



Calibration Laboratories

Quality Manual

Section 4

Management System

4. Management System

This section describes the overall quality system including the legal identity, organization and management arrangements at HN Calibration Laboratories.

4.1 Organization

4.1.1 Legal identity

HN Calibration Laboratories is a corporation incorporated in the state of Indiana.

4.1.2 Commitment to meet requirements and satisfy needs

HN Calibration Laboratories is committed to carry out its calibration activities in such a way as to satisfy the requirements of ISO/IEC 17025 and to satisfy the needs of its clients as well as regulatory organizations and accreditation bodies.

4.1.3 Scope of management system

The laboratory management system documented in this quality manual and associated documentation applies to work carried out at HN Calibration Laboratories' permanent facilities, at customers' sites and in associated temporary or mobile facilities.

4.1.4 Responsibilities of key personnel

HN Calibration Laboratories is not a part of a larger organization. There is no key personnel outside HN Calibration Laboratories that have an involvement in, or influence on the calibration activities of HN Calibration Laboratories.

4.1.5.a Authority and resources

The authority vested in the Technical Manager is described in the *Technical Manager Job Description*.
The authority vested in the Quality Manager is described in the *Quality Manager Job Description*.

Between them they have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system described in this quality manual and related documentation or from the procedures for performing calibrations, and to initiate actions to prevent or minimize such departures.

4.1.5.b Undue pressure

The laboratory's policy for employees accepting gifts and gratuities from clients is documented in the *Gifts and Gratuities Policy (POL-03)*.

Internal complaints or concerns from employees are handled according to the *Internal Complaint Policy (POL-04)*.

All client interaction is handled by the **Technical Manager** and the **Quality Manager**.

Employees are never asked to meet productivity goals that will jeopardize the quality of the work.



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4.1.5.c Confidential information and proprietary rights

For HN Calibration Laboratories' policy regarding clients' confidential information and proprietary rights, see the *Confidentiality Policy (POL-02)*. The procedure for instructing new employees in the quality system and requiring them to sign the *Confidentiality Agreement* is found in the *New Hire Introduction Agenda*.

A signed copy of the laboratory's *Confidentiality Agreement* can be found in each employee's personnel file.

The procedure for protecting the electronic storage of results is given in the *Data Protection and Backup Procedure (PRO-13)*.

The procedure for protecting clients' confidential information during electronic transmission of results is given in the *Electronic Transmission Procedure (PRO-15)*

4.1.5.d Independence of judgment and integrity

HN Calibration Laboratories' policy for acceptable activities is documented in the *Acceptable Activities Policy (POL-09)*. **HN Calibration Laboratories'** procedure to avoid involvement in unacceptable activities is documented in the *Activity Evaluation Procedure (PRO-16)*.

4.1.5.e Organization and management structure

The organization and management structure for HN Calibration Laboratories is defined in the *Organizational Chart*.

4.1.5.f Responsibility, authority and interrelation of personnel

The responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests are defined in the following documents:

- *Organizational Chart*
- *Technical Manager Job Description*
- *Quality Manager Job Description*
- *Technician Job Description*
- *Administrative Assistant Job Description*

4.1.5.g Supervision

Supervision is provided by the technical manager and the quality manager. For details of the education, experience and training of the technical manager and the quality manager, see their *personnel files*.

4.1.5.h Technical Manager

The **Technical Manager** has overall responsibility for the technical operations, see the *Technical Manager Job Description*. The Technical Manager has the resources needed to ensure the required quality of laboratory operations.

4.1.5.i Quality Manager

The **Quality Manager** has responsibility for the quality system and its implementation, see the *Quality Manager Job Description*.

The quality manager has direct access to the technical manager and management controlling the laboratory policies and resources see the *Organizational Chart*.



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4.1.5.j Deputies

The technical manager and the quality manager function as each other's deputy in case of absence.

4.2 Quality system

4.2.1 Quality system

HN Calibration Laboratories has established, implemented and maintains the quality system documented in this quality manual and related documentation. HN Calibration Laboratories has documented its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of calibration results. The system's documentation has been communicated to, understood by, is available to and implemented by all personnel. For documentation, see the *Quality System Training Form* and *Quality Documentation Update Form(s)*, as applicable, in each employee's *employee file*.

4.2.2 Quality policy statement

HN Calibration Laboratories' quality policy statement is documented in the *Quality Policy (POL-01)*, which is issued under the authority of the chief executive.

