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## Approval Signatures

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## Revision Summary:

1. Updated reference of the ISO/IEC 17025 Standard from the 2005 version to the 2017 version.
2. Updated step 2.1.1 to define the laboratory's management team.
3. Rewrote the Procedure Section to describe the new approach for completing this process.
4. Removed reference to ADMIN-009. Replaced with the 3 related work instructions: LAB-WI-0329, LAB-WI-0330 and LAB-WI-0331.
5. Added references to the 2 new forms: LAB-FORM-0514 and LAB-FORM-0531.
6. Updated format to MasterControl format and included Collaborators section.

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## 1. Purpose

To describe the procedure employed for conducting management reviews of the Laboratory's Quality Management System.

## 2. Scope/Definitions

This procedure governs the management review of the Laboratory's Quality Management System as required in Section 8.9 of the ISO/IEC 17025:2017 Standard.

### 2.1 Definitions:

- 2.1.1 Management Team – Consists of the Laboratory's managers which includes: Laboratory Director, Technical Manager and Quality Manager.
- 2.1.2 Management Review Team – Consists of the Management Team members, the Quality Assurance Officers (QAOs), the Unit Supervisors and other appropriate staff identified by the Laboratory Director.

## 3. Procedure

3.1 The Management Team shall annually administer meetings with each member of the Management Review Team to conduct a review of the laboratory's quality management system and testing activities to ensure their continuing suitability, adequacy and effectiveness, and to introduce necessary changes or improvements. Other individuals may also be present during the review. The order and schedule of the topics listed in this section may be adjusted at the discretion of the Laboratory Director, but all topics must be covered upon conclusion of the management review process.

### 3.2 Preparation Prior to the Initial Meeting with the Management Review Team:

3.2.1 Managers and Unit Supervisors shall make a summary of issues regarding their work unit by completing LAB-FORM-0514, Management Review – Unit Summary, which is based upon input topics from Section 8.9 of the ISO/IEC 17025:2017 Standard and includes other items of interest to Management. These will be presented at the meetings convened by the Management Team for review and consideration.

### 3.3 Management Team Meeting:

3.3.1 The Management Review Meeting will address topics identified for attention by management that result from the summary reports in step 3.2.

### 3.4 Documentation and Response by the Management Team to the Management Review Findings:

3.4.1 The Management Review – Unit Summary, that each unit completed, shall be used by the Laboratory Director, or designee, to complete LAB-FORM-0531, Management Review Checklist. The checklist will include decisions relating to the effectiveness of the management system and its processes and identification of any improvements needed.

3.4.2 Action items that must be addressed, along with an action plan, the person(s) responsible for the actions and specific deadlines for each action item will be documented in LAB-FORM-0531. The Management

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Review Checklist will be the official record documenting the management review.

- 3.4.3 All quality issues resulting from the management review shall be entered into the MasterControl Quality Event Management (QEM) module per the associated work instructions, as needed, LAB-WI-0329, "Work Instructions for QEM: Completing the "Incident Reporting" Form in MasterControl", LAB-WI-0330, "Work Instructions for QEM: Completing the "Issue Review" Form in MasterControl", and LAB-WI-0331, "Work Instructions for QEM: Completing the "CAPA" Form in MasterControl".

## 4. Responsibilities

- 4.1 The Laboratory Director shall chair and conduct the meeting following this procedure.
- 4.2 The Laboratory Director assigns a specific person(s) to address review findings and establishes deadlines for their completion. Management is responsible to ensure that assigned actions are carried out within an appropriate and agreed upon timescale.
- 4.3 The Laboratory Director shall assign a staff member to record meeting minutes and help prepare LAB-FORM-0531, Management Review Checklist, which summarizes the action items, and the goals and objectives for the upcoming year.
- 4.4 Managers, Unit Supervisors, QAO's and other staff shall provide any necessary information requested by the Laboratory Director and Management Team Members.

## 5. References

- 5.1 International Standard, ISO/IEC 17025, *Section 8.9 Management reviews*. Third edition 2017-11, Reference number ISO/IEC 17025:2017(E).
- 5.2 LAB-FORM-0514, Management Review – Unit Summary.
- 5.3 LAB-FORM-0531, Management Review Checklist.
- 5.4 LAB-WI-0329, "Work Instructions for QEM: Completing the "Incident Reporting" Form in MasterControl".
- 5.5 LAB-WI-0330, "Work Instructions for QEM: Completing the "Issue Review" Form in MasterControl".
- 5.6 LAB-WI-0331, "Work Instructions for QEM: Completing the "CAPA" Form in MasterControl".

## 6. Collaborators:

Gary Horvath, Laboratory Director  
Quality Committee