

Project Plan: TNI Standard Implementation

Document: ProjectPlan-NewTNIStandardImplementation-11-28-10-v11

#	Date Assigned	Category	Assigned To	Project Title / Details	Expected Completion Date	Next Review Date	Status Update (Include Date of Review and Action Items)	Completed
1	02/12/10	Implementation Tools	QAM Template Subcommittee	<p>QAM Template Update Update 2003 NELAC QAM Template. Create a tool that will help laboratories prepare a QA Manual compliant with the new TNI Standard. Include multiple examples of documents, forms and procedures that might be helpful to laboratories. Work with Expert Committees, TAC and SLAG to provide these examples. Draft should be done for the Washington, DC meeting to get input from membership.</p>	12/31/10	12/20/10	<p>5/28/10: Manual has been broken down into sections to make it easier to update. Subcommittee members are choosing sections to work on. Plans are being made for face-to-face meeting in California to work on manual. 6/4/10: Sections have been assigned to subcommittee members. Re-write is in progress and needed tools for implementation are being looked for. On-line tool will be used to coordinate the update. 6/10/10: Sections for the Manual have been distributed and are being worked on. 7/26/10: Progress continues to be made. Drafts for each section are to be completed by 8/3/10. Most of the subcommittee is able to use the on-line tool to distribute their draft sections for comment. 8/9/10: There are still 3 sections that need to be completed and then Ilona will compile and do a first edit DRAFT. The subcommittee has started listing the tools they feel will be helpful to labs to implement the template. The DRAFT is anticipated late September/early October. 11/28/10: DRAFT template was distributed for comment. Comments are due first week of December. Updates will be incorporated and Jan will help with formatting. Tools are being collected for the website to help people update lab procedures. Training will be done in Savannah.</p>	
2	01/27/10	Implementation Tools	QS Expert Committee	<p>Guidance Document - On-going DOCs Clarify need for on-going DOCs through providing examples to QAM Template Subcommittee. (V1:M4 1.6.3) Original LASC Recommendation.</p>	08/31/10	12/20/10	<p>6/10/10: QS will be asked to review and update Section 22 of the QAM template. This section covers this topic. Examples can be posted as tools for implementation of the QAM. Ilona will forward the section and Jane will work with QS on the action item. 7/26/10: Silky is working with the QAM Template subcommittee to update Section 22. A Draft will be complete by 8/3/10 and reviewed in DC. Silky is also looking at the tools needed to help implement this section. 9/1/10: The draft was completed and will be reviewed as part of the QAM template review process.</p>	

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3	01/27/10	Implementation Tools	PT Expert Committee	<p>Guidance Document - PTRL Issue There is still an issue regarding the clarification and use of the PTRL. Include LASC in final review of document. (V1:M1, V2:M1, V3) Original LASC Recommendation. Need a plan from the PT Providers on how this is being addressed.</p>	06/30/10	CLOSED	<p>3/9/10: Ilona met with the PT Expert Committee. They are looking at formulating a document that answers three basic questions: 1. Lab: How do I report? 2. PT Provider: How do I score? 3. AB: What do I do with the PT data? A subcommittee has been formed to work on this and they will look at possible formats. Adding this to a master list of FAQs is a possibility. They hope to have something together by May 2010. 4/12/10: The work group is working on the draft document that will be discussed during the PT call this week. The document will most likely be finalized for presentation at the August meeting. 5/13/10: The PT Expert Committee discussed this action item and Ilona contacted a number of PT providersg got input. The conclusion was that no one felt there is any confusion on this topic. It was felt that the Standard Interpretation Request system should be sufficient to deal with any issues that should arise, but no one expects anything. It is requested that this be taken off the list. 6/10/10: Agreement from LASC and PA's. Item is closed.</p>	X
4		SOP/Policy Documents	AB Expert Committee	<p>Guidance/Policy - Timelines for Renewal Need a guidance document or perhaps an additional "Note" in the standard to refer to specific policies and SOPs that put specific timelines on the renewal process. (V2:M1 7.7.3) Original LASC Recommendation.</p>	10/31/10	12/20/10	<p>5-9-10: From ABC - The timelines previously used (for the NELAC Standard) are being carried forward into the Evaluation SOP for the TNI Standard. This SOP has been in progress for about a year and should be complete soon. Dan Dickinson will provide a copy of the current draft to the LASC. It is being worked on by the evaluators. The AB Committee agreed to complete this evaluation SOP by October 2010. See Item #22 in this spreadsheet. 11/28/10: Evaluation SOP has been completed and it is now in review.</p>	

