

NATIONAL ENVIRONMENTAL  
LABORATORY ACCREDITATION  
CONFERENCE

*DRAFT*  
ACCREDITING AUTHORITY

June 1, 1996

# TABLE OF CONTENTS

## ACCREDITING AUTHORITY

6.0	Accrediting Authority . . . . .	1
6.1	Foreword . . . . .	1
6.2	PROCESS FOR AN ACCREDITING AUTHORITY TO BE NELAC/NELAP RECOGNIZED/APPROVED . . . . .	1
6.3	ORGANIZATIONAL RESPONSIBILITIES FOR ACCREDITING AUTHORITIES . . . . .	4
6.4	RECOGNITION/APPROVAL CRITERIA BY NELAC/NELAP TO BECOME .	6
6.5	RESPONSIBILITIES, ROLES AND QUALIFICATIONS OF THE NELAC/NELAP RECOGNITION/APPROVAL ASSESSMENT TEAM . . . .	8
6.6	ACCREDITING BODIES . . . . .	22
6.7.	COMPLETING A NELAC/NELAP APPROVAL/RECOGNITION AGREEMENT . . . . .	22
APPENDIX A	. . . . .	A-1
APPENDIX B	. . . . .	B-1
APPENDIX C	. . . . .	C-1

## **6.0 Accrediting Authority**

### **6.1 Foreword**

This section defines the process and operating requirements established by the National Environmental Laboratory Accreditation Conference (NELAC) for an Accrediting Authority to become nationally recognized. It provides the policies and criteria that an Accrediting Authority must meet to apply for and maintain recognition.

The section is organized based upon ISO/IEC Guide 25:1990, ISO/IEC Guide 58:1993 and ILAC Fourth Draft:1994. Where necessary to clearly define requirements, the standards given contain more information and are more clearly stated than the text found in the ISO/IEC Guides and ILAC Fourth Draft. Portions of this chapter were also taken from the National Assessment Training of Australia (NATA) and the Assessment of Laboratories Quality Systems--Course Notes, 4th Edition, 1995 (American Association For Laboratory Accreditation).

In all cases the Accrediting Authority is a government organization at the state or federal level. The Accrediting Authority may elect to employ another public or non-public organization to perform some of its activities. These are known as Accrediting Bodies. Accrediting Bodies report to the Accrediting Authority and are the responsibility of the Accrediting Authority. NELAC/NELAP Recognition/Approval cannot be delegated or transferred to an Accrediting Body. This section defines those functions that can be delegated to an Accrediting Body and those functions that must be the responsibility of the Accrediting Authority.

It should be noted that as a precondition for an Accrediting Authority to gain NELAC/NELAP Recognition/Approval it must grant reciprocity to all other Accrediting Authorities with other NELAC/NELAP Recognition/Approval. It is recognized that agreements on mutual recognition of Accrediting Authorities aimed at the removal of barriers to across-border trade may have to cover other aspects not explicitly specified in these general requirements. To create confidence and harmonize the interpretation and implementation of standards, each Accrediting Authority should encourage technical cooperation and exchange experience among laboratories accredited by it, and it should be prepared to exchange information on accrediting procedures and practices with other Accrediting Authorities.

### **6.2 PROCESS FOR AN ACCREDITING AUTHORITY TO BE NELAC/NELAP RECOGNIZED/APPROVED**

6.2.1 An Accrediting Authority applying for NELAC/NELAP Recognition/Approval shall submit an application to NELAC/NELAP at

the following address:

XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXX

- a) The Accrediting Authority shall submit an application to NELAP/NELAC at the time it wishes to become recognized/approved.
  - i. The Accrediting Authority will also submit a renewal application at least every two years in order for it to maintain recognition/approval status.
- b) The Accrediting Authority shall complete the application supplied by NELAC/NELAP, and the application will include, but not be limited to, the following:
  - i. The name of the Accrediting Authority;
  - ii. The analytical areas in which the Accrediting Authority seeks Recognition/Approval;
  - iii. The primary responsible person for administering the Accrediting Authority Program;
  - iv. The names and responsibilities of Accrediting Bodies used by the Accrediting Authority;
  - v. The names and education/experience of Accrediting Authority staff responsible for performing on-site audits;
  - vi. The source of performance evaluation samples used by the Accrediting Authority for proficiency testing;
  - vii. The funding structure used to support Accrediting Authority functions;
  - viii. The program details (Standard Operating Procedures) used by the Accrediting Authority to enforce its program;
  - ix. The program details (Standard Operating Procedures) used by the Accrediting Authority to evaluate laboratories;
  - x. All information outlined in section 6.4.2;
  - xi. Any other information which is reasonably necessary to enable the NELAC/NELAP to determine whether the applicant should be accredited.

6.2.2. The Accrediting Authority will be required to have an on-site audit of its program by NELAC/NELAP Program staff in order to be granted NELAC/NELAP Recognition/Approval. A repeat audit will be conducted every 4 years.

- a) At the on-site audit the Accrediting Authority will provide all necessary records and staff in order for the evaluation team to make an accurate recommendation to NELAC/NELAP for its Recognition/Approval.

