March 24, 2014

TO NOCSAE LICENSEES:

SEI Certification Bulletin #4 – Optional Pre-Audit

The SEI staff and auditors have developed a process for NOCSAE participants interested in having an advance review of their quality manual and key procedures prior to the required on-site audit(s). The optional, Pre-Audit process was originally referred to as a desk audit in Mike Oliver's December 9, 2013 letter to NOCSAE licensees.

The Pre-Audit will be conducted for your informational purposes only, and will have neither a positive or negative effect on the third party certification on-site quality audit when performed. The goal of the Pre-Audit is to perform a "gap analysis" of your organization's quality system in comparison to the NOCSAE QC/QA requirements and SEI quality requirements as outlined in the SEI *Certification Program Manual* (CPM) Section 11.10.

NOCSAE participants who wish to have a Pre-Audit review will submit their Quality Manual and suggested supporting documentation to the auditor assigned by SEI. It is possible the SEI auditor may need to request supporting documentation in order to adequately perform the Pre-Audit review. The SEI Auditors will be using the SEI Audit Checklist, CPM Section 13 (attached), to conduct the document review. At the conclusion of the review, the SEI auditor will provide the NOCSAE participant with his observation(s). Per accreditation requirements and SEI procedures, SEI auditors cannot provide consulting services or advice as to how to meet requirements. If consulting services are desired, it is recommended to contact the NOCSAE Technical Director, Dave Halstead, who can assist in identifying qualified industry consultants.

In addition to submitting your quality manual for the Pre-Audit, SEI suggests submitting the following supporting documentation, if available:

- Quality Manual
  - Demonstrate the Quality Manual is a controlled document.
- Design Control and Verification
  - Provide procedure(s) demonstrating evidence of design control and verification.
- Design Changes
  - Provide procedure(s) demonstrating evidence of design changes, including SEI notification.
- Supplier Control
  - Provide procedure(s) demonstrating evidence of selection criteria, re-evaluation, and supplier audits.
- Traceability
  - Provide procedure(s) demonstrating evidence of identification of raw materials to delivered products, batch / lot identification, and finished product traceability to inspection and test records.
- Process Control
  - Provide procedure(s) and/or work instruction(s) demonstrating evidence of a manufacturing process.
- Inspection and Testing
  - Provide procedure(s) demonstrating evidence of inspection and testing.
  - Provide an example of a test record as required by NOCSAE Doc 001-13m13 Section 6.2 and NOCSAE Doc 011-13m13 Section 3.

- Nonconforming Products
    - Provide procedure(s) demonstrating evidence of handling nonconforming products as required by SEI CPM Section 15, NOCSAE Doc 001-13m13 Section 6.2, and NOCSAE Doc 011-13m13 Section 4.
- Corrective Action
    - Provide procedure(s) demonstrating the corrective action process.
    - Provide an example of a corrective action that has gone through your quality system.
- Preventative Action
    - Provide procedure(s) demonstrating the preventative action process.
    - Provide an example of a preventative action that has gone through your quality system.
- Quality Records
    - Provide procedure(s) demonstrating the control of quality records.
- Internal Audit
    - Provide procedure(s) demonstrating the internal audit process.
    - Provide an example of an internal audit that has gone through your quality system.
- Product Audit
    - Provide current QC/QA procedure(s) for product audits, and if different, an updated procedure complying with NOCSAE Doc 001-13m13 Section 6.2 and NOCSAE Doc 011-13m13 Section 3.
- Product Recall
    - Provide procedure(s) demonstrating product recall (refer to CPM Section 18 for specific SEI product recall requirements).
- Use of the SEI Logo
    - Demonstrate how the "SEI Certifies MEETS NOCSAE Standard" logo will be transitioned and used for certified products.
    - Provide procedure(s) demonstrating how the SEI logo will be terminated upon receipt of a catastrophic noncompliance (refer to NOCSAE Doc 011-13m13 Section 4 and SEI CPM Section 15 (G)).

The Pre-Audit will take place off-site where it is anticipated the review time expended will not exceed a full day, or eight (8) hours. There will be a Pre-Audit flat fee of $500, plus a 10% surcharge. If, during the Pre-Audit, it is determined the review is more complex than anticipated you will be notified by the auditor. If additional time is needed and approved by you, an hourly rate of $50/hour will be charged (in addition to the flat fee). In an effort to maintain the full day Pre-Audit timeframe, it is recommended that the Pre-Audit review cover a single product line, assuming it is representative of all NOCSAE product lines manufactured.

We are providing tools, such as the Pre-Audit review, in an effort to help make the transition to third-party certification as straightforward as possible for your company. If you have any questions or concerns regarding the SEI Pre-Audit process or quality requirements, we encourage you to contact a member of the SEI staff to discuss these matters.

Sincerely,

Tricia Hock
Program Development Director

ENCLOSURES: SEI CPM Section 13: Audit Checklist