The Texas A&M University System Internal Audit Department

Monthly Audit Report
January 9, 2019

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System Internal Audit

THE TEXAS A&M UNIVERSITY SYSTEM

TEXAS A&M TRANSPORTATION INSTITUTE

PROVING GROUNDS RESEARCH FACILITY COMPLIANCE WITH ISO STANDARDS

January 9, 2019

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Chief Auditor

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Overall Conclusion

Overall, the controls established over the Proving Grounds Research Facility (Laboratory) at Texas A&M Transportation Institute (TTI) are operating as intended and in compliance with the specific International Organization for Standardization 17025:2017 Standards (ISO Standards) evaluated. Significant improvements are needed in internal audit processes, documentation of the responsibilities of principal investigators for Laboratory activities, and information systems access. Additional opportunities for improvement were noted in risk assessments, management reviews, document system form authorizations, and management system guidance.

ISO Standards Audited
- General requirements
- Structural requirements
- Resource requirements*
- Process requirements*
- Management system requirements

* Select sections

Management concurred with the audit recommendations and indicated that implementation will occur by the end of June 2019.

Summary of Audit Results

Significant Observations

- Internal audits conducted by the Laboratory are not in compliance with ISO Standards.
- The roles, responsibilities, and authority of principal investigators for Laboratory activities are not fully documented.
- Employees not designated as part of the Laboratory have access to information systems containing confidential files and controlled documents.

Notable Observations

- The Impartiality Risk Assessment has not been finalized.
- The Risks and Opportunities Assessment has not been finalized.

- Quality survey information and internal audit results are not being communicated during management review meetings.
- Approvals for changes made to forms are not adequately documented.
- A comprehensive review of the Laboratory's management system guidance has not been conducted to ensure written guidance reflects current practice.

Detailed Results

1. Internal Audits

Internal audits conducted by the Laboratory are not in compliance with ISO Standards. Laboratory employees complete a checklist noting that procedures are in place for ISO Standards, quality procedures, and methods, but employees do not verify that current practices are compliant with the procedures. The Deputy Quality Manager indicated that an accreditation assessor told her that completing the checklist was sufficient to meet the ISO internal audit standard.

In addition, internal audits of calibration procedures and work instructions do not include documentation required by the ISO Standards such as the audit criteria, audit scope, description of work performed, results of work performed, and indication of reporting to management. As a result, it is difficult to determine if the internal audits of calibration procedures and work instructions include verification that current practices are compliant with the procedures. The internal audit quality procedure and corresponding form do not include guidance to ensure documentation of necessary audit elements.

ISO Standard 8.8, *Internal Audits,* Section 8.8.1, requires laboratories to conduct internal audits at planned intervals to provide information on whether the management system conforms to the laboratory's own requirements and the ISO Standards. Without documented verification that current practices conform to ISO Standards and Laboratory policies and procedures, the Laboratory is not in compliance with ISO Standard 8.8, *Internal Audits*, Section 8.8.1.

ISO Standard 8.8, *Internal Audits*, Section 8.8.2, requires laboratory internal audits to include documentation of audit criteria, audit scope, planning activities, results of work performed, and evidence of reporting to management.

Recommendation

Update Quality Procedure 8.8-01, *Internal Audits*, to comply with ISO Standard 8.8, *Internal Audits*. Ensure that procedures address performing tests of compliance with ISO Standards and the Laboratory's management system, and documentation requirements outlined in ISO Standard 8.8, *Internal Audits*. Monitor to ensure implementation of, and compliance with, the updated procedures.

Management's Response

We concur with the auditors' observation and recommendations.

Quality Procedure 8.8-01 *Internal Audits* and Quality Form 8.8-02 *Technical Internal Audit Worksheet* will be updated to comply with the requirements of ISO Standard 8.8, *Internal Audits*. An Internal Audit Plan matrix will be created to assist in internal audit planning, compliance, and monitoring. Together, these procedures and documents will address the performance of tests for compliance to ISO Standards and the Laboratory's management system and the document requirements outlined in ISO Standard 8.8, *Internal Audits*. The target date for implementation is June 30, 2019.

2. Proving Ground Personnel

The roles, responsibilities, and authority of principal investigators for Laboratory activities are not fully documented. The Laboratory does not classify principal investigators as Laboratory employees; however, principal investigators sign contracts and forms, design tests, review reports, and are listed as authors on reports. These key roles in Laboratory activities are not defined and documented in the management system, recognized on the organizational chart, or assessed to ensure these individuals understand their roles and responsibilities to comply with ISO Standards. Principal investigators are not classified as Laboratory employees to limit the perception of conflicts of interest.