#### 6.2.3. Granting and Suspension of NELAC/NELAP Approval/Recognition

- a) After completion of a successful assessment by the NELAC/NELAP Approval/Recognition Assessment Team the Accrediting Authority will be granted approval based on the review and procedures of NELAC/NELAP.
- b) NELAC/NELAP Approval/Recognition shall be granted for two year periods.
- c) NELAC/NELAP Approval/Recognition can be suspended within the two year period if the Accrediting Authority is found to be deficient in following NELAC standards.
  - i. When NELAC/NELAP Approval/Recognition is suspended the Accrediting Authority shall within thirty days notify all the laboratories participating in its program.

#### 6.2.4. Provisional NELAC/NELAP Approval/Recognition status.

- a) If an Accrediting Authority with NELAC/NELAP Approval/Recognition is found to be deficient in following NELAC standards it will be given thirty days to submit a corrective plan of action to the NELAC/NELAP Approval/Recognition Assessment Team Leader.
- b) During the time period between the notification of the Accrediting Authority's deficiencies and the correction of these deficiencies the Accrediting Authority will have Provisional Status.
  - i. When an Accrediting Authority receives notice from NELAP or the NELAC/NELAP Approval/Recognition Assessment Team Leader that it has been found not be following NELAC standards and that it has been given Provisional Status it has fourteen days to notify the laboratories in its program.
  - ii. Provisional Status will be rescinded and full status granted if and when the Accrediting Authority corrects all deficiencies as given in its corrective action plan.



### 6.3 ORGANIZATIONAL RESPONSIBILITIES FOR ACCREDITING AUTHORITIES

6.3.1. The Accrediting Authority will have an organization with the necessary authority and resources to carry out its program responsibilities, which shall include the following:

- a) A document granting the Accrediting Authority the authority to administer an accreditation program;
- b) The ability to demonstrate that it is a legally identifiable public entity;
- c) The ability to cover liabilities arising from its operations and/or activities;
- d) The financial stability and resources needed to support all the activities necessary to be an Accreditation Authority;
  - i. The Accrediting Authority shall have and make available on request a description of the means by which it receives its financial support.
- e) A document detailing its quality system that includes an organizational structure that enables it to give confidence in its ability to perform the necessary activities to a Recognized/Approved Accrediting Authority;
- f) The documents detailing its policies and procedures for operating an Accrediting Authority, that will include the following:
  - i. Policies and decision-making procedures that distinguish between activities surrounding the activities for evaluating laboratories and any other activities in which the Accrediting Authority and the agency it is part of is engaged;
  - ii. Policies and Procedures for the resolution of complaints and appeals received from laboratories about the handling of laboratory accreditation matters, or from the users of the users of the services provided by an accredited laboratory.
- g) Policies and Procedures that demonstrate that the Accrediting Authority program manager and staff to be free from any commercial, financial and any other pressures which might influence the results of the accrediting process;
- h) Rules and structures for the appointment and operation of committees involved in the assessment and future activities of the Accrediting Authority;

- i. Committees shall be free from any commercial, financial or other pressures that might influence decisions, or;
  - ii. Shall have a structure where members are chosen to provide impartiality through a balance of interests where no single interest predominates.
- i) The Accrediting Authority shall not offer consultancies or other services that may compromise the objectivity of its accrediting process and decisions;
  - j) The Accrediting Authority will operate consistent with applicable laws to safeguard, at all levels of the organization, confidentiality of the information obtained relating to applications, assessments and accrediting of laboratories;
  - k) The Accrediting Authority will have the rights and responsibilities needed to administer its accrediting activities;
  - l) The Accrediting Authority will employ a sufficient number of personnel with the necessary education, training, technical knowledge and experience needed to handle the type, range and volume of the accrediting activities it administers;
    - i. These personnel will be assigned to the Accrediting Authority program manager (or senior executive) that is responsible to organization or agency to which the Accrediting Authority Program reports.
  - m) The Accrediting Authority shall have policies for either controlling the ownership, use and display of accrediting document; or for controlling the manner in which an accredited laboratory may refer to its accredited status; or both.

6.3.2. The procedures under which an Accrediting Authority operates shall be administered in a non-discriminatory manner.

- a) Ability of a laboratory to have access to, and be able to participate in, a program operated by an Accredited Authority shall not be conditional upon the size of the laboratory or membership in any association or group;
- b) There shall be no undue financial conditions to restrict the participation of laboratories in an Accrediting Authority Program.

6.3.3 The competence of laboratories applying for accreditation or for laboratories wishing to maintain accreditation shall be assessed on at least a minimum of those established by NELAC.

- a) The Accrediting Authority may need to interpret NELAC standards for a specific calibration or test. When this is necessary the interpretations shall be made by relevant and impartial committees or persons possessing the appropriate technical competence.
  - i. The Accrediting Authority shall publish information for which interpretations are made.
- b) The Accrediting Authority shall require accredited laboratories to maintain impartiality and integrity.
- c) The Accrediting Authority shall confine its requirements, assessments and decisions on accreditation to those matters specifically related to the scope of the accreditation being considered.

6.3.4 The Accreditation Authority shall not delegate its responsibility for granting, maintaining, extending, suspending or withdrawing the accreditation of laboratories.

#### 6.4 RECOGNITION/APPROVAL CRITERIA BY NELAC/NELAP TO BECOME AN ACCREDITING AUTHORITY

6.4.1 The Accrediting Authority must be successfully audited by a NELAC/NELAP team of auditors at least once every two years.

