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1.0 Purpose and Applicability

This document describes the procedures used by The National Environmental Field Activities Program (NEFAP) Executive Committee, henceforth referred to as the NEFAP Executive Committee, to evaluate NEFAP Accreditation Bodies (AB) for initial or continuing recognition. This program is based on the TNI Field Activities Standards: FSMO-V1-2008 and FSMO-V2-2008.

This Standard Operating Procedure is applicable to initial or continuing reviews of Accreditation Bodies conducted by NEFAP Evaluators. It is based on the policies of the TNI NEFAP Executive Committee and the TNI Field Sampling and Measurement Organizations (FSMO) Standards.

The evaluation principles and policy developed by the TNI NEFAP Executive Committee are presented in Appendix F.

2.0 Summary

This document includes the procedures used to:

- Perform a completeness check of an AB's application and its attachments.
- Perform a document review of these materials.
- Perform an on-site evaluation of an AB, as applicable.
- Perform a witness assessment of the AB's assessor(s) performing a FSMO assessment.
- Complete the on-site evaluation report.
- Perform the review of and response to the AB's corrective action plans and corrective action implementation.
- Provide recommendations of the evaluation team to the TNI NEFAP Executive Committee.

The examination of the systems, processes and procedures of the AB must provide a determination of the AB's conformance with the policies of the TNI NEFAP Executive Committee and its capabilities to perform FSMO assessments in a consistent, uniform manner.

3.0 Related Documents

FSMO-V1-2008: General Requirements for Accrediting Field Sampling and Measurement Organizations.

FSMO-V2-2008: General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations.

POL-104: Management of Records

4.0 Definitions

See ISO 17000 and the TNI FSMO Standards.

If conflicts in definitions or interpretations arise between the ISO/IEC and TNI FSMO standards, the TNI FSMO Standards shall govern.

| | |
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| Comment: | Finding about documents or AB's practices with a potential of improvement; but still fulfilling the requirements |
| Concern: | Finding where, in the opinion of the evaluation team, the AB's practice may develop into a non-conformity. The evaluated AB is not expected to |

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| | respond to a concern but may do so if it wishes. |
| Nonconformity: | Finding where the AB does not meet a requirement of the applicable standard (FMSO-v2-2008), its own management system or the Arrangement requirements in a way that discredits its competence or jeopardizes the quality of its work. The evaluated AB is expected to respond to any nonconformity by taking appropriate corrective action and providing the team with evidence of implementation. |

5.0 Personnel Qualifications and Responsibility

- 5.1 All evaluation team members must meet minimum requirements for training and professional qualifications as defined in this Section.
- 5.2 The evaluators must successfully complete the appropriate NEFAP accreditation body evaluator-training course. The training course is in two parts: Part 1: TNI FSMO standard additional requirements and Part 2: ISO/IEC 17011 requirements. All evaluators must complete Part 1 training from a TNI-recognized training course. If the evaluator has successfully completed ISO/IEC 17011 from an IAF/ILAC recognized training course this may be used for completion of Part 2 training.
- 5.3 All members of the evaluation team must sign the conflict of interest statement. See Appendix A for the *Conflict of Interest* form.
- 5.4 All evaluation team members must comply with the policies of the TNI NEFAP Executive Committee and the following criteria
The NEFAP evaluation team shall:
 - *have at least one member of the NEFAP evaluation team who meets the education, experience and training requirements for FSMO assessors specified in Section 5; and*
 - *have at least one other member with experience that includes at least one of the following:*
 - *qualification as a lead assessor from an assessor training program recognized by TNI;*
 - *one year of experience implementing an accreditation program; or*
 - *one year experience developing or participating at a managerial level in FSMO or related accreditation programs.*
 - *Have documentation (Appendix A) that verifies freedom from any conflict of interest that would compromise acting in an impartial nondiscriminatory manner.*
 - *All experience required by this subsection must have been acquired within the five year period immediately preceding appointment as a NEFAP evaluation team member.*
- 5.5 The Lead Evaluator (LE) is responsible for planning activities. All members of the evaluation team must be involved to ensure that the evaluation is well planned and consistent with the evaluations of other ABs.
 - 5.5.1 The LE provides direction to the evaluation team throughout the evaluation process.
 - 5.5.2 The LE is responsible for obtaining consensus of the evaluation team for the final recommendation of AB recognition status to the NEFAP Executive Committee.
 - 5.5.3 The LE reviews and approves all reports sent to the AB by the Evaluation Coordinator.

