Supplementary Laboratory Management Review

Reviewed by Laboratory Management:

Names:

Signatures:

Date(s):

Background and Compliance Deadlines:

Information for this Supplementary Management Review may be taken from the 2019 Internal Audit and summarized to share during the laboratory management reviews in 2019. The information is being requested during the 2019 Annual Submission to assess and summarize levels of laboratory compliance with the 2019 NIST Handbook 143, Program Handbook. Handbook 143 includes updated recognition requirements to reference and ensure compliance with ISO/IEC 17025:2017. Training on the new ISO/IEC 17025 standard has been provided via Laboratory Metrology Info Hours, OWM Webinars, and at Regional Measurement Assurance Program (RMAP) training each year since 2016 with feedback provided to laboratories during the annual review evaluations. Note: This supplementary evaluation is a *sampling* of compliance and not a full assessment; the laboratory is responsible for a complete internal audit of the laboratory against the new ISO/IEC 17025:2017 standard, hereafter called the *standard*.

The deadline for full compliance to the 2019 Handbook 143, Program Handbook and ISO/IEC 17025:2017 is no later than the submission cycle beginning November 2020 for issuance of Recognition certificates in 2021.

Evaluation of Laboratory Policies and Management Systems:

1. Impartiality and Confidentiality (4.1, 4.2).

The *standard* includes new language regarding the assurance of laboratory impartiality and confidentiality of customer information and laboratory data. OWM has observed in many State governments the availability of employee handbooks and government policies intended to ensure impartiality, including the avoidance of conflict of interest activities. In addition, many State government have provided feedback that all information produced by the laboratory is considered public information. However, the standard requires that such policies be documented and customers notified (as appropriate).

Describe how your State policies and guidance have been implemented in your laboratory. Describe how any requirements you have for ensuring confidentiality or public availability of information are communicated to laboratory customers. What types of risks have been considered and/or minimized related to impartiality and confidentiality.

2. Requirements regarding Risk Management (sections noted below).

The *standard* includes a number of references to risk based thinking. The Introduction to the standard states the following:

> *This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.*

Key sections in the *standard* that identify risk include the following 1) Section 4.1.4, risks to impartiality; 2) Section 7.8.6.1, risks associated with decision rules (related to stating that standards meet documentary standards such as the 105-x standards); 3) Section 7.10, minimizing risk related to actions of non-conforming work (e.g., continuing to perform calibrations outside documented environmental limits, untrained staff performing calibrations, use of standards past calibration due dates); 4) identification and actions to address risks and opportunities (e.g., identified in the 2018 version of the OWM Management Review form). Training was conducted by OWM during the 2016 and 2018 Regional Measurement Assurance Program sessions on "risk management" concepts and techniques in anticipation of the *standard* changes. The OWM management review form was updated in 2018 in anticipation of these changes as well.

Describe what has been completed to address RISK topics in the laboratory quality management system (e.g., inclusion of risk policies in the quality documents and procedures) and laboratory management reviews?

Provide highlights and explanations for the top three actions that have been completed over the past three years related to addressing Risk and Opportunities.

3. Changes and updates needed to the management system (e.g., quality documents) (Section 8).

OWM provided training and recommendations during the 2018 RMAP sessions on approaches that could be used to ensure compliance in current laboratory quality documents, including the inclusion of a cross-walk between the 2007 version of Handbook 143 and the new standard

and an assessment to compare prior quality manual sections with the new *standard*. Additional discussions at the RMAPs included the level of effort required to completely rewrite and update quality manuals that was desired by a number of laboratories (but not required according to the *standard* itself).

Describe the efforts that have been made or will be made to update the laboratory Quality Management System so that it is compliant with the 17025:2017 standard or will be compliant by the 2020 deadline.