- a) If NELAC/NELAP suspects that the Accrediting Authority is experiencing problems or that it is not following the standards as established by NELAC, the Accrediting Authority may be audited more frequently.
- b) NELAC/NELAP Recognition/Approval Agreements will normally be comprehensive in nature.
  - i. When the Accredited Authority is applying for recognition/approval in limited analytical areas, the recognition/approval agreements may only cover portions of the full scope of NELAC standards.

6.4.2. The Accrediting Authority will be expected to prepare for the process for receiving NELAC/NELAP Recognition/Approval. Following are some requirements that Accrediting Authorities shall follow when preparing for the recognition/approval process;

- a) The Accrediting Authority shall be an operational/active program and not a proposed program;
- b) The Accrediting Authority shall have at least ??? months/years of operational experience;



- i. Includes completing the initial stage of all activities necessary to accredit laboratories in its program;
  - ii. A reasonable number of laboratory accreditations shall have been granted, and these shall have based on the requirements and guidelines established by NELAC.
- c) The Accrediting Authority shall have a full-time program manager;
- i. The program manager shall have sufficient experience in the development and/or operation of a laboratory accrediting authority.
- d) The Accrediting Authority shall have access to an appropriate measurement system that allows accredited laboratories to make measurements that are traceable to national or international standards of measurement;
- e) The Accrediting Authority shall have a quality manual or other document(s) that contains its policies and procedures and the responsibilities for implementation;
- f) The Accrediting Authority shall have available all current technical and non-technical criteria it has published. To include;
- i. Formal rules and regulations affecting the Accrediting Authority's operations and the obligations of the laboratories it accredits;
  - ii. Explanatory material describing the mechanics of operation of the laboratory accreditation system; such as annual reports, questionnaires, newsletters, guidance documents, reports of proficiency test programs, etc.
- g) The Accrediting Authority shall have available the full details and backgrounds of its staff. To include;
- i. Educational backgrounds;
  - ii. Work experience prior to employment with the Accrediting Authority;
  - iii. Work experience in laboratory accrediting activities.
- h) The Accrediting Authority shall have available a directory (or other listing) of the laboratories it accredits and the accreditation status of each laboratory.

- i) The Accrediting Authority shall have available all formal recognitions and reciprocal agreements it holds either nationally or internationally.
  - i. To include recognitions/agreements with government authorities, private sector organizations, other laboratory accreditation systems, etc.
- j) The Accrediting Authority shall have compared its activities with those established by NELAC, and have a document available defining its findings.

**6.5 RESPONSIBILITIES, ROLES AND QUALIFICATIONS OF THE NELAC/NELAP RECOGNITION/APPROVAL ASSESSMENT TEAM**

6.5.1 The NELAC/NELAP Recognition/Approval Assessment Team will review the application and the information given in 6.2 prior to the on-site audit.

- a) As part of the review process the NELAC/NELAP Recognition/Approval Assessment Team will appoint a team leader.

6.5.2 The NELAC/NELAP Recognition/Approval Assessment Team leader will prepare an agenda detailing the schedule of activities to be performed during the on-site audit of the Accrediting Authority. The agenda will be given to the Accrediting Authority as soon as available, and in most cases at least one month prior to the on-site audit.

- a) The agenda will include the following;
  - i. All activities with time schedules to be evaluated during the on-site audit;
  - ii. The names, titles, affiliations, and on-site audit responsibilities of the members of the NELAC/NELAP Assessment Team;
  - iii. The names and titles of all Accrediting Authority staff that need to be available during the on-site audit;
  - iv. The dates and times of scheduled audits of the Accrediting Authority's laboratory assessors, to include attending the actual on-site laboratory audit of selected assessors.

6.5.3 The Accreditation Authority shall respond to the NELAC/NELAP Approval/Recognition Team with comments concerning the audit at least two weeks prior to the scheduled audit.

6.5.4. The NELAC/NELAP Approval/Recognition Assessment Team will perform pre on-site audit, on-site audit (opening meeting, assessment of Accreditation Authority policy and procedures, assessment of the activities of laboratory assessors) and exit interview activities relating to the evaluation of an Accreditation Authority.

- a) The pre on-site audit will include the following activities.
  - i. Initial appraisal of all documents submitted by the Accreditation Authority either at the request of the NELAC/NELAP Approval/Recognition Assessment Team or submitted with the application;
  - ii. Preparation of a detailed agenda for the evaluation of the Accreditation Authority;
  - iii. Assembling of all necessary checklists, questionnaires, and information needed to audit the Accreditation Authority;
  - iv. Documenting the responsibilities of all NELAC/NELAP Approval/Recognition team members;
    1. The team leader should give to all team members the overall division of work responsibilities, to include estimates of time needed to complete assigned tasks and the schedule for completing the audit of the Accrediting Authority.
- b) The components and responsibilities of the on-site audit of an Accreditation Authority are as follows.
  - i. The NELAC/NELAP Approval/Recognition Assessment Team will begin the on-site activities associated with the evaluation of an Accrediting Authority with an Opening Meeting. The purpose of the Opening Meeting is as follows:
    1. To confirm the objectives of the audit;
    2. To present the scope of the activities to be covered during the audit;
    3. To confirm the activities associated with the on-site auditing of laboratory assessments;
    4. To make arrangements for reporting the outcomes of the audit.

