate by organizational structure that the laboratory's Technical Director and the environmental laboratory accreditation program manager do not report within the same chain-of-command; and
 - 2) demonstrate by policies and procedures that conflicts-of-interest do not exist; or
 - 3) apply for NELAP accreditation through any other NELAP-recognized accrediting authority.
- i) In order that all laboratory applications for NELAP accreditation are treated equally, accrediting authorities shall initiate processing applications for NELAP accreditation in the chronological order that the applications are received.

6.2.3 Documentation Maintained by Accrediting Authorities

- 2) The document or documents shall be reviewed annually. A written record of this review must be available for inspection by the NELAP evaluation team.

6.8 USE OF ACCREDITATION BY NELAP ACCREDITED LABORATORIES

- 1) NELAP accredited laboratories post or display their most recent NELAP accreditation certificate or their NELAP-accredited fields of accreditation in a prominent place in the laboratory facility;

6.9 REQUIREMENTS OF THE NELAP

a) The NELAP evaluation team shall submit all documents, letters, evaluation notes, checklists, etc.

to the NELAP headquarters office within:

- 1) 30 calendar days of the final decision on the application by the NELAP Director, or
- 2) 30 calendar days after the final recommendation by the Accrediting Authority Review Board (AARB) as set forth in Section 6.10 of this chapter.

b) The NELAP Director shall maintain complete and accurate records of all documents relating to the application and on-site evaluation processes for each accrediting authority for a minimum of ten years or a longer period of time if required by contractual obligations or pertinent federal laws and regulations.

c) The NELAP Director shall maintain an electronic directory to display the status of all NELAP-recognized accrediting authorities, pending applications for NELAP recognition and currently scheduled announced on-site evaluations.

6.9.1 NELAP Evaluation Team

a) The NELAP Director shall appoint NELAP evaluation team members as set forth in Section 6.3.3

(a)(4) and delegate the responsibilities required by this chapter to evaluation teams.

b) The NELAP evaluation team shall consist of at least one member who is an employee of the USEPA and at least one member who is an employee of a NELAP-recognized accrediting authority.

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c) Prior to conducting the on-site evaluation of an accrediting authority's program, at least one member of the NELAP evaluation team shall complete the NELAP Accrediting Authority Evaluator Training Course.

d) The NELAP evaluation team shall:

- 1) have at least one member of the NELAP evaluation team who meets the education, experience and training requirements for laboratory assessors specified in the NELAC standards, Chapter 3, On-site Assessment; and
- 2) have at least another member with experience that includes at least one of the following:
 - i) certification as a management systems lead assessor (quality or environmental) from an internationally recognized auditor certification body;
 - ii) one year of experience implementing federal or state laboratory accreditation rulemaking;
 - iii) laboratory accreditation management; or
 - iv) one year experience developing or participating in laboratory accreditation programs.
- 3) Have documentation that verifies freedom from any conflict of interest that would compromise acting in impartial nondiscriminatory manners.
- 4) All experience required by this subsection must have been acquired within the five year period immediately preceding appointment as a NELAP evaluation team member.

6.10 APPEALING FINDINGS BASED UPON DIFFERENCES IN STANDARDS INTERPRETATIONS

a) Though standards are written as clearly and succinctly as possible, conflicts regarding interpretation of standards may arise between the NELAP evaluation team and an accrediting authority, a laboratory and the accrediting authority or between two or more accrediting authorities. Appendix A of this chapter outlines the procedures that must be followed in these instances.

b) The outcome of the procedure outlined in Appendix A is a final consensus interpretation of a standard. This interpretation must be communicated to the relevant standing committees. The decision shall be posted on the NELAC Website and be accessible to all accrediting authorities and laboratories within 14 days.

c) The consensus interpretation must be recognized by the NELAP Director, the NELAP evaluation teams, all accrediting authorities and laboratories until such a time as the standard is changed or another consensus interpretation has been issued.

6.11 APPEALING DECISIONS TO DENY OR REVOKE NELAP RECOGNITION

a) Within 20 calendar days of official notification of the NELAP action on an accrediting authority's application for NELAP recognition, the accrediting authority shall notify the NELAP Director if the accrediting authority chooses to appeal the NELAP action. If the accrediting authority does not receive satisfactory resolution, the accrediting authority may request a review by the AARB. This request shall be made within 20 calendar days of the Director's decision.

b) If any AARB member is not free of financial connection to the appealing accrediting authority, or

is not free of any other relationship that would bias their review of the case, that AARB member shall be excluded from participating in deliberations on that appeal.

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c) The AARB shall carry out an independent review of all relevant parts of the record.

d) The AARB shall conduct interviews with the accrediting authority and the NELAP Director. The AARB also may conduct interviews with the NELAP evaluation team member(s) or other individuals deemed appropriate by the AARB.

e) If the accrediting authority so desires, an opportunity for both the NELAP and the accrediting authority to meet jointly with the AARB shall be granted.

f) The AARB shall complete its review and render a final decision to the NELAP Director within 90 calendar days following receipt of the notice of appeal. This time frame may be extended by mutual agreement of all parties up to a maximum of 60 additional calendar days.

g) The ultimate decision to grant, maintain, deny or revoke NELAP recognition remains with the NELAP Director. The NELAP Director shall notify the appealing accrediting authority of his/her the final AARB decision within 20 calendar days of receipt of the recommendation from the AARB.

h) Accrediting authorities shall be limited to one appeal for each application cycle.

i) Upon filing an appeal, the status existing prior to the decision shall remain in effect pending resolution of the appeal.