ISO Standard 5, *Structural Requirements*, Section 5.5, requires laboratories to specify the responsibility, authority, and interrelationship of all employees who manage, perform or verify work affecting the results of laboratory activities. Without documenting the principal investigators' roles in Laboratory activities covered by ISO Standards, the principal investigators' responsibilities and authority are unclear. In addition, the Laboratory is not compliant with ISO Standard 5, *Structural Requirements*, Section 5.5.

Recommendation

Clearly define the relationship between the principal investigators and the Laboratory. Clarify the principal investigators' responsibilities and authority for activities covered by ISO Standards. Ensure all relevant policies and procedures clarify the interrelationship between principal investigators and Laboratory employees.

Management's Response

We concur with the auditors' observation and recommendations.

Section 5 of the *Quality Policy Manual* will be revised to clearly define the principal investigator's responsibility, authority and interrelationship with TTI's Proving Ground and its activities. The Competence/Job Requirement document CR 6.2-01 *Job Function Assessment* for principal investigators will be reviewed and updated to more accurately define the principal investigator's responsibilities and authorities. The target date for implementation is June 30, 2019.

3. Information Systems Access

Employees not designated as part of the Laboratory have access to information systems containing confidential files and controlled documents. Thirty-two TTI employees that are not part of the Laboratory (including ten principal investigators) have access to the Laboratory's network drive. This drive contains management system documents and in-process project (test) files. In addition, system access is not restricted to particular projects and does not limit users' abilities to make changes to files. Some of these employees also have access to the electronic document repository and the Computer Assisted Drawing system.

Roles and responsibilities of employees not designated as part of the Laboratory who require information systems access have not previously been defined. Laboratory management was aware of the lack of project access restrictions, but was not fully aware of who had information systems access.

ISO Standard 7.11, *Control of Data and Information Management*, Section 7.11.3, requires laboratory information management systems to be protected from unauthorized access. Employees without documented Laboratory roles and responsibilities that have information systems access would be considered unauthorized resulting in noncompliance with ISO Standard 7.11, *Control of Data and Information Management*, Section 7.11.3.

Recommendation

Review all access to Laboratory information systems to ensure access is appropriate based on job duties. Implement monitoring processes to ensure access is reviewed regularly to ensure it is appropriate. Restrict access to Laboratory information systems containing confidential files and controlled documents based on documented Laboratory roles and responsibilities. Define and document access given to employees that are not part of the Laboratory but require access to the Laboratory's information systems, including the electronic document repository and Computer Assisted Drawing system.

Management's Response

We concur with the auditors' observation and recommendations.

The Proving Ground will define and document allowed access based on roles and job duties. A member of the Proving Ground team will be identified to determine and monitor required access and maintain an accurate, current list of all individuals and their allowed access. In conjunction with TTI's Network Information Systems, the Proving Ground will set up a secure information system drive independent from the shared information system drive and continually monitor access. The target date for implementation is June 30, 2019.

4. Impartiality Risk Assessment

The Impartiality Risk Assessment has not been finalized. The Laboratory has developed procedures to identify, assess, and mitigate risks to impartiality through an Impartiality Assessment Committee. At the time of the audit, the committee had been formed, but had not met and the procedures had not been fully implemented. The Laboratory's American Association for Laboratory Accreditation (A2LA) certificate for compliance with the 2005 ISO Standards is valid until April 2019. The Laboratory must be compliant with the new 2017 ISO Standards for the upcoming A2LA accreditation in spring 2019.

ISO Standard 4.1, *Impartiality*, Sections 4.1.4 and 4.1.5, require laboratories to identify risks to impartiality on an ongoing basis and to demonstrate how it eliminates or minimizes such risks. Until the impartiality risk assessment is complete, the Laboratory is not compliant with ISO Standard 4.1, *Impartiality*, Sections 4.1.4 and 4.1.5.

Recommendation

Complete the impartiality risk assessment and develop any necessary corrective actions to eliminate or minimize risks to impartiality in accordance with ISO Standard 4.1, *Impartiality* and Quality Procedure 4.1-01, *Ensuring Impartiality*.

Management's Response

We concur with the auditors' observation and recommendations.

The Proving Ground will develop an Impartiality Assessment matrix and a Risk Priority Level matrix to identify and minimize risks, revise the Quality Policy Manual Section 4.1, *Impartiality* and create a quality procedure to ensure compliance with ISO Standard 4.1. These documents will be reviewed by the Impartiality Assessment Committee. The target date for implementation is June 30, 2019.

5. Risks and Opportunities Assessment

The Risks and Opportunities Assessment has not been finalized. The Laboratory has developed procedures to identify, assess, and mitigate risks through a Risk/Opportunity Assessment Committee. At the time of the audit, the committee had been formed, but had not met and the procedures had not been fully implemented. The Laboratory's A2LA accreditation certificate for compliance with the 2005 ISO Standards is valid until April 2019. The Laboratory must be compliant with the new 2017 ISO Standards for the upcoming A2LA accreditation in spring 2019.

ISO Standard 8.5, *Actions to Address Risks and Opportunities*, requires laboratories to consider the risks and opportunities associated with the laboratory activities and plan actions to address these risks and opportunities. Until the risks and opportunities assessment is complete, the Laboratory is not compliant with ISO Standard 8.5, *Actions to Address Risks and Opportunities*.

Recommendation

Complete the risks and opportunities assessment and develop any necessary corrective actions to mitigate potential impact on the validity of results in accordance with ISO Standard 8.5, *Actions to Address Risks and Opportunities* and Quality Procedure 8.5-01, *Risks, Opportunities, and Actions Assessment*.

Management's Response

We concur with the auditors' observation and recommendations.

The Proving Ground will develop a Risk and Opportunities Assessment matrix and a Risk Priority Level matrix to identify and minimize risks, revise the Quality Policy Manual Section 8.5, *Actions to Address Risks and Opportunities* and create a quality procedure to ensure compliance with ISO Standard 8.5. These documents will be reviewed by the Risk/Opportunity Assessment Committee. The target date for implementation is June 30, 2019.

6. Management Reviews

Quality survey information and internal audit results are not being communicated during management review meetings. Results of internal audits conducted by Laboratory employees, including completion of the accreditation checklist, review of calibration procedures, and review of work instructions are not being discussed in the management review meetings. In addition, not all quality survey results containing pertinent feedback are presented at the management review meetings. The Deputy Quality Manager reviews the completed quality surveys and determines if the results should be presented at the management review meetings.

ISO Standard 8.9, *Management Reviews*, Section 8.9.2, requires laboratories to include outcomes of recent internal audits and customer feedback in management review meetings. In addition, ISO Standard 8.6, *Improvement*, Section 8.6.2, requires laboratories to analyze and use feedback from its customers to improve the management system, laboratory activities, and customer service. The Laboratory is not in compliance with ISO Standard 8.9, *Management Reviews*, Section 8.9.2, and ISO Standard 8.6, *Improvement*, Section 8.6.2.

Recommendation

Update quality procedures for quality surveys and internal audits conducted by the Laboratory regarding communication of results at management review meetings as required by ISO Standard 8.9, *Management Reviews*, Section 8.9.2. Update quality procedures to ensure survey results are analyzed and reported to management to improve the management system, testing activities, and customer service as required by ISO Standard 8.6, *Improvement*, Section 8.6.2. Monitor to ensure implementation of, and compliance with, the updated procedures.

Management's Response

We concur with the auditors' observation and recommendations.

A standing agenda item for Internal Audit review and discussions will be added to all quarterly management review meetings. Quality Form 8.8-02, *Technical Internal Audit Worksheet* will be revised to include more detail on Internal Audit activities. Quality Procedure 8.6-01, *Improve/Service to Sponsor* will be revised to include a final review for the completion of all paperwork and the quality survey procedure will also be revised to require the review of any quality surveys with an evaluation lower than "Good" (i.e. "Average"; "Fair"; "Poor"). The target date for implementation is June 30, 2019.

7. Document System Forms

Approvals for changes made to forms are not adequately documented. Ten of 10 (100%) forms tested did not have a written signature, electronic signature, or other indication of approval. In order to save space on the forms, the approvals are tracked in an Excel spreadsheet with the quality manager's name typed in to document the approval.

ISO Standard 8.3, *Control of Management Information System Documents*, Section 8.3.2, requires laboratories to ensure that documents are approved for adequacy prior to issue by authorized employees. The process for documenting the review and approval of changes to the forms does not include controls to ensure the quality manager has actually reviewed and approved the changes. The Laboratory is not compliant with ISO Standard 8.3, *Control of Management Information System Documents*, Section 8.3.2.

Recommendation

Update Quality Procedure 8.3-01, *Management System Documentation*, to improve the method of documenting authorization of forms prior to implementation. Monitor to ensure implementation of, and compliance with, the updated procedures.

Management's Response

We concur with the auditors' observation and recommendations.

Quality Procedure 8.3-01 will be revised to include steps for the approval of forms as noted below:

6.9 Revisions to the QPM, Quality Procedures and Work Instructions will be identified by change control notation at the end of the document. Revisions to all forms and LF-COC will be recorded in *EIR-019: Records and Document List* spreadsheet in their respective tabs with a signed approval *QF 8.3-01 Management System Documentation Amendment Request* form filed in the Amendment Requests folder. QF 8.3-01 will be filled out and approved by the QM for any further changes.

The target date for implementation is June 30, 2019.