- ii. After the Opening Meeting the NELAC/NELAP Approval/Recognition Assessment Team will conduct a detailed evaluation of the activities of the Accrediting Authority. This involves a process of discussions with the full-time manager and staff, and the examination of the Accrediting Authority's implementation of its policies and procedures to determine compliance with NELAC standards. The accreditation criteria of the Accrediting Authority and the operations of the laboratories it accredits will be compared to NELAC standards. This will include, but not be limited to, the following elements.
1. The scope of the system;
  2. Assurance that there are no restrictions to access to the system;
  3. The legal status of the Accrediting Authority;
  4. The financial stability, sources of funds and resources of the Accrediting Authority;
  5. The availability and backgrounds of technical staff;
  6. The organization structure of the Accrediting Authority and the responsibilities of individual staff assigned to the structure;
  7. The effectiveness of the Accrediting Authority's quality system as compared to the criteria given NELAC Section 5.0.
  8. The roles of the governing body and any external committees, and their relationships to the Accrediting Authority and its full-time manager (or officer);
  9. The procedures for the selection, training, contracting and appointment of laboratory assessors;
  10. The procedures for maintaining records of laboratory assessors and the usage of these records;
  11. The procedures for submitting and processing applications to the Accrediting Authority to become an accredited laboratory;

12. The procedures for preparing and issuing laboratory assessment reports;
13. The procedures for granting, maintaining, suspending, withdrawing and reinstating laboratory accreditation;
14. The policies for preparing laboratory accreditation schedules;
15. The procedure for maintaining the records of each applicant and accredited laboratory;
16. The procedures for ensuring confidentiality by staff, laboratory assessors and external committees where applicable;
17. The procedures for dealing with complaints and disputes;
18. The availability of accreditation criteria documentation and assessment procedural documentation to Accrediting Authority technical staff, Accrediting Bodies and external committees;
19. The procedures by which laboratories may appeal the decisions of the Accrediting Authority;
20. The Accrediting Authority's relationships with technical and other organizations both nationally and internationally;
21. The existence and extent of Accrediting Authority activities conducted by Accrediting Bodies;
22. The existence and content of recognition agreements with other Accrediting Authorities;
23. The conditions for use of the Accrediting Authority's logo or reference to accreditation by a laboratory;
24. The policies and procedures for use of proficiency testing data by the Accrediting Authority, for both tests conducted by the Accrediting Authority and tests conducted by other programs;
25. The policies for involvement of accredited laboratories in proficiency testing programs;



26. The policies for use of proficiency testing data for granting and maintenance of accreditation.

iii. As part of the on-site audit the NELAC/NELAP Approval/Recognition Assessment Team will audit the assessments of laboratories by the Accrediting Authority staff. This will involve, wherever practicable, both attendance at initial assessments of laboratories seeking accreditation and attendance at reassessment and/or surveillance assessments of laboratories already holding accreditation. The purpose of attending and witnessing assessments include the following.

1. To confirm that laboratory assessors are properly briefed and trained to conduct assessments;
2. To confirm that assessment teams/individuals are using the criteria and procedures established by NELAC and adopted by the Accrediting Authority;
3. To confirm that the assessment teams/individuals are effective in determining and recording/reporting the technical competence of laboratories for the tests for which accreditation is sought or held, and that they are effective in identifying any noncompliance with NELAC and Accrediting Authority requirements for accreditation.
4. To review the quality of guidance documents available for laboratory assessors, together with any supplementary criteria or rules used to evaluate laboratories accredited by the Accrediting Authority.

iv. The NELAC/NELAP Approval/Recognition Assessment Team will conduct an exit interview with the Accrediting Authority at the end of the on-site audit. At the exit interview the Team will present and discuss a draft report of its findings.

v. The Accrediting Authority will be given the opportunity to review the NELAC/NELAP Approval/Recognition Assessment Team draft report before the final report and recommendation is given.

6.5.5. The activities of the NELAC/NELAP Approval/Assessment Team will also include, but not be limited to, the following items.

- a) The Team will evaluate the published accreditation criteria of the Accrediting Authority to determine whether there is

sufficient documentation to evaluate the technical competence of the laboratories in the fields in which it grants accreditation.

- i. The evaluation will be conducted either as part of the pre on-site audit or during the course of the on-site audit.
  - ii. The evaluation will be based both on the criteria established by NELAC and interpretations of the supplementary criteria for specific fields of testing in which the Accrediting Authority operates.
- b) The pre on-site audit and on-site audit will include an initial appraisal of the documented policies and procedures used by the Accrediting Authority when compared to NELAC standards. This will be followed by an evaluation of the implementation by the Accrediting Authority of those policies and procedures, and appraisal of the effectiveness of the systems accreditation process to accredit technically competent laboratories that comply with NELAC standards and any other specified technical criteria.
- i. Evaluation with NELAC standards will require the exercising of some judgment and perhaps interpretation by the NELAC/NELAP Approval/Recognition Assessment Team. It is unlikely that each topic will be addressed in exactly the same manner by different Accrediting Authorities.
    1. The collection of sufficient detailed information on each topic to allow appraisal of the suitability of the practices used by the Accrediting Authority is required.
    2. Significant differences in approach by different Accrediting Authorities should not effect NELAC/NELAP Recognition/Approval. But these should be highlighted as they could effect the establishing of future Accrediting Authority recognition agreements.
- c) The NELAC/NELAP Approval/Recognition Assessment Team should prepare a set of briefing notes, checklists or questionnaires to detail their understanding of the operations of the various facets of the NELAC standards. These will be based on guidance established by NELAP.
- d) The witnessing of on-site laboratory assessments conducted by the Accrediting Authority will be to determine whether applicant and/or accredited laboratories are technically

competent to perform the tests or calibrations for which they seek or hold accreditation.