Evaluation of Laboratory Resources:

4. Staffing Requirements (Section 6.2).

Little has changed in the new *standard* regarding personnel requirements. The *standard* addresses requirements for impartiality; documentation of competence for each laboratory function including requirements for education, qualification, training, technical knowledge, skills and experience; ensuring competence and evaluation of the significance of any deviations; communication to personnel duties, responsibilities, and authority; and authorization for laboratory functions, including validation of methods, analysis, reporting, reviewing, and releasing measurement results. Handbook 143, Program Handbook lists specific training requirements for State laboratories to ensure compliance with the *standard* and to ensure uniformity in calibration practices and measurement results in support of the United States weights and measures system. OWM recognizes laboratory staff as Authorized Signatories once training requirements have successfully been met.

Describe your laboratory challenges and efforts to ensure compliance with Handbook 143 requirements and support for hiring competence staff, completing on-the-job training, preparing staff to attend the required OWM training seminars, ensuring staff complete the required Laboratory Auditing Program problems, and to ensure succession planning. Address related risk considerations as well.

5. Facility Maintenance and Operational Support (Section 6.3).

Little has changed in the new standard regarding facility requirements. The *standard* addresses requirements for 1) suitability and ensuring no adverse effects to measurement results; 2) documented environmental conditions; 3) monitoring, recording, and controlling environmental conditions, and measures to control the facilities including access/use, prevention of contamination, and effective separation of incompatible areas; and 4) activities performed at sites or facilities outside of permanent laboratory control. OWM has regularly provided guidance, training, and feedback to laboratories regarding designing, validating, monitoring and controlling laboratory conditions. OWM calibration procedures all include environmental requirements for each measurement area. In addition, OWM has provided guidance, feedback, and restrictions in recognition for calibrations that are performed in

locations outside of permanent laboratory control.

Describe your laboratory challenges and efforts to ensure compliance with Handbook 143 and ISO/IEC 17025:2017 requirements and support for ensuring suitable facilities, control, and monitoring.

6. Calibration and Maintenance Requirements for Standards and Equipment (Sections 6.4, 6.5, 6.6).

These three sections of the *standard* include metrological traceability for laboratory standards and equipment, as well as evaluation of calibration providers to ensuring metrological traceability.

OWM publishes Good Measurement Practice (GMP) 11 and GMP 13, as well as associated job aids (Excel tools) that define suitable baseline calibration intervals, document traceability hierarchies, maintain records of calibration history, evaluate suitable calibration and service providers. Implementation of these GMPs requires detailed maintenance and records of calibrations of standards and service to laboratory equipment. Maintenance of the laboratory equipment and standards is a significant cost for most laboratories and generally requires long-term thinking as a planned effort. Language in many of the State regulations/statutes directs the laboratory to ensure traceability of laboratory standards to NIST or the International System of Units (SI). The OWM 2017 Annual Submission provided the opportunity to summarize and evaluate the status and assurance of laboratory metrological traceability. Long-term balance replacement plans have been recommended to State laboratories and "obsolete balance" lists obtained from balance manufacturers have been provided to States to support planning efforts.

Summarize a LIST of actions taken in the last three years to ensure that laboratory standards have up-to-date calibrations, that equipment such as balances have suitable maintenance, repair, evaluation, and replacement, and that standards and equipment are cared for properly. Describe the challenges your laboratory has addressed to ensure ongoing measurement traceability is assured to support your program.

Evaluation of Laboratory Processes

7. Selection, Verification, and Validated of Methods (7.2)

The *standard* specifies that the laboratory shall use appropriate and validated procedures for measurements and uncertainty evaluations. OWM publishes standard operating procedures, good laboratory practices, good measurement practices, and a good laboratory practice for validating laboratory-developed procedures. OWM training seminars and webinars cover application of OWM procedures. Laboratory Auditing Program (LAP) problems assess the compliance and implementation of OWM-published procedures. In general, if the laboratory applies, and does not deviate from, OWM published procedures, the criteria in this section are met. Laboratory developed methods and deviation from OWM procedures will require special

assessments, records of evaluation, and special record retention policies (records must be retained as long as the procedure is in use).