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5		SOP/Policy Documents	AB Expert Committee	<p>Guidance/Policy - Surveillance On-site Assessments</p> <p>"Surveillance on-site assessments" needs to be defined. There is a limited definition in V2M3 but this too needs to be explained in guidance. (V2:M1 – 7.7.1) Original LASC Recommendation. Jerry is concerned that this might not be allowed in the standard - if it is not - perhaps it should be considered.</p>	07/10/10	12/20/10	<p>5-9-10: From ABC - A guidance Statement on surveillance on-site assessment is being drafted by the AB committee for review in the July 2010 teleconference.</p> <p>6/24/10: Update provided at TNI strategy meeting: The current standard does not allow it because a full assessment every 2 years is written into the standard as a requirement.</p> <p>7/31/10: An update was requested.</p> <p>8/20/10: Committee chair said an update would be provided after the September AB meeting.</p> <p>11/30/10: A copy of some guidance the committee worked on was forwarded to the LAS EC Chair on 11/30/10. LAS EC needs to review and comment.</p>	
6		SOP/Policy Documents	Policy Committee	<p>Procedure - Complaint Process</p> <p>Prepare procedure to resolve conflicts/complaints.</p>	01/31/10	12/20/10	<p>6/10/10: The committee has completed the list of what needs to be completed and is now ready to begin writing this SOP. This should be complete before the DC meeting.</p> <p>7/22/10: The committee discussed the procedure at the last Policy Committee meeting and there will be further discussion in DC. The procedure will not be complete by 8/9/10.</p> <p>8/9/10: A DRAFT SOP was prepared for review in DC. Comments are being incorporated.</p> <p>11/28/10: Expected Completion date changed to 1/31/10. This SOP is still being worked on.</p>	
7		Implementation Tools	LASC	<p>Standard Interpretation Requests (SIRs)</p> <p>Review current interpretations from 2003 Standard and map to new TNI Standard. Is an interpretation still relevant and if so, what is the section reference in the new standard?</p>	02/15/11	01/31/11	<p>6/10/10: Jerry's notes should be a helpful start on this. This can be completed by Jerry and Ilona if it does not fit in LASC's schedule.</p> <p>11/28/10: Completion date set to 2-15-11.</p>	
8		Implementation Tools	LASC	<p>SIRs</p> <p>Set-up site for interpretation requests for the new TNI Standard. Include old interpretations that are still relevant.</p>	CLOSED	CLOSED	<p>6/10/10: Ilona will work with William on this.</p> <p>8/4/10: This action item is complete. Inquirers can now select which standard the question is relevant to.</p>	X