- i. For a comprehensive system it will normally be necessary to witness at least three and preferably four on-site laboratory audit per assessment of an Accrediting Authority. This will require that NELAC/NELAP Approval/Recognition Assessment Teams will need to split up to visit separate laboratory assessments.
  - ii. During the course of the assessment of an on-site laboratory audit it is essential that NELAC/NELAP Approval/Recognition Assessment Team members act only as observers. Team members must avoid influencing the performance and activities of the laboratory assessors and the responses of laboratory staff. Any of the Teams observations of the laboratories, laboratory assessors or to the practices of the Accrediting Authority should only be provided to the Accrediting Authority's representatives at the exit interview or in the draft and final reports.
  - iii. Part of the assessment of an on-site laboratory audit should include consideration of any guidance documents provided to laboratory assessors, and any supplementary criteria or rules needed to evaluate laboratories covered by the Accrediting Authority.
  - iv. The assessment team should examine the procedures used to report the finding of on-site laboratory assessors and to ensure that corrective actions are carried out by laboratories within required time periods.
  - v. The roles and interactions of any Accrediting Bodies used by the Accrediting Authority to conduct laboratory on-site assessments, with the laboratory assessors employed full time and directly with the Accrediting Authority should be evaluated.
- e) The NELAC/NELAP Approval/Recognition Assessment Team should schedule its activities to include the preparation of a draft recommendation report. The report should be presented to the Accrediting Authority as part of the exit interview.
- i. The draft report should include at least an overview of the observations made by the Assessment Team during the full course of the on-site assessment.
    1. The overview should summarize the main findings of the NELAC/NELAP Approval/Recognition Assessment

Team and it should be signed by all the Teams members.

- f) The NELAC/NELAP Approval/Recognition Assessment Team leader shall present at least a detailed verbal summary of the content of the draft final report to the Accrediting Authority as part of the exit interview.
    - i. The Accrediting Authority will have the opportunity to comment on and discuss the draft findings of the NELAC/NELAP Approval/Recognition Assessment Team for the purpose of correcting any misunderstandings that may have arisen.
  - g) The NELAC/NELAP Approval/Recognition Assessment Team leader shall complete a final report.
    - i. The final report will be given to all team members for their approval and signature.
    - ii. After approval by all team members the final report will be given to the Accrediting Authority.
    - iii. The fully signed final report will be given to the NELAC Accrediting Authority Standing Committee and to NELAP.
    - iv. The NELAC Accrediting Authority Standing Committee will review the report, make recommendations and present it to the Chair, NELAC.
- 6.5.6. The NELAC/NELAP Approval/Recognition Assessment Team will be composed of persons that have the necessary expertise, experience and competency to evaluate and environmental laboratory Accrediting Program. The composition of the team will vary depending on the scope of the Accrediting Program. The Team will be composed of persons with the necessary education, training, technical knowledge and experience for evaluating the type and scope of accreditations offered.
- a) The number of persons on the Assessment Team will vary depending on the scope of the laboratory Accreditation Program.
    - i. The Assessment Team will be composed of at least three members.
  - b) The Assessment Team members need to be will qualified to assure that only high quality accreditation programs are granted NELAC/NELAP Approval/Recognition.



- i. For instance, an Accrediting Authority that offers accreditation for the analysis of air, drinking water, solid and hazardous wastes, water quality or other program would need to be evaluated by a team that has expertise in each of the represented areas.
- ii. The Assessment Team members must be familiar with accreditation processes, NELAC standards, and be knowledgeable of laboratory practices, procedures and regulations.
- iii. The Assessment Team members must be familiar with applicable laboratory standards for which the Accrediting Authority serves.
- iv. The Assessment Team members must have a thorough knowledge of relevant assessment methods and assessment documents.
- v. The Assessment Team members must be able to communicate effectively, both in writing and orally.
- vi. The Assessment Team members must be free of any commercial, financial or other pressures or conflicts of interest that might cause them to act in other than an impartial or nondiscriminatory manner.

c) Requirements for Assessors

- i. Professional Requirements - A university degree (or equivalent) is a pre-requisite for an Assessor. Although, it must be recognized that people occasionally change their career path and sometimes achieve professional standards in areas of science and technology unrelated to their first degree.
  1. Assessor candidates shall have competed at least secondary education. That is, that part of national education system that comes after the primary or elementary stage, but prior to that which qualifies for a degree.
  2. Assessor candidates shall have demonstrated competence in clearly and fluently expressing concepts and ideas orally and in writing in their national language.
- ii. Auditing Competence - Assessors shall have a sound understanding of the philosophy of accreditation systems.