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- 5.6 The Evaluation Coordinator (EC) is a TNI staff person that has the following duties
 - 5.6.1 Assists the evaluation team by assuring all communication between the evaluation team and the AB, and between the evaluation team and the NEFAP Executive Committee occurs in a timely manner.
 - 5.6.2 Tracks and documents that all aspects of AB evaluations are performed in a timely manner in conformance with this Standard Operating Procedure.
 - 5.6.3 Reviews the AB application for completeness, with concurrence of the LE.
 - 5.6.4 Reviews the evaluation reports for completeness and consistency according to the evaluation SOP and the TNI standards.

6.0 Procedures

6.1 Frequency and Scope of Evaluation

- 6.1.1 The TNI FSMO standards require Accreditation Bodies to be evaluated initially and at a minimum of once every four (4) years thereafter. This evaluation must include:
 - 6.1.1.1 Completeness and technical reviews of the application package,
 - 6.1.1.2 An on-site evaluation (in coordination with International Accreditation Forum (IAF)/International Laboratory Accreditation Cooperation (ILAC) evaluations, if applicable)
 - 6.1.1.3 Observation of the AB conducting an FSMO assessment in the field,
 - 6.1.1.4 On-site evaluation report(s) with findings for both the on-site evaluation and the observation, and
 - 6.1.1.5 Recommendations to the TNI NEFAP Executive Committee regarding recognition or denial of recognition.

Once the evaluation team makes a recommendation to the NEFAP Executive Committee for granting or denying recognition, all subsequent communications shall be between the TNI NEFAP Executive Committee and the AB, with copies given to the EC.

Note: Review Appendix F (TNI NEFAP Executive Committee - Evaluation Policy). ILAC Mutual Recognition Arrangement (MRA) signatory ABs may submit their ILAC evaluation report (or a report from one of ILAC's regional bodies) to demonstrate compliance with ISO 17011. Where conformance to ISO 17011 is demonstrated in the report, these areas do not need to be reassessed by the NEFAP evaluation team. Non-ILAC signatory ABs will be assessed for compliance to ISO 17011 by the NEFAP evaluation team.

6.2 Selection of the Evaluation Team

- 6.2.1 The NEFAP Executive Committee approves the evaluation team. The evaluation team shall include:
 - 6.2.1.1 a representative of another IAF/ILAC and NEFAP-recognized AB
 - 6.2.1.2 a technical expert knowledgeable in the scope (this may be one or more) and without a COI.
 - 6.2.1.3 a representative of the users of the FSMO services (data user or FSMO users)
- 6.2.2 All evaluation team members work under the direction of the LE.
- 6.2.3 The applicant/renewal AB has ten (10) calendar days after notification of the evaluation team members to submit a written objection with reason for the

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objection to the appointment of a LE or any team member(s). The NEFAP Executive Committee shall consider the objection within ten (10) calendar days and appoint other team members as appropriate.

- 6.2.4 The EC must document the role and qualifications of each evaluator selected. The documentation must demonstrate that the requirements of Sections 6.2 and 5.4 are met.

6.3 Application/Renewal Process

6.3.1 Initial Application

- 6.3.1.1 Initial Application forms for NEFAP recognition are obtained from the NEFAP Executive Committee or TNI website.
- 6.3.1.2 The application must be signed and dated by an officer or authorized representative of the accreditation body
- 6.3.1.3 The completed application and supporting documents shall be submitted to the Evaluation Coordinator.
- 6.3.1.4 Upon receipt of the application and supporting documents the Evaluation Coordinator shall send an acknowledgement to the AB. The NEFAP Executive Committee Chair and the Evaluation Coordinator (EC) must establish an evaluation team, followed by the approval of the NEFAP Executive Committee. The review process shall begin.

6.3.2 Renewal Applications

6.3.2.1 Notification

The NEFAP Executive Committee chairperson or designee must send a letter with a renewal application form to the AB at least 270 calendar days prior to the expiration of the AB's current NEFAP recognition. The letter must include a request for any changes since the previous application along with any updated documentation.