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9		Training	NELAP AC	<p>Can I Implement the New Standard Now? LASC needs to prepare an answer to this question for a Training Workshop PPT slide. Consider preparation of guidance on how to move to the new standard - what do you need to add and when? What can you stop doing? etc ...</p>	TBD	12/20/10	<p>3/3/10: Needs to be turned into a mini document since the presentation is not available on the website. Jerry will send update and LASC will be asked to review specific parts that Jerry will outline. 6/10/10: Jerry prepared a memo to outline implementation of the new standard. It summarizes information discussed during the review of the Training Workshop PPT. This document needs to be reviewed by LASC and the NELAP Board so that it can be made available. 7/31/10: Jerry prepared a document and the LASC was asked to review it before it goes to the NELAP Accrediation Council for review. A reminder for comments was sent 7/31/10. Expected completion date extended to 9/1/10. 8/3/10: Comments from LAS EC were forwarded to Jerry. 9/7/10: Jerry updated the document based on comments and forwarded to the NELAP AC for comment. 9/27/10, 12/6/10: Asked NELAP AC for update.</p>	
10	2/2010	Training	LASC	<p>Review Workshop Training PPT Review slides 31 and forward. Is there anything missing? Use info to help with Action Item #9.</p>	CLOSED	CLOSED	2/28/10: Completed	X
11		Implementation Issues	LASC / NELAP Board	<p>Resolution for Potential New TIA Implementation Issues Will states have an issue implementing any new TIAs? Can they enforce them? Should Policies and SOPs be used instead?</p>	CLOSED	CLOSED	<p>3/3/10: There will not be any new TIAs for Volume 1. There may be a request for a standards interpretation. A new TIA for Volume 1 would require everything to start over.</p>	X

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12	01/27/10	Implementation Tools	Quality Systems	<p>Quality Systems Checklist - Laboratory Assessments Checklist needs to be prepared for ABs to use during laboratory assessments.</p>	12/31/10	12/20/10	<p>3/3/10: This will need to be done and ready for AB training in Savannah (1/2011) 4/9/10: QS Committee had said it was done and ready for LASC review. A subcommittee has been formed within LASC to review, but LASC has not received it. A request was made on 4/8/10. It needs to come through LASC before June so that the subcommittee can review and comment with a enough time for an update to happen before DC. 5/13/10: The standard was received from QS. Each of the NELAP states is being contacted to see what they are currently doing, what ideas they have for improvement and how they feel about a checklist that is essentially the standard line by line. These responses will be evaluated and a recommendation will be made regarding the checklist. 7/31/10: LASC has formed a subcommittee to review the checklist and make recommendations to the Quality Systems Expert Committee. The checklist will be discussed in DC. 9/27/10: Comments were forwarded to Quality Systems Expert Committee. Will request status from QS after their October meeting. 11/28/10: Update requested.</p>	
13	03/12/10	Implementation Tools	TAC	<p>LOD/LOQ Guidance PDF of presentation given in Chicago is on the website. A subcommittee has been formed to evaluate the best way to give this training? Most feel a webinar would be the most effective and that there needs to be a charge for this training.</p>	07/01/10	12/20/10	<p>TAC subcommittee has met and agree webinar would be best way to move forward. 6/10/10: Carole will work with TAC to complete this action item. The following options should be considered: <u>Webinar:</u> Training course, workshop or seminar provided at a specific time with a moderator and attendees viewing materials on-line. <u>Webcast:</u> A downloadable streaming video file of a training course, workshop or seminar <u>On-line course:</u> A training course taken on line that allows participants to progress at their own pace by moving though a computerized menu. No speaker is present. 6/24/10: There will be a charge for this training. 11/28/10: A webinar will be developed for January. Richard Burrows and Brooke Conner are working on this.</p>	