4.2.3 Structure of quality documentation

HN Calibration Laboratories' internally generated quality documentation is made up of this quality manual, quality policies and quality procedures as well as a calibration manual and a number of supporting documents.

References to documents within the quality system are made in *italic* throughout the internally generated quality documentation. Each document contains a list of references at the end of the document.

In addition, HN Calibration Laboratories' quality system encompasses a number of externally generated documents by reference from internally generated quality documents.

The *Quality Document Master List* outlines the structure of the documentation and lists all the quality documents, both internal and external, that make up the quality system. It also gives the current revision number and approval date of each document.

The quality documentation also makes reference to various files and logs (also in *italic*) throughout the text. The *Quality Document Master List* does not cover these files and logs, as they are updated as part of normal laboratory operations without necessitating a revision change. However, they are considered part of the quality system.

4.2.4 Roles and responsibilities

The roles and responsibilities of the Technical Manager and Quality Manager, including their responsibility for ensuring compliance with ISO/IEC 17025 is documented in the *Technical Manager Job Description* and *Quality Manager Job Description*, respectively.



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4.3 Document control

4.3.1 General

HN Calibration Laboratories has established and maintains the *Quality Documentation Maintenance and Distribution Procedure (PRO-01)* to control all internally generated documents that form part of this quality system.

HN Calibration Laboratories has established and maintains the *Externally Generated Quality Documentation Maintenance and Distribution Procedure (PRO-17)* to control the maintenance and distribution of all externally generated documents that form part of this quality system.

4.3.2 Document approval and issue

All documents issued to personnel at HN Calibration Laboratories as part of the quality system is reviewed and approved by authorized personnel in accordance with either the *Quality Documentation Maintenance and Distribution Procedure (PRO-01)* or the *Externally Generated Quality Documentation Maintenance and Distribution Procedure (PRO-17)* prior to issue. The *Quality Documentation Master List* identifies the current revision status and distribution of documents in the quality system. The *Quality Documentation Master List* is readily available to all staff in order to preclude the use of invalid and/or obsolete documents.

Obsolete documents retained for either legal or knowledge preservation purposes are suitably marked and kept in the *Obsolete Documents File*.

All internally generated quality system documents are uniquely identified. The identification includes the revision level, date of issue, page numbering and total number of pages, as well as the authority approving the document.

4.3.3 Document changes

Changes to documents are reviewed and approved by the same function that performed the original review, unless specifically designated otherwise, see the *Quality Documentation Maintenance and Distribution Procedure (PRO-01)* and the *Externally Generated Quality Documentation Maintenance and Distribution Procedure (PRO-17)*. The designated personnel have access to pertinent background information upon which to base their review and approval. The altered text is identified in the document by underlining added text and using strikethrough for deleted text, as follows:

Added text.

~~Deleted text.~~

HN Calibration Laboratories' documentation control system does not allow for the amendment of documents by hand.

The *Maintenance of Electronic Documents Procedure (PRO-18)* describes how documents maintained in computerized systems are made and controlled.

4.4 Review of requests, tenders and contracts

HN Calibration Laboratories' procedure for the review of requests, tenders and contracts is given in the *Work Flow Procedure (PRO-03)*.

The reviews are recorded and retained in the *Work Order File*.

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HN Calibration Laboratories does not subcontract any calibration work.

The client is informed of any deviation from the contract.

If the contract needs to be amended after work has commenced, the *Work Flow Procedure (PRO-03)* spells out that the same contract review process is repeated and that any amendments shall be communicated to all affected personnel.

4.5 Subcontracting of calibrations

This section describes the arrangements in place at HN Calibration Laboratories for ensuring the quality of calibrations placed with sub-contractors.

4.5.1 Eligible sub-contractors

It is the policy of HN Calibration Laboratories to only use accredited laboratories to perform calibrations as sub-contractors. The calibrations have to be within the scope of accreditation of the sub-contracting laboratory.

4.5.2 Advising the client

HN Calibration Laboratories will advise the customer in advance of any intention to sub-contract calibrations in writing. When appropriate, HN Calibration Laboratories will gain the approval of the client in writing, when possible.

4.5.3 Responsibility for sub-contractor work

HN Calibration Laboratories considers itself responsible to the client for the sub-contractor's work, except in the case where the client or a regulatory authority specifies which sub-contractor is to be used.

4.5.4 Register of sub-contractors

HN Calibration Laboratories maintains a *Sub-contractor File* on each subcontractor that it uses for calibrations. This file contains the record of the evidence of the sub-contractor's compliance with ISO/IEC 17025, i.e. evidence of accreditation.