6.3.2.2 Renewal Submittal

- 6.3.2.2.1 The AB must submit an electronic copy of the completed renewal form and any changes since the initial evaluation to the EC within thirty (30) calendar days of receipt of the renewal letter. The renewal form identifies the information on file and requests any updates to this information.
- 6.3.2.2.2 If the AB does not submit a renewal application within thirty (30) calendar days, the AB receives final notification from the NEFAP Executive Committee by any method providing receipt confirmation that, if an application is not submitted within another twenty (20) calendar days, the AB's recognition expires on the date of the current NEFAP recognition certificate.

6.3.2.3 Application Communications

Once the renewal package is given to the EC, and the LE is assigned, all subsequent communications shall be between the LE and the AB, with copies provided to the EC. The LE must respond to these communications as necessary.

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- 6.3.3 Application/Renewal Completeness Review
 - 6.3.3.1 Following receipt of the Application/Renewal information, the EC shall review it for completeness within twenty (20) calendar days, using the "Application/Renewal Completeness Review Checklist" Appendix B, and report to the LE
 - 6.3.3.2 If the information is not complete, the EC sends the completeness report to the LE for review. The LE sends the AB a Completeness Report (Appendix C includes a possible example of a report letter) in writing. The NEFAP Executive Committee and evaluation team members receive a copy of the Completeness Report.
 - 6.3.3.3 The AB shall have twenty (20) calendar days from receipt of the Completeness Report to supply any missing information. If the missing material is not submitted, renewal must not proceed. Once the EC determines that the application is complete, he/she shall notify the LE, who shall in turn notify the AB and the NEFAP Executive Committee of this determination.
 - 6.3.3.4 Extensions up to twenty (20) calendar days may be granted.
- 6.3.4 Application Document Review
 - 6.3.4.1 The Lead Evaluator shall conduct a document review to verify that all required items have been addressed. The applicant's completed NEFAP Application/Renewal Checklist is used as a guide to determine accreditation body conformance with the TNI FSMO Standard. The LE may request other members of the evaluation team to assist with the document review. The same LE assigned to the on-site evaluation shall perform the review.
 - 6.3.4.2 The LE shall review the application and supporting documents to evaluate whether the AB's accreditation program requires its FSMOs to meet FSMO-V1-2008 as well as any applicable media-specific standards;
 - 6.3.4.3 Also, the document review shall follow the requirements of the TNI FSMO Standard and relevant scope requirements. (Appendix D includes a possible example of a report letter.)
 - 6.3.4.4 The LE has thirty (30) calendar days to conduct this review after the application is determined complete and respond in writing to the AB. The LE must send the outcome of the document review including any nonconformance report to the AB.
 - 6.3.4.5 The AB must respond in thirty (30) calendar days to any nonconformances with documentation of implementation of corrective actions. If the AB requires more than thirty (30) days to implement corrective action, the corrective action plan must be submitted within thirty (30) calendar days. The LE shall review and respond to the AB's corrective actions within thirty (30) calendar days of receipt.
 - 6.3.4.6 If the accreditation body's corrective actions do not address all nonconformances, the NEFAP LE must notify the accreditation body that it must submit another corrective action document for the remaining nonconformances within twenty (20) calendar days of the accreditation body's receipt of this notification.
 - 6.3.4.7 The LE shall review the AB's second corrective action response within twenty (20) calendar days of receipt. If application nonconformances

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remain after the second attempt to resolve them, the LE shall document the unresolved nonconformances and recommend to the NEFAP Executive Committee that:

- the AB's application for initial recognition be denied, or
- the AB's recognition be revoked.

6.3.4.8 If the initial application/renewal information contains no nonconformances or if the nonconformances were resolved, the NEFAP LE shall schedule the on-site evaluation.

6.3.4.9 Disagreements with matters concerning recognition can be addressed through the TNI NEFAP Executive Committee Dispute Resolution Procedure.

6.4 Scheduling the On-Site Program Evaluation

6.4.1 Once the evaluation team determines that the documentation is satisfactory and the application is accepted, the AB is notified within thirty (30) calendar days to schedule the on-site evaluation. An on-site evaluation shall be conducted within sixty (60) calendar days of completion of the application technical review and at the mutual convenience of the evaluation team and the AB.

6.4.2 The LE, on behalf of the evaluation team, sends written confirmation to the AB of the logistics required to conduct the evaluation, and to all of the evaluation team members. The written confirmation shall include, but is not limited to:

6.4.2.1 onsite evaluation date and agenda or schedule of activities,

6.4.2.2 copies of the standardized evaluation checklists,

6.4.2.3 the names, titles, affiliations, and on-site responsibilities of the NEFAP evaluation team members, and

6.4.2.4 If the evaluation team selects specific AB staff for interviewing, the LE presents the names and titles of AB staff that are requested to be available during the on-site evaluation as part of the confirmation.