8. Management System Guidance

A comprehensive review of the Laboratory's management system guidance has not been conducted to ensure written guidance reflects current practice. A review of select procedures and forms identified several instances where operations varied from the written procedures.

Examples include the following:

- Quality Survey Procedures – The Laboratory is not conducting investigations for quality survey ratings lower than 'Excellent' as required by Quality Procedure 8.6-01, *Improvement-Service to Sponsor*.

- Management System Documentation Procedures - Forms tested did not have revision history at the end of the document, as required by Quality Procedure 8.3, *Management System Documentation*, Section 6.9.

- Externally Procured Products and Services Procedures - The routing and approval of the Laboratory's purchasing request form are not in alignment with Quality Procedure 6.6-01, *Procuring Quality External Services and Products*.

In several cases, the expectations set forth in the Laboratory's quality procedures exceed the requirements of the ISO Standards.

ISO Standard 8.2, *Management System Documentation*, Section 8.2.1 and 8.2.3, requires laboratory management to ensure implementation and maintenance of the management system, while continually improving its effectiveness. Without routine reviews of the management system documentation to ensure it reflects current practices, management may not recognize areas requiring improvement or areas performing well. The Laboratory is not compliant with ISO Standard 8.2, *Management System Documentation*, Section 8.2.1 and 8.2.3.

Recommendation

Review management system guidance. Update guidance as needed to ensure that guidance is reflective of the Laboratory's practices and expectations. Ensure updated procedures comply with ISO standards.

Management's Response

We concur with the auditors' observation and recommendations.

All quality procedures will be reviewed and revised to ensure they are current and aligned with laboratory practices and expectations. The target date for implementation is June 30, 2019.

Basis of Review

Objective and Scope

The objective of this audit was to review areas of the Laboratory's management system for compliance with select International Organization for Standardization 17025:2017 (ISO Standards).

The audit focused on the following areas of the ISO Standards:

- 4 General requirements
  - 4.1 Impartiality
  - 4.2 Confidentiality
- 5 Structural requirements
- 6 Resource requirements
  - 6.2 Personnel
  - 6.6 Externally provided products and services
- 7 Process requirements
  - 7.1 Review of requests, tenders, and contracts
  - 7.8 Reporting of results
    - 7.8.1General
    - 7.82 Common requirements for reports
  - 7.9 Complaints
  - 7.10 Nonconforming work
  - 7.11 Control of data and information management
- 8 Management system requirements
  - 8.1 Options
  - 8.2 Management system documentation
  - 8.3 Control of management system documents
  - 8.4 Control of records
  - 8.5 Actions to address risks and opportunities
  - 8.6 Improvement
  - 8.7 Corrective action
  - 8.8 Internal audits
  - 8.9 Management reviews

The audit period was primarily September 2017 to August 2018. Fieldwork was conducted from September 2018 to October 2018.

Methodology

Our audit methodology included interviews, observation of processes, review of documentation, and testing of data using sampling as follows:

- To determine if the Laboratory's documentation for laboratory personnel is in compliance with selected general requirements, structural requirements, and resource requirements, the auditors judgmentally selected a non-statistical sample of personnel records for ten Laboratory employees designed to be representative of the population. Selected ISO Standards included 4.1, *Impartiality*; 4.2, *Confidentiality*; 5, *Structural Requirements*, Sections 5.5 and 5.6; and 6.2, *Personnel*.
- To determine if the Laboratory's documentation of purchasing processes for externally procured products and services is in compliance with ISO Standard 6.6, *Externally provided products and services*, Section 6.6.2, and Laboratory procedures, the auditors judgmentally selected a non-statistical sample of ten vouchers designed to be representative of the population.
- To determine if the Laboratory's project (test) documentation for accredited tests is in compliance with selected process and management system requirements from the ISO standards, the auditors judgmentally selected a non-statistical sample of thirty-three project files designed to be representative of the population. Selected ISO Standards included 7.1, *Review of requests, tenders, and contracts*; 7.8.1*, Reporting of results – General*; 7.8.2, *Reporting of results – Common requirements for reports*; 8.4, *Control of records*; and 8.6, *Improvement*.
- To determine if the Laboratory's document system is in compliance with selected management system requirements from the ISO standards, the auditors judgmentally selected a non-statistical sample of twenty documents to be representative of the population. Selected ISO Standards included 8.2, *Management system documentation*; and 8.3, *Control of management system documents*.

Criteria

Our audit was based upon standards as set forth in the following:

- Texas A&M University System Policies and Regulations
- International Organization for Standardization 17025:2017 *General requirements for the competence of testing and calibration laboratories*
- Proving Ground Research Facility Policies and Procedures
- Other sound administrative practices

The audit was conducted in conformance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*. Additionally, we conducted the audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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