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14		Implementation Issues	CSDB	TIA Implementation TIAs already approved have a window of time that they can be in place. What happens if this time runs out before the new language is voted in.	CLOSED	CLOSED	Working drafts to be done by August to include the TIA language. These specific portions of the standard will be voted on. This shouldn't be an issue.	X
15		Implementation Issues	PT Expert Committee	PT TIAs Incorporate TIAs and prepare a working DRAFT standard by May 2010. Public comment should happen in June and then they will be ready for additional discussion in DC in August.	TBD	01/15/11	6/10/10: Jane Wilson will work with PT and QS to develop a schedule to ensure that everything is completed on time. 6/21/10: Message from PT Expert Committee Chair: The PT committee will not have the WDS prepared in time. The TIA process has taken longer than expected. We will discuss our intent for release of the WDS at our meeting in Washington and expect to release the WDS for public comment after the meeting. 8/12/10: TIAs were reviewed with the membership in DC and many ideas were given. Comments will be reviewed and assessed at the next PT Expert committee meeting. The committee will continue to move forward on the WDS. 11/28/10: The committee plans to have a new WDS for the Savannah meeting. We will review the WDS then, then release for public comment / vote after Savannah and use the Seattle meeting as the public forum to discuss / resolve comments.	
16	01/27/10	Training	TAC	Nationwide New Standard Training Workshops Make training on the new standard available to laboratories across the country.	04/01/10	CLOSED	On-going.	X
17	03/12/10	Training	On-Site AB Expert Committee LASC	AB Training Training for ABs needs to be developed and performed.	08/01/10	12/20/10	Given in DC. Will become Webinar after that in the fall. 6/10/10: Jerry is working on a first DRAFT of this training. It will be distributed to On-site and ABC for comment. LASC will be asked to review the final draft. 8/3/10: Training is complete and will be presented in DC. 9/10/10: Committee is not aware of anything further to be done on this. They did the training session in Washington, it should be closed now as far as they know. Ilona had heard discussion of doing additional web based training. 11/28/10: E-mailed Jerry and Carol to see if web based training is still needed.	

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18		Implementation Tools	On-Site	Basic Assessor Training Curriculum Guidance	07/20/10	CLOSED	<p>6/10/10: Disclaimer language is being added and then this document will be complete. Information will be presented at DC meeting.</p> <p>9/10/10: Document submitted to TNI Webmaster for posting. Closed as far as committee is concerned.</p>	X
19		Implementation Tools	On-Site	Technical Assessor Training Curriculum Guidance	07/20/10	CLOSED	<p>6/10/10: Disclaimer language is being added and then this document will be complete. Information will be presented at DC meeting.</p> <p>9/10/10: Document submitted to TNI Webmaster for posting. Closed as far as committee is concerned.</p>	X
20		Implementation Tools	On-Site	Laboratory On-site Assessment Guidance	07/20/10	CLOSED	<p>6/10/10: Disclaimer language is being added and then this document will be complete. Information will be presented at DC meeting.</p> <p>9/10/10: Document submitted to TNI Webmaster for posting. Closed as far as committee is concerned.</p>	X
21		Training	TAC	<p>Evaluator Training Training for the evaluators needs to be performed. Needs to be developed and training needs to be done.</p>	12/15/10	01/15/11	<p>Needs to be done by Savannah (Jan 2011.)</p> <p>6/10/10: Evaluation SOP needs to be complete before training can be prepared. An RFP will be distributed by October 2010 to find a trainer.</p> <p>11/28/10: An RFP was issued and Marlene Moore was selected to do the training. She has been given a Final DRAFT of the Evaluation SOP to assist with development of the course material. The course will be given in Savannah in February 2011.</p>	
22		SOP/Policy Documents	AB Committee (NELAP Board) (LASC)	<p>Update Evaluation SOP Update Evaluation SOP to be consistent with new standard. Prepare DRAFT before DC so that comments can be received at the meeting.</p>	10/31/10	12/20/10	<p>6/10/10: The DRAFT SOP will be reviewed during the NELAP AC Meeting in DC.</p> <p>8/20/10: The SOP was completed and approved by the AB Committee. It has been forwarded to the LAS EC and NELAP AC for review and comments.</p> <p>9/5/10: LAS EC is still reviewing SOP through e-mail correspondence. Reminder for comments was sent 9/5/10.</p> <p>11/28/10: The Evaluation SOP has been completed and it is now in final review.</p>	

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24		Implementation Issue	PT Board NELAP Board?	PT Board Acceptance/Adoption of Vol 3 & 4 How is the 2003 NELAC standard referenced in state regulations? Though Vol 3 & 4 may not be referenced in the state updates, are there topics that Vol 3 & 4 cover in the state regulations now? Doesn't the PT Board adoption cause some problems?	05/31/10	CLOSED	A2LA will be auditing against the new Standard. There is a timing issue. 3/18/10: A2LA and PT Board are working on a transition plan that will be discussed on 4/15/10. 6/10/10: A2LA has prepared a checklist based on the new TNI standard. They have forwarded the checklist to the PT providers and have included footnotes where an item is not required for implementation until after 7/01/11. After that date A2LA will receive additional documentation from the PT providers to ensure that the standard has been implemented. Action Item is Closed.	X
25		SOP/Policy Documents	Consistency Improvement Task Force	Code of Ethics for Assessors		12/20/10	6/10/10: The TNI Board prepared an Ethics Statement for all TNI members. Need more feedback on this item. 9/10/10: On-Site did not think this was an action item for them. Need guidance from LAS-EC. 11/29/10: This item is being transferred from On-Site to the Consistency Improvement Task Force as per Carol.	
26		SOP/Policy Documents	AB Expert Committee	AB Provisional Recognition Procedures When is a suspension appropriate, withdrawal, etc ...	12/31/10	12/20/10	6/10/10: A working DRAFT has been prepared for the ABC to review. The term being used is Provisional Recognition - not Suspension. The SOP is relevant to issues that can not be immediately resolved that interfere with an ABs accreditation. It is a last step before revocation. 6/24/10: This is expected to be out of the committee by 9/20/10. It will then need to go through Policy Committee, etc ... The expected completion date should be extended to 12/31/10. 11/28/10: This SOP has been completed and is now in LAS EC review. Some concerns were expressed and a subcommittee was formed to look at the details of the SOP. It will be discussed at the 11/29/10 LAS EC meeting. 11/29/10: Final LAS EC comments are being incorporated into the SOP and then the SOP will be sent back to ABC for final comment. ABC will need to respond to the comments and then get final DRAFT back to LAS EC.	
27		SOP/Policy Documents	AB Expert Committee	Add language to appropriate procedure to clearly state that there will be no interpretations of the AB standards during the assessment process.	10/31/10	12/20/10	6/10/10: Language will be added to the Evaluation SOP. See Action Item #22.	
28		SOP/Policy Documents	LASC	Update SIR Procedure	12/15/10	12/20/10	6/10/10: Ilona will work on a DRAFT for LASC review after the DC meeting. 11/28/10: Completion date set to 12/15/10.	

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29	06/10/10	Implementation Issues	NELAP AC	Establish AB Renewal Schedule Revise renewal schedule for ABs to allow migration to new standard.	08/12/10	CLOSED	<p>6/10/10: Draft memo prepared summarizing new schedule has been shared with evaluation coordinators. Memo to be sent to NELAP AC by June 14. New certificates to be issued by August.</p> <p>6/24/10: Memo was sent to NELAP AC.</p> <p>8/17/10: A table has been prepared to show the dates of the next round of AB recognition renewals. This change will put everyone on a renewal cycle that allows use of the new standards in their next evaluation. It was approved by the NELAP AC and new certificates were distributed in DC.</p>	X
30	06/10/10	Implementation Issues	On-site LAS Exec Committee	Review language related to technical assessor training and evaluate impact.		12/20/10	<p>6/10/10: Jerry will summarize issue for consideration by NELAP by 6/14.</p> <p>6/24/10: E-mail was sent to Aaren. This issue will be worked on by On-site. Can you take a test and test out? Florida may have some helpful information to share. On-site's proposed resolution to this issue should go to LAS Executive Committee for review.</p> <p>8/11/10: Update from On-site - There was a spirited discussion in the OSA meeting regarding training. The standard is clear that technical training with a passing score on a test is required in all disciplines an assessor will assess, testing out not allowed, but the specific training required for each assessor is defined by the AB. OSA has provided a guidance document that shows what OSA feels is important in each discipline. Is a guidance document indicated?</p> <p>11/28/10: SIR #136 was submitted to On-site for a response on 9/29/10. This SIR relates to this issue. A status request was sent to On-site.</p>	