6.5 Conducting the On-Site AB Evaluation

6.5.1 The evaluation team shall conduct an opening meeting prior to the start of the evaluation.

6.5.2 The evaluation team shall conduct a comprehensive evaluation of the AB's accreditation program to determine the accuracy of information contained in the AB application and the AB's conformance to the TNI Standards and relevant program requirements. The evaluation team must do this by:

6.5.2.1 interviewing management and technical staff (AB assessors) and reviewing internal AB audits to determine if corrective actions were taken to address noted nonconformances; Interviewing of technical staff may be performed remotely

6.5.2.2 reviewing a representative number of files adequate for the ABs program size from the list of TNI accredited FSMOs, (more files should be reviewed if significant nonconformities warrant);

6.5.2.3 reviewing evaluation forms submitted by FSMOs;

6.5.2.4 reviewing records of FSMO complaints, disputes and appeals;

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- 6.5.2.5 reviewing the training records and conduct interviews of AB staff designated as qualified assessors to evaluate their training, knowledge of assessment techniques and the TNI Standard; and
- 6.5.2.6 observing the AB during its on-site assessment of a FSMO. The FSMO selected should hold sufficient fields of accreditation to allow the team to observe a comprehensive on-site assessment by the AB. A second FSMO assessment observation may be necessary if an FSMO with multiple fields of accreditation is not due for an AB assessment.
- 6.5.2.7 reviewing the last NEFAP evaluation report for renewals.
- 6.5.3 When selecting FSMO files to review, the evaluation team selects those with varying fields of accreditation and different assessors as appropriate. The evaluation team must include files from (i) a FSMO that has lodged a complaint, if applicable; and (ii) a FSMO that was subject to administrative action through severe quality system nonconformances if applicable. At a minimum, the team reviews the following information in each FSMO file:
 - Application
 - Selection of assessors including review of conflict of interest
 - TNI FSMO standard requirements
 - Proficiency testing (PT) results for compliance with methodological and program requirements if applicable
 - Nonconformance report(s)
 - Corrective action report(s)
 - Correspondence
 - Final report
 - Certificate if granted
- 6.5.4 The team conducts an exit debriefing to discuss all noted nonconformances, concerns and comments. In general, the Evaluation Team should follow the auditing principles as defined in ISO 19011. If any disputes or interpretation are identified, these are to follow the dispute resolution SOP.
- 6.6 Documentation of Findings from the On-Site Program Evaluation
 - 6.6.1 Documentation of the findings shall be delineated in the final report, along with the observations of the accreditation body's on-site assessment of a FSMO.
 - 6.6.2 Findings include identification of nonconformities, concerns and comments. The AB is only required to respond to nonconformities.
 - 6.6.3 The evaluation team has thirty (30) calendar days to prepare and send the findings and report of the on-site evaluation to the AB by any method providing receipt confirmation. (Note: The AB evaluation is not considered complete until the on-site evaluation and FSMO assessment(s) are complete.)
- 6.7 Scheduling of the Observation of the FSMO Assessment
 - 6.7.1 At least one member of the NEFAP evaluation team must observe the AB conducting an actual on-site FSMO assessment. This team member must have the technical competence in the area being assessed by the AB. At the time of the scheduling of the on-site evaluation, the LE should request from the AB a schedule of upcoming FSMO assessments. The LE uses this schedule to select the FSMO assessment which is observed during the on-site evaluation or other mutually

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agreed time. (Note: Although the observation can be conducted prior to the on-site AB evaluation, it should not take place until after the technical review issues have been resolved).

- 6.7.2 The LE (in consultation with the AB) may elect to send more than one member of the evaluation team to observe the assessment. This decision should be based on: (1) the scope of the FSMO assessment and the number of AB assessors involved, and (2) the availability of members of the evaluation team. This decision is disputable under TNI NEFAP Executive Committee Dispute Resolution Procedure
- 6.7.3 The number and type of FSMO assessments scheduled is based on the key activities of the AB. The evaluation team recommends to the AB and NEFAP Executive Committee the rationale for the selection of the number and type of FSMO assessment to be performed as part of the evaluation.