Select the applicable laboratory policy and practice(s) from the following:

___ *Our laboratory only uses OWM or internationally/nationally published procedures and has demonstrated competency with proficiency testing for each procedure;*

___ *Our laboratory uses OWM or internationally/nationally published procedures, and the following list of laboratory-developed procedures with suitable validation and record retention policies, and has demonstrated competency with proficiency testing for each procedure: {insert list of procedures};*

___ *Our laboratory uses OWM or internationally/nationally published procedures, and the following list of laboratory-developed procedures and exceptions (e.g., have NOT been validated, do NOT have special record retention policies, or have NOT demonstrated competency with proficiency testing): {insert list of procedures};*

___ *Objective evidence of software verification and validation is available for all calibration procedures where software is used in our laboratory (7.11).*

Describe any unique issues or action items for your laboratory regarding the selection, verification, and validation of calibration procedures and software verification and validation. Describe any situations that did not meet one of the prior selection statements and list associated action items as appropriate.

8. Evaluation of Measurement Uncertainty (7.6)

The *standard* specifies that each laboratory shall identify contributions to measurement uncertainty, evaluate significance of each component, and evaluate uncertainties for all calibrations, including those performed for the laboratory equipment and standards. This is not a new requirement. OWM and accreditation bodies also require the inclusion of uncertainty on calibration certificates with an uncertainty statement that describes compliance with suitable methods for determining the uncertainty. This is not a new practice or requirement.

OWM has published a standard operating procedure for performing uncertainty identification to reporting, and includes sample uncertainty budget tables and practices within each calibration procedure. Further, OWM evaluates laboratory compliance with uncertainty identification, calculations, and reporting each year during the annual submission process and includes policy requirements that include reporting actual calibration uncertainties for calibrations and proficiency testing. OWM believes that this ISO/IEC 17025:2017 requirement is fully met for State laboratories.

Describe any unique issues or action items for your laboratory regarding uncertainty evaluations and reporting.

9. Ensuring Validity of Results (7.7)

The *standard* specifies that each laboratory shall have a procedure for monitoring the validity of results, record results to detect trends, and apply statistical techniques where possible. This is not a new requirement.

State laboratories have implemented measurement assurance practices for many years. OWM has published good laboratory practices and standard operating procedures for applying measurement assurance methods, which include activities such as training, use of check standards, replicate measurements, proficiency testing, and evaluating calibration certificates prior to release. Each measurement procedure includes a section on measurement assurance. The procedures and practices for ensuring validity of measurement results is covered in all OWM seminars. OWM also coordinates proficiency testing through the Regional Measurement Assurance Programs and requires participation in PTs for each measurement area on the laboratory Scope where possible. In 2018, OWM requested submission of measurement assurance evaluations and control charts and provided review and feedback to all State laboratories. Where PTs or measurement assurance systems were absent, the laboratory Scope was modified for the 2019 recognition cycle. OWM believes that this ISO/IEC 17025:2017 requirement is fully met for State laboratories; as long as it is supported through internal auditing and as long as OWM-provided feedback and corrective actions have been implemented.

Describe any unique issues or action items for your laboratory regarding measurement assurance and control chart evaluations. List specific corrective action(s) that were completed since the last OWM assessment of your laboratory measurement assurance system.

10. Calibration Certificates (7.8)

The *standard* specifies requirements for calibration certificates and reporting of measurement results. In general, requirements for calibration certificates are not a new, however there are some additional reporting requirements regarding conformity assessment that are important. SOP 1, for preparing and reporting calibration data was updated in 2018 to comply with the standard. All SOPs were updated in 2019 to address Conformity Assessment requirements to ensure decision rules were documented for ensuring uncertainties are less than specified limits in documentary standards (e.g., uncertainty must be less than one-third of the applicable tolerances for all mass calibrations). OWM provided training on conformity assessment statements during the 2018 RMAP and 2019 C-RMAP training sessions.

Describe the assessments your laboratory has performed in the past year to evaluate your calibration certificate templates or calibration certificates against SOP 1 (as updated to comply with ISO/IEC 17025:2017). List specific corrective action(s) that have been made in the past year to update your calibration certificates.