1. Assessors shall have a thorough knowledge of the content of accreditation system standards
  2. Assessors shall be able to apply the requirements of accreditation systems to different organizations.
  3. Assessors shall be able to conduct an assessment effectively.
  4. Assessors shall be trained in the skills and techniques of auditing and shall be able to demonstrate their skills and proficiency in assessing.
- iii. Inter-personal and Administrative Skills - Assessors shall have effective administrative and leadership skills. To include, but not be limited to the following.
1. Administrative skills;
  2. Planning and organizing ability;
  3. Flexibility and ability to adapt to changing circumstances;
  4. Capacity to work independently and systematically;
  5. Leadership (especially for team leader);
  6. Communication skills (all forms);
  7. Ability to secure cooperation from others;
  8. Conflict resolution skills;
  9. Decision making skills.
- iv. Personal attributes - The following will have an influential role in generating confidence in and respect for an assessment team and assessment team members.
1. Objective and unbiased approach;
  2. Sensible and practical outlook;
  3. Commitment to the assessment activities;
  4. Good outward impression.

- v. Training - Assessor candidates shall have undergone training to the extent necessary to ensure their competence in the skills required for conducting on-site assessments and for managing on-site assessments. Training in the following areas shall be regarded as particularly relevant.
1. Standards against which on-site assessments (quality system audits) are performed;
  2. Assessment techniques for examining, questioning, evaluating and reporting
  3. Skills required for managing an on-site assessment (audit), such as planning, organizing, communicating and directing;
  4. Competence shall be demonstrated through written or oral examination, or other acceptable means.
- vi. Experience - Assessor candidates shall have minimum of four years full-time appropriate practical workplace experience (not including training).
1. At least two years of the four years experience shall have been in a laboratory.
  2. Assessor candidates shall have experience in auditing prior to leading an Assessment Team or participating as an Assessment Team member. Experience shall include participating in a minimum of four on-site assessments that include documentation, review, actual laboratory auditing and audit reporting.
  3. All necessary experience shall be reasonably current.
- viii Language - Assessors shall be fluent in the agreed upon language of the audit or have language support staff as part of the Assessment Team.
1. No assessor shall participate in an audit without language support staff where he/she is not fluent in the agreed upon language of the audit.
  2. Where language support staff is necessary the person shall be fluent in the agreed upon language of the audit, have the necessary technical language skills, and shall not be subject to any pressures that would effect the performance of the audit.

- d) Duties of the NELAC/NELAP Approval/Recognition Assessment Team members.
- i. Duties and Responsibilities of the Assessment Team leader.
1. The Assessment Team leader is ultimately responsible for the proper implementation of all phases of the assessment process as given in 6.5.
  2. The Assessment Team leader is specifically responsible for the leadership of the Assessment Team during planning and preparation, the on-site assessments, and completion of the final report/recommendation.
  3. The Assessment Team leader is responsible for tracking any corrective actions or follow-up activities required of the Accredited Authority.
  4. During the planning and preparation phase of the on-site assessment, the principal tasks of the Team Leader will include, but are not limited to, the following.
    - \* Reviewing the Accrediting Authority's documentation to determine compliance with NELAC standards.
    - \* Preparing the assessment checklists to be used during the on-site assessment.
    - \* Selecting and briefing the Assessment Team.
    - \* Developing the assessment plan.
    - \* Making all the arrangements associated with the assessment.
    - \* Acting as the primary contact with the Accrediting Authority.
  5. During the on-site assessment, the principal tasks of the Team Leader will include, but not be limited to, the following:
    - \* Managing the assessment to ensure that it is conducted properly and that its objectives are achieved.

- \* Monitoring the activities of the Assessment Team members, and providing them with necessary support.
  - \* Playing a central role in assessment of the important accreditation elements.
  - \* Assembling the findings of the assessment, and confirming the nature of any nonconformities.
  - \* Acting as the spokesperson for the Assessment Team, especially in the presentation of the results of the assessment to the Accreditation Authority and NELAC/NELAP.
6. On completion of the on-site assessment, the principal tasks of the Team Leader will include, but not be limited to, the following.
- \* Completing the draft and final assessment team reports.
  - \* Following up on nonconformities raised during the assessment to ensure that effective corrective action is taken.
  - \* Completing the administrative tasks associated with the completion of the assessment in accordance with NELAC/NELAP procedures.
- ii. Duties and responsibilities of Assessment Team Members.
1. The role of Assessment Team Members will be to assist the Team Leader and perform the functions necessary to conduct an effect on-site assessment of an Accrediting Authority.
  2. Team Members shall fulfill the roles and tasks that have been assigned to them by the Team Leader.
  3. Team Members shall conduct and complete their assigned roles and tasks within the constraints of the assessment plan.
  4. Team Members shall keep the Team Leader informed of their findings, especially any major nonconformities they discover.
  5. Team Members shall accumulate and record the objective evidence needed to support their findings.

6. Team Members shall assist the Team Leader in the preparation of the draft and final written reports on the on-site assessment.

e) Roles of the Assessment Team Members

- i. Team Leader - The Team Leader shall be a professionally qualified member appointed by NELAC/NELAP. He/she shall be thoroughly familiar with the policies, rules and procedures of NELAC/NELAP, and shall be able to draw upon all the resources of NELAP in arranging the assessment and preparing the briefing documents.
  1. The Team Leader shall manage the assessment to ensure that its objectives are maintained.
  2. The Team Leader shall coordinate and monitor the activities of the assessment team and ensure that they receive all the cooperation necessary from the Accrediting Authority.
  3. The Team Leader shall have a primary role in the auditing of the accrediting program.
  4. The Team Leader shall be the spokesperson for NELAC/NELAP and the assessment team throughout the audit.
  5. The Team Leader at the end of the audit shall implement NELAC/NELAP's procedures for reporting the results of the audit and for initiating any follow up action that is needed.
- ii. Team Members - Team Members will help to ensure that every assessment team acts on behalf of NELAC/NELAP and that the team contains experts who have a sound understanding of NELAC standards and auditing processes.
  1. Team Members shall assess the technical integrity of the Accrediting Program.
  2. Team Members shall assist the Team Leader in assessing the Accrediting Authority, especially at the interfaces between the program and the laboratories included in its program.
  3. Team Members shall identify for the Team Leader the technical deficiencies disclosed by the assessment so that these can be summarized in the exit interview.