6.8 Conduct of the FSMO Assessment Observation

- 6.8.1 During the FSMO assessment observation, the evaluation team member's role is to observe the AB's FSMO assessment team. The evaluation team members are not active participants in the FSMO assessment. The evaluation team member(s) should make every effort to observe as many aspects of the AB's assessment as possible and should make sure to concentrate on areas where the technical review may have revealed weaknesses in the AB's program.
- 6.8.2 A copy of the current version of the checklist, "NEFAP Evaluation of AB Assessment of an FSMO", shall be completed.
- 6.8.3 Prior to the evaluation of the FSMO assessment, the evaluator must determine the need for specific safety training, safety equipment or other site-specific requirements (e.g. security, confidentiality and insurance). A review of the site logistics between the evaluator and the AB assessor must be completed at least one week prior to the evaluation assessment.

6.9 Documentation of the FSMO Assessment and On-site Evaluation

- 6.9.1 Each member of the evaluation team that participates in the FSMO assessment observation and the on-site evaluation must transmit his/her observations to the LE for inclusion in the evaluation report. The findings must be transmitted to the LE within fourteen (14) calendars following the FSMO witness assessment or following the on-site evaluation
- 6.9.2 Following completion of the evaluation report by the LE and review by the team and EC, the evaluation report shall be sent to the AB within thirty (30) calendar days of completion of the on-site evaluation and the witness evaluation of the FSMO assessment.
- 6.9.3 The AB is requested to respond within thirty (30) calendar days from receipt of the report with corrective actions or comments on the report.

6.10 Response to the AB Corrective Action Report (CAR)

- 6.10.1 Each member of the evaluation team must review the AB's response to the on-site evaluation report, including its proposed corrective actions, and transmit their review to the LE within ten (10) calendar days. The LE shall respond to the AB in writing, within twenty (20) calendar days of receipt of the AB CAR.
- 6.10.2 If the AB CAR does not address all nonconformances, the LE shall notify the AB by any method providing receipt confirmation that it must submit another CAR for the remaining nonconformances within twenty (20) calendar days of receipt of this notification.

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6.10.3 If the AB corrects all the nonconformances, the LE shall recommend to the NEFAP Executive Committee that the AB be granted NEFAP recognition.

6.10.4 The LE must consider the AB's responses in preparing written recommendations to the NEFAP Executive Committee.

6.11 Recommendations to the NEFAP Executive Committee

6.11.1 All recommendations to the NEFAP Executive Committee regarding NEFAP recognition must be made in accordance with the TNI Standards. The LE shall be responsible for preparing the written recommendation with input from, and on behalf of, the entire evaluation team. Appendix E provides a model recommendation letter.

6.11.2 Copies of the evaluation team's document review report, the applicant's document review report corrective action response, evaluation team's on-site evaluation report including the witness assessment of the FSMO(s), and the applicant's on-site evaluation corrective action plan must be provided with the recommendation letter. The NEFAP Executive Committee must evaluate the information for consistency according to the evaluation SOP and the TNI standards.

6.12 Issuance of Certificate of Recognition to the AB

The issuance of Certificates of Recognition shall be the responsibility of the NEFAP Executive Committee Chair and shall be done in accordance with the requirements of this procedure. The renewal or dismissal letter and the certificate, if one is awarded, must be issued and mailed by the NEFAP Executive Committee Chair and EC.

A new applicant AB has one year to complete the application process from application through resolution of corrective action. If recognition is not granted within one year of the application date the AB must reapply. Reapplication requires the resubmittal of the application package including any applicable fees.

Note: If delays are caused by NEFAP the re-application process does not apply.

6.13 Handling of Unexpected Circumstances

In the event that the team encounters an unexpected or unusual circumstance, the LE should seek guidance from the NEFAP Executive Committee.

7.0 Criteria, Checklists, Standards

7.1 All evaluators must ensure that they are using the correct version of the TNI FSMO standards and FSMO checklists.

7.2 The complete TNI FSMO Standard must be available at the accreditation body. The checklist used by the accreditation body for the assessment of FSMOs must include all requirements found in Volume 1.

7.3 The evaluation checklist is presented in the order of the TNI FSMO standard. The relevant parts of the checklist are completed to provide objective evidence of conformance to the requirements.

7.4 Current editions of the accreditation and evaluation checklists are available on The NELAC Institute (TNI) website at: www.nelac-institute.org

8.0 Records Management

8.1 Records associated with the evaluation of the ABs shall be stored in accordance with the TNI policy for records management (POL-104).