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31	06/10/10	Implementation Issues	QS Expert Committee	Quality Systems TIAs Incorporate TIAs and prepare a working DRAFT standard. Public comment should happen and then they will be ready for additional discussion in DC in August.	TBD	12/20/10	6/10/10: Jane Wilson will work with PT and QS to develop a schedule to ensure that everything is completed on time. TIAs involve both the addition and deletion of some ISO language. 7/13/10: The announcement with copies of the Working DRAFT standards were posted on the TNI website. People have until 8/12/10 to comment. Comments will be received through 8/12/10. 8/13/10: The committee presented the working draft standard during the Forum to solicit comments and suggestions. 9/13/10: The committee was presented with a draft that included comments and requests from the workshop. A vote to move the standard forward is scheduled for 10/11/2010. 11/28/10: Update requested.	
32	06/10/10	Implementation Tools	AB Expert Committee	Technical Review Checklist for AB Evaluation	CLOSED	CLOSED	6/24/10: See Item #23 above. There may be some overlap. 8/3/10: See #37 below.	X
33	06/24/10	Implementation Issues	Policy Committee	Mutual Recognition Agreement needs to be completed.	TBD	12/20/10	9/6/10: This policy has been completed and adopted by the NELAP AC. It has been forwarded to the Policy Committee. 9/27/10: It is on the Policy Committee's next agenda to review this document. 11/28/10: Still needs to be reviewed.	
34	06/24/10	Implementation Tools	AB Expert Committee	AB Application needs to be updated.	09/30/10	CLOSED	6/24/10: ABs will need this to apply in October/November. 8/3/10: Application is needed before end of September in order to complete Completeness Checklist by 10/15 (see #37 below). 11/28/10: This is part of the Evaluation SOP and will be completed as part of #22. This item will be closed out.	X
35	06/24/10	Implementation Tools	AB Expert Committee	The Completeness Checklist and Observation Checklist need to be updated.	CLOSED	CLOSED	See # 36 and 37 below.	X

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36	08/03/10	Implementation Tools	AB Evaluators	AB Checklist	09/30/10	12/20/10	<p>8-3-10: AB Evaluators took on the task of preparing a checklist for evaluation of the ABs. On-site was also working on a part of this checklist - independent of the Evaluators. On-site version is in Excel, the Evaluators used Word. The Evaluators version covered the entire standard and they used On-Site's version to verify the content of the version they prepared. The comparison showed they were equivalent. The checklist has been forwarded to LAS EC for review/recommendations.</p> <p>9/1/10: LAS EC is still reviewing the checklist by e-mail correspondance.</p> <p>11/28/10: NELAP AC is voting on this.</p>	
37	08/03/10	Implementation Tools	AB Evaluators	AB Evaluation Completeness Checklist	10/15/10	CLOSED	<p>8/3/10: The checklist can not be completed until the application is complete. It will then be forwarded to the LAS EC.</p> <p>11/28/10: This is part of the Evaluation SOP and will be completed as part of #22. This item will be closed out.</p>	X
38	08/03/10	Implementation Tools	AB Evaluators	AB On-site Report Template	09/30/10	CLOSED	<p>8/3/10: Expect to forward to LAS EC in September.</p> <p>11/28/10: This is part of the Evaluation SOP and will be completed as part of #22. This item will be closed out.</p>	X
39	10/18/10	Implementation Issues	PT Expert Committee NELAP AC	<p>PT Standard Implementation Issues</p> <p>The NELAP AC prepared a list of concerns they feel make the PT part of the standard difficult to implement:</p> <ul style="list-style-type: none"> - Analysis Date - LOQ Reporting - Non-Accredited PT Providers - Experimental Analytes 	07/01/11	12/20/10	<p>11/28/10: The NELAP AC prepared a detailed document that included excerpts from the standard to highlight their concerns. An update has been requested from the PT Expert Committee.</p> <p>12/2/10: PT Expert Committee is working with NELAP AC on standard language changes.</p>	