4. Team Members will help to prepare the draft and final written reports in accordance with NELAC/NELAP procedures.

f) Assessment Team Members will be required to have training relating to the evaluation of Accrediting Authorities.

- i. Training should either be conducted by NELAP or be approved for use by NELAC/NELAP.

- ii. Training in the following areas is appropriate.

1. Knowledge and understanding of the standards against which assessments may be conducted.

2. Assessment techniques for examining, questioning, evaluating and reporting.

3. Skills for managing an assessment, such as planning, organizing, communicating and directing.

## 6.6 ACCREDITING BODIES

6.6.1. The Accrediting Authority may use Accrediting Bodies to perform some of the functions in the accreditation process. Accrediting Bodies are non-government agencies.

a) Accrediting Bodies cannot be used to grant, suspend, revoke or assess penalties on accredited laboratories.

6.6.2. Accrediting Bodies shall provide descriptions to the NELAC/NELAP Approval/Recognition Assessment Team of any separate functions or affiliations it has to activities other than laboratory accreditation.

6.6.3. The Accrediting Authority will need to clearly define the roles of the Accrediting Bodies for each Accrediting Body it has subcontracted part of the laboratory assessment process.

## 6.7. COMPLETING A NELAC/NELAP APPROVAL/RECOGNITION AGREEMENT

6.7.1. After completion of the on-site assessment and final report it is necessary for the Accrediting Authority and NELAP to have documented all actions taken as a result of the Assessment teams activities.

6.7.2. The final text of the agreement needs to be approved by the Accrediting Authority and NELAP.

a) For some agreements the text is standardized.

- b) Agreements shall reflect any special circumstances.
- c) NELAP/NELAC Recognition Agreements shall in most cases follow a standardized format (see Appendix C).

6.7.3. Recognition Agreements shall have at least the following information.

- a) Purpose - Explaining the aim of the agreement.
- b) Background - A brief description of the key feature of the Accrediting Authority covered by the agreement.
- c) Understanding - A list of the obligations of the Accrediting Authority and of NELAC/NELAP. Normally, this includes declaring equivalence of confidence in the Accrediting Authority's ability to administer its program; the willingness for the Accrediting Authority to accept NELAC standards and to promote the use of NELAC standards; the capability of the Accrediting Authority to resolve differences between laboratories; and the willingness of the Accrediting Authority to exchange information and literature.
- d) Name and address of parties to the agreement.
- e) Liaison Officers - The identification of staff in the Accrediting Authority and NELAC/NELAP who will be the primary contact points for matter included in the agreement.
- f) Period of Agreement - Two years is typical for an agreement unless a shorter time period is necessary.
- g) Appendix - Comparison of Practices and Criteria - A summary of the analyses of the similarities and differences of the Accrediting Authority to the NELAC standard. This could be an important component of some agreements as it is a recognition that although different techniques may be used for certain aspects of the program, all parties accept that the end result is a comparable level of confidence in each systems operation.

## APPENDIX A

Example of a timetable for a NELAC/NELAP Approval/Recognition Assessment Team to evaluate an Accreditation Authority (by a Team of at least two (2)).

### Before Visit

A NELAC/NELAP Approval/Recognition Assessment Team leader is appointed. Authority's documentation is examined by team members and questions prepared. Allocation is made of specific evaluation tasks to individual team members. A team meeting is conducted before-site assessment.

Day 1 - At offices of Accrediting Authority presentations by team leader outlining aims, objectives and procedure to be adopted by audit team; background presentation on authority's operation by senior staff of Accrediting Authority, discussions with staff of Accrediting Authority on its administration and its quality system and its implementation.

Day 2 - Attendance as observers at laboratory assessment visit(s): typically one or two members of team at one laboratory with Accrediting Authority's assessors and two at another; or one team member at each of two assessments.

Day 3 - Attendance as observers at laboratory reassessment or surveillance visit(s): typically one or two members of team at one laboratory with Accrediting Authority's assessors and one or two at another, or one team member at each of two reassessment or surveillance visits.

Day 4 - Audit of authority's assessor training, and proficiency testing activities plus any administrative aspects not covered on Day 1.

Day 5 - Completion of summary of report completion of draft final report presentation and discussion of findings to accreditation authority at offices of Accrediting Authority\*. Each evening the team should assemble at their hotel and discuss the day's findings as recorded on checklists and questionnaires and then prepare a draft report.

### Post-evaluation

Team leader should complete a draft report, checking its accuracy with team members and submit it to the authority that has been evaluated for comment.

After receiving comments the Team Leader is responsible for preparing the final report.