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- 8.2 The EC, under the direction of the LE, is responsible for submitting all documents, letters, evaluation notes, checklists, etc., to the NEFAP Executive Committee within thirty (30) calendar days of the team's final recommendation.
- 8.3 The LE and evaluation team members must submit all records to the EC within thirty (30) calendar dates of the recognition decision. The LE and team members should not retain records of the evaluation following the NEFAP Executive Committee decision.
- 8.4 Final storage of records is to be in accordance with the TNI policy for records management (POL-104).
- 8.5 Records are stored for at least two (2) evaluation cycles.

9.0 Quality Control

- 9.1 The NEFAP Executive Committee must review this SOP annually. Input from recognized ABs and evaluation teams must be solicited.
- 9.2 This review must be documented and any changes deemed necessary must be made following the TNI procedure.
- 9.3 If the document is revised, the revisions must be distributed to the recognized ABs and the NEFAP Executive Committee

10.0 References

TNI FSMO Standards Volume 1 and 2, latest edition
ISO/IEC17000, latest edition
ISO/IEC 17011, latest edition
ISO/IEC 17025, latest edition
ISO 19011, latest edition

11.0 SOP Approved Changes

| Prev. SOP No. | New SOP No. | Date of Change | Description of Change |
|---------------|-------------|----------------|-----------------------|
| N/A | 5-005 Rev 0 | 08/07/10 | New Document. |
| | | | |
| | | | |

APPENDIX A
Evaluation Team Conflict of Interest Form

Name _____

Organization _____

Date of NEFAP Evaluator Training Course _____

Name of Accreditation Body Being Reviewed _____

This statement shall be signed by the team leader, team members, and observers of an NEFAP evaluation team; additionally by NEFAP Executive Committee members and observers of any NEFAP Executive Committee meeting considering the recognition of an accreditation body.

I declare that I shall act impartially and I shall not reveal information gained through evaluations and/or evaluation reports to anyone who does not have the right to access such information or who has not signed this statement.

Additionally, I declare that I do not have a conflict of interest with the parties involved in the evaluations that I shall participate in.

Signature _____

Date _____

APPENDIX B Application/Renewal Completeness Review Checklist

AB Applicant _____

Lead Evaluator _____

Evaluation Team Members _____

EC Name _____

| Item | Calendar Days Allowed | Date Completed | Completed By |
|---|--|----------------|--------------|
| Assignment of Evaluation Team | | | |
| Renewal Notification, if applicable | 270 days before expiration | | |
| NEFAP Executive Committee sends out renewal letter | 270 - before expiration | | |
| AB returns complete application or renewal material | 30 | | |
| NEFAP Executive Committee notifies AB of late application | -- | | |
| AB must respond to late application notice | 20 | | |
| Conflict of Interest forms submitted to LE by all evaluators | Before assignment | | |
| LE informs NEFAP Executive Committee of COI (Y/N) | -- | | |
| NEFAP Executive Committee assigns Evaluation Team and notifies the AB | -- | | |
| AB make objections to Evaluation Team, (optional) | 10 | | |
| The NEFAP Executive Committee considers objection and appoints new members of the evaluation team | 10 | | |
| EC Application Completeness Review | 20 | | |
| AB responds to request for providing any missing information | 20 up to 20 day extension request allowed | | |
| LE conducts and reports on the document review | 30 | | |
| AB response to nonconformances | 30 Plan or implement | | |
| LE reviews response of Corrective Action | 30 | | |
| LE 2nd notice of nonconformances to AB | 20 | | |
| AB 2nd response to nonconformances | 20 | | |

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| Item | Calendar Days Allowed | Date Completed | Completed By |
|---|--|----------------|--------------|
| LE reviews 2nd response | | | |
| Schedule On-Site AB Evaluation | 30 | | |
| LE notifies AB of on-site review logistics | | | |
| Conduct on-site review, if applicable | | | |
| Conduct Witness of AB Assessment of FSMO | | | |
| Prepare Final Report – Evaluation Team | 30 | | |
| Send Report to AB, including nonconformance(s), if any | 30 calendar days on-site or witness assessment | | |
| AB response to Final Report | 30 calendar days from receipt of Rpt. | | |
| Evaluation team reviews response and LE reports on the review | 20 calendar days | | |
| Re-evaluation requirement | 4 years | | |

APPENDIX C

Model Letter for Application/Renewal Completeness Review

EXAMPLE

Dr. Xxxxx N. Yyyyyyy
Xxy State Dept. of Health
P.O. Box XXX
Xxxx, Xxx 45690

Dear Dr. Yyyyyyy,

The National Environmental Field Activities Program (NEFAP) Evaluation Team Leader (LE) assigned to the Xxxx Accreditation Body has completed its review of the (renewal information) (initial application) dated DATE. As you are aware, the Lead Evaluator conducts a completeness review in order to determine whether or not the information and supporting documentation required in the TNI Standards has been included in the application.