4.6 Purchasing services and supplies

The *Outside Support Services and Supplies List* defines the scope of services and supplies covered by the provisions in this section.

4.6.1 Selection and purchasing of services and supplies

The *Use of Outside Support Services and Supplies Policy (POL-08)* defines the measures put in place for selection and purchasing of services and supplies to ensure that the quality of these services and supplies is adequate to sustain confidence in HN Calibration Laboratories' calibrations.

Consumable materials used for the technical operations of HN Calibration Laboratories that can affect the results of calibration are identified in the *Outside Support Services and Supplies List*. The *Consumable Material Procedure (PRO-14)* provides details of how these materials are purchased, received and stored.



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4.6.2 Verification of services and supplies

It is the policy of HN Calibration Laboratories to require purchased equipment, materials and services to comply with the specified requirements.

HN Calibration Laboratories will, wherever possible, ensure that purchased equipment and consumable material are not used until they have been inspected, calibrated or otherwise verified as complying with all standard specifications relevant to the calibrations concerned.

4.6.3 Purchasing documents for services and supplies

The *Consumable Material Procedure (PRO-14)* provides details of how the purchasing documents are issued, reviewed and approved for technical content.

4.6.4 Evaluation of suppliers

The *Outside Supplier File* contains records of all approved suppliers from whom HN Calibration Laboratories obtains support services or supplies required for calibration, including records of evaluations of the suppliers.

4.7 Service to client

HN Calibration Laboratories affords clients and their representatives cooperation to clarify the client's request and to monitor HN Calibration Laboratories' performance in relation to the work performed, provided that this can be done while ensuring the confidentiality of other clients.

4.8 Complaints

This section defines the policies and procedures put in place by HN Calibration Laboratories to resolve complaints from clients and other parties about the laboratory's activities.

The policy adopted by HN Calibration Laboratories for the resolution of complaints from clients and other parties about the laboratory's activities is documented in the *External Complaint Policy (POL-05)*.

The procedure for resolving complaints is documented in the *Complaint Procedure (PRO-06)*.

Records of all complaints and the actions taken by HN Calibration Laboratories to resolve them are contained in the *Corrective Action Log*.

4.9 Control of nonconforming calibration work

4.9.1 Policy and procedure for nonconforming work

HN Calibration Laboratories' policy regarding nonconforming calibration work is documented in the *Nonconforming Calibration Work Policy (POL-10)*.

The procedure for feedback and corrective action, which is used whenever nonconforming calibration work is detected or departures from documented policies and procedures occur, is documented in the *Feedback and Corrective Action Procedure (PRO-05)*.



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HN Calibration Laboratories notifies customers promptly, in writing, of:

- Any event such as the identification of defective calibration equipment that casts doubt on the validity of results given in any calibration certificate or report, or amendment to a calibration certificate or report. The notification will quantify the magnitude of the error created in the calibration result.
- Any customer's measuring or test equipment found significantly out of tolerance during the calibration/verification process. Measurement data will be reported so that appropriate action can be taken.

4.9.2 Corrective action

Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of HN Calibration Laboratories' operations with its own policies and procedures, the corrective action procedures given in section 4.10 are promptly followed.

4.10 Corrective action

HN Calibration Laboratories' policy regarding corrective action is documented in the *Corrective Action Policy (POL-11)*.

The procedure for feedback and corrective action, which is used whenever nonconforming calibration work is detected or departures from documented policies and procedures occur, is documented in the *Feedback and Corrective Action Procedure (PRO-05)*.

Where the identification of nonconformances or departures casts doubts on HN Calibration Laboratories' compliance with its policies and procedures or its compliance with ISO/IEC 17025, the appropriate areas of activity are audited in accordance with section 4.13 as soon as possible.

4.11 Preventive action

HN Calibration Laboratories strives to identify needed improvements and potential sources of nonconformances, either technical or concerning the quality system.

If preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement.

Preventive action is implemented in accordance with the *Preventive Action Procedure (PRO-19)*.

4.12 Control of records

4.12.1 General

HN Calibration Laboratories' procedure for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records is documented in the *Record Control Procedure (PRO-20)*.

4.12.2 Technical Records

HN Calibration Laboratories retains records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each calibration certificate issued, for 5 years. The records



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for each calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the calibration to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for the sampling, performance of each calibration and checking of results.

Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task.

When mistakes occur in records, each mistake is crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records are signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.

4.13 Internal audits

HN Calibration Laboratories periodically conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and ISO/IEC 17025.

Planned audits are documented in the *Internal Audit Plