

TNI NELAC Assessment Readiness Review Checklist

Below are listings of questions and/or instructions that are essential to complete your assessment. Please complete this checklist and return via fax to PJLA at (248) 213-0737 or by email at insert APA email address. Also, please note that PJLA has updated documents and policies that can found on our website at www.pjlabs.com, please take the time to review these at your earliest convenience.

Company Name:

1) Has there been any major changes in your organization? Yes No

If yes, please provide details of these changes:

2) Has your laboratory completed an internal audit cycle within the last 12 months? If yes, did this address all requirements of the TNI NELAC? Yes No

3) Has your laboratory completed a management review within the last 12 months? If yes, did this address all requirements of the TNI NELAC? Yes No

4) Has your laboratory completed Proficiency Testing for all areas of your scope to be accredited? Yes No

If no, please explain.

Note: The laboratory has the right to declare information gathered during an assessment as confidential business information according to procedures established by the accreditation body or to restrict access to information requested during an assessment when such information directly affects nation security. Please submit this request directly to PJLA Headquarters.

Thank you for completing this readiness review checklist. In order for your assessment team to conduct a document review of your laboratory, please submit the following material to PJLA at least 30 Days prior to your assessment.

- Your proposed scope of accreditation including matrix, method and technology. See item 6, the scope may be completed on the PT tracking sheet.
- 2) Quality Manual and Associated Operating Procedures
- 3) Technical Standard Operating Procedures for test methods on your scope of accreditation
- 4) Laboratory Control Limits/Charts for Laboratory Control Sample for each method



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- 5) Verification of Limit of Detection and Limit of Quantitation for each analyte/method
- 6) Three Rounds of Proficiency testing results for all tests applied for or currently on your scope of accreditation ; (data shall not be older than 18 months and the latest PT shall be within the last 6 months from the date of the assessment)
- 7) New Accreditations: A completed TNI NELAC Checklist LF-56elap (Can be accessed on the PJLA website: <u>http://www.pjlabs.com/resources/pjla-documents</u>). Note-Please refrain from simply indicating Y or N. Comments reflecting related processes, procedures or records should be made to address each question. Checklist should be typed and submitted in Microsoft Word or Excel format; each relative comment should point to the related procedure and specific section demonstrating compliance. Assessors will verify entries and gather objective evidence during the assessment.
- 8) Reaccreditation/Surveillances: A completed TNI NELAC Checklist LF-56elap for updated or changed information since the previous assessment (Can be accessed on the PJLA website: <u>http://www.pilabs.com/resources/pila-documents</u>). Note-Please refrain from simply indicating Y or N. Comments reflecting related processes, procedures or records should be made to address each question. Checklist should be typed and submitted in Microsoft Word or Excel format; each relative comment should point to the related procedure and specific section demonstrating compliance. Assessors will verify entries and gather objective evidence during the assessment.
- 9) Cross reference of the TNI NELAC requirements and with quality manual, procedures and records. This can be addressed through annotation and references to specific procedures and records on the TNI NELAC noted in item 9-10 above.
- 10) Evidence of internal audits and management review specifically addressing the requirements of the TNI NELAC including the appendices. This evidence can be examples rather than an exhaustive audit, but it will be expected that all the TNI NELAC specifics will have been implemented and in effect. An internal audit of these would assure compliance and effectiveness.

Please submit items 1-10 to PJLA headquarters at least 30 days prior to your assessment. It is highly recommended and preferred for this documentation to be copied onto a CD and mailed directly to PJLA at: 755 Big Beaver Road, Suite 1325, Troy, MI 48084, Attention PJLA Scheduling Department

Completed By:

Completion Date: _____