The LE and Evaluation Coordinator found that the Xxxx application is incomplete because:

[List nonconformances and reference TNI FSMO Standard for each nonconformance]

[List concerns, comments related to the documentation]

According to the TNI NEFAP procedure, you have 20 calendar days from receipt of this letter in which to provide the requested information. Thank you for your prompt attention to this matter. If you have any questions, please feel free to contact me at (xxx) yyz-zzzz.

Sincerely,

Yyyy Y. Zzzzz
NEFAP Lead Evaluator

cc: NEFAP Executive Committee

APPENDIX D Model Letter for Document Review Nonconformances

EXAMPLE

Dr. Xxxxx N. Yyyyyyy
Xxy State Dept. of Health
P.O. Box XXX
Xxxx, Xxxx 45690

Dear Dr. Yyyyyyy,

The National Environmental Field Activities Program (NEFAP) Evaluation Team (ET) assigned to the **NAME** Accreditation Body (AB) has completed its document review of the renewal application dated **DATE**. As you are aware, a document review is conducted in order to determine whether or not the accreditation body's environmental FSMO accreditation program requires its accredited FSMOs to meet the standards set forth in the TNI FSMO Standards. The ET review is based on the 2008 National Environmental Field Activities Accreditation (FSMO) Standards for Volumes 1 and 2 as well as XXX (insert media-specific standard if applicable).

The ET has identified a number of findings on Attachment 2, "Checklist to Determine Accreditation Body Conformance." Items checked "No" are nonconformances. Specific comments relative to each nonconformance have been provided in the "Document Location/Comments" column. In addition to the items which have been checked "No," there are some items where we have included a "?" in either the Yes or No column. In these instances the ET could not determine if the requirement had been met or not. [List concerns, comments related to the documentation] Addition information to clarify what has been provided is needed by the ET in order to make a final determination. This additional clarifying information should be provided in your response to this report. Please note that while some items have been checked "Yes," the actual implementation of these requirements cannot be assessed until the actual on-site assessment of the XYX AB program takes place later this month.

Per NEFAP requirements, you have 30 calendar days in which to provide a corrective action response to this technical report. Please attach to your response any new or updated documents cited in your corrective action response.

If you have any questions or require clarification regarding any of our findings, please feel free to contact me at (xxx) xxx-xxxx.

Sincerely,

Yyyy Y. Zxzz
NEFAP Lead Evaluator

Attachments

cc: NEFAP Executive Committee
[Insert Evaluation Team members]

APPENDIX E

Model Recommendation Letter to the TNI NEFAP Executive Committee

EXAMPLE

Recommendation for (Renewal) or (Initial) of Recognition of XXXXX as a NEFAP Accreditation Body

[insert name and title]

National Environmental Field Activities Program Board (NEFAP Executive Committee)

The National Environmental Field Activities Program (NEFAP) evaluation team assigned to the XXXXX has completed its evaluation of this Accreditation Body. In accordance with Volume 1 and 2 of the TNI FSMO Standards and with xxx (insert media-specific standard here if applicable). The evaluation consisted of the following: 1) a technical review of the XXXXX application for renewal and its supporting documentation 2) an on-site evaluation of the XXXXX FSMO accreditation program, and 3) an observation of XXXXX conduct of an on-site FSMO assessment. Each of these parts of the evaluation is discussed below.

Team members (appointed by the NEFAP Executive Committee):

- [insert Evaluation Team members]

Document Review

The evaluation team completed its document review and issued a report detailing findings on DATE. In a response dated DATE - XXXXX provided a list of corrective actions taken to address the nonconformances noted. The team reviewed these corrective actions and determined that they adequately addressed the findings noted.