## APPENDIX B

### Contents of Audit Reports

It is recommended that audit reports follow a format similar to the following:

1. A cover page - identifying team leader, team members, dates of audit and organizations involved.
2. A summary page - prepared and signed by team members and handed over to the Accrediting Authority at the exit interview. This should contain the main conclusions and recommended actions needed to conclude an agreement.
3. An introduction - reason for audit, participants, criteria against which audit is performed, activities undertaken during audit, provision of documentation and translations, planning of laboratory visits and object of report.
4. A history of the Accreditation Authority under assessment including:
  - Relationship to government, responsibilities, management, numbers of accreditation, staffing levels and agreements with other authorities.
5. Observations on administration of system:
  - Covering compliance with the NELAC Standard. Comments should follow headings of NELAC Sections 6.1 - 6.7.
6. Observations on the assessment of the authority's technical criteria (against the NELAC Standard and supplementary criteria) providing details of examination of the Accrediting Authority's technical criteria and guidance documents.
7. Observations on evaluation of the performance of laboratory assessors used by the system, including observations made at visits as compared with the NELAC Standard and on organization of visits, compliance by laboratories traceability in laboratories, non-compliance reporting and assessment reports.
8. Observations on use of proficiency testing by the Accrediting Authority.
9. Where appropriate, compliance with any other standards in addition to the NELAC Standard.
10. Summary

## 11. Appendices

List of documents supplied before evaluation  
Details of visit program  
Miscellaneous material



## APPENDIX C

### Typical Content of a NELAC Recognition Agreement between an Accrediting Authority and NELAC

#### 1. Agreement

##### Accrediting Authority Recognition Agreement

The Accrediting Authority denotes the {to be defined} who are responsible for operating accreditation systems for testing in {to be defined}.

The criteria for the operation of accredited testing laboratories and for the operation of the recognized Accrediting Authority are specified in the {to be defined}.

The cooperation of the NELAC for testing started formally In {to be defined} and is based on the NELAC Standards. An ongoing program of cooperation has been set up which is aimed at establishing confidence between authority's, so that agreements can be entered into that recognize the technical equivalence of the operation of their accreditation systems for testing laboratories.

## RECOGNITION AGREEMENT

1. This Agreement is based on the results of the evaluations carried out in accordance with the NELAC Standard Section 6 - Accrediting Authority.
2. The parties entering this Agreement are the Accrediting Authority in the {to be defined} and NELAC that have signed the Agreement on behalf of the accrediting systems for testing for which they are responsible.
3. On the basis of the equivalence of the operation of the Accrediting Authority, hereinafter also referred to as "Systems(s)", hereby declared, each signatory to this NELAP Agreement states that his/her agency will:
  - I recognize the operation of the other systems by the Accrediting Authorities that are Signatories of this NELAP Agreement as equivalent to its own;
  - II recommend acceptance on an equal basis with those of its own accredited testing laboratories of the Test Reports and Test Certificates from the testing laboratories that are accredited by the other Accrediting Authorities that are Signatories to this NELAP Agreement;
  - III promote the acceptance of Test Reports and Test Certificates of accredited laboratories of Systems that are operated by the Accreditation Authorities that are Signatories to this NELAP agreement by all users in its own state;
  - IV investigate all complaints by a Signatory to this NELAP Agreement resulting from Test reports and Test Certificates issued by the accredited laboratories of its own System;
  - V notify all other Signatories as soon as possible of any significant changes that have or will occur in the status and or operational practices of its own Accrediting Authority and System.
4. If a Signatory wishes to withdraw from this Agreement for any reason whatsoever, NELAP shall be notified in writing not later than six months in advance of withdrawing. Upon withdrawing of the Accrediting Authority, this Agreement shall be null and void.
5. Any amendment of the text of the Agreement shall be made in accordance with the rules of procedure of NELAC.
6. This Agreement consists of three pages and is signed on behalf of each participating recognized accreditation agency that operates a recognized accreditation system for testing laboratories.

7. This Agreement has come into force on {to be defined}.

8. Signatories

Authorized Representatives of Nationally Recognized Accreditation  
body responsible for operating NELAC and of the Accredited  
Authority which are party to the Agreement.  
{to be defined}  
{to be defined}

## CODE OF CONDUCT FOR ASSESSORS

The NELAC/NELAP requires each of its assessors to adhere to code of conduct. The following code covers the essential ethical behavior of assessors.

### CODE OF CONDUCT

All assessors are required to confirm formally their willingness to observe and be bound by the following code.

- (a) To act in a strictly trustworthy and unbiased manner in relation to NELAC/NELAP and any organizations involved in an assessment by them or personnel for whom they are responsible;
- (b) To disclose to NELAC/NELAP any relationships they may have with the organization to be assessed before undertaking any assessment function of that organization;
- (c) To not accept any inducement, gift, commission, discount or any other profit from the organizations assessed, from their representatives, or from any other interested person nor knowingly allow personnel for whom they are responsible to do so;
- (d) To not disclose the findings, or any part of them, of the assessment team or which they are responsible, or any other information gained in the course of the assessments to any third party, unless authorized in writing by both the assessee and NELAC/NELAP to do so;
- (e) To not act in any way prejudicial to the reputation or interest of the NELAC/NELAP or to the Accrediting Organization;
- (f) To in the event of any alleged breach of this code, cooperate fully in any formal enquiry proceedings.