On-Site Evaluation

The team conducted an on-site evaluation of the XXXXX NEFAP FSMO accreditation program on DATE. The team interviewed ## XXXXX staff members, reviewed FSMO files, training files, complaint files, and PT records as applicable. The team documented ## instances in which XXXXX was determined to be in non-conformance with the NEFAP standards. A report was prepared and sent to XXXXX on DATE. XXXXX provided a corrective action plan for the ## findings on DATE. The evaluation team has reviewed these corrective action responses and finds them to be acceptable.

Observation

The Lead Evaluator performed an observation of XXXXX's on-site assessment of FSMO NAME (City State) on DATE. The conduct of this assessment was found to be in conformance with the TNI FSMO standards. No significant deviations were observed.

Recommendation

The evaluation team recommends that NEFAP recognition of XXXXX's Accreditation Program be continued for all the fields of accreditation in the attached list.

Please find copies of the following documents:

- 1) evaluation team's document review report,
- 2) XXXXX document review report corrective action response,
- 3) evaluation team's on-site evaluation report including the witness assessment of FSMO(s), and
- 4) XXXXX on-site evaluation corrective action plan.

If you have any comments or questions, please contact me at (xzx) zzz-yyyy.

Attachments

cc: XXXXX, XXXXX

APPENDIX F

TNI NEFAP Executive Committee – Evaluation Policy

Base Requirements for ILAC MRA Signatories for FSMO Testing

- Submittal of application and fee for recognition to the NEFAP Executive Committee, along with appropriate documentation (i.e. quality manual, Standard operating procedures, etc.). This information will be used for a document review by the NEFAP assigned evaluation team
- Submittal of the Accreditation Body (AB) training program to the NEFAP evaluation team. The AB training program is for AB assessor training to conduct assessments in accordance to the TNI FSMO standard. AB assessors shall have documented training in evaluating to the TNI FSMO Standard
- Evidence of ILAC MRA signatory status for testing (i.e. copy of the ILAC MRA)
- Documented management system to meet the requirements of Volume 2 of the TNI FSMO Standard
- Review by the NEFAP Executive Committee for recognition
- Recognition granted after review of documentation, completion of the NEFAP evaluation team document review report and closure of all documentation non-conformances
- Initial ABs receiving NEFAP Recognition, the NEFAP evaluation team will witness the accreditation body performing an initial assessment of the FSMO in accordance to the ABs policies and procedures. This witnessing may include an office visit and/or field visit. Based on the scope of recognition, the NEFAP Executive Committee may recommend additional witness evaluations
- Continued recognition granted by NEFAP Executive Committee upon closure of all non-conformances arising from witness evaluations
- NEFAP evaluation team participation in AB's next ILAC re-evaluation (ILAC re-evaluation of AB every 4 years)

Base Requirements for Non-ILAC FSMO Accreditation Bodies

- Submittal of application and fee for recognition to the NEFAP Executive Committee, along with appropriate documentation (i.e. quality manual, Standard operating procedures etc.). This information will be used for a document review by the NEFAP assigned evaluation team.
- Assignment of evaluation team leader and team members appropriate to the size of the accreditation body by the NEFAP Executive Committee. Team leader and one of the two team members will be made up of personnel from the other NEFAP recognized ABs participating in the NEFAP process. The remaining team member to include a representative from NEFAP to verify conformance to Volume 1 and 2 of the TNI FSMO standard. At least one team member must be familiar with the technical standards applicable to the scope of the accreditations being granted.
- Quality manual/documentation review to ensure conformance to Volume 2 of the TNI FSMO standard

TNI NEFAP Executive Committee Evaluation Procedure

- On-site evaluation of the AB by the evaluation team with a combination of evaluating the office as well as evaluating the AB conducting assessments of FSMO field activities to ensure conformance with Volumes 1 and 2 of the TNI standard. Witnessing of the AB of an FSMO must include at a minimum an initial accreditation assessment, (if available and for continuing recognition a surveillance assessment and a reassessment may be selected.) Initial ABs receiving NEFAP Recognition, the NEFAP evaluation team will witness the accreditation body performing an initial assessment of the FSMO in accordance to the ABs policies and procedures. This witnessing may include an office visit and/or field visit. Based on the scope of recognition, the NEFAP Executive Committee may recommend additional witness evaluations
- NEFAP AB evaluators shall have documented training in evaluating to ISO/IEC 17011 and to Volume 1 and 2 of the TNI FSMO Standard.
- Recognition granted by NEFAP Executive Committee upon closure of all non-conformances
- Evaluations are performed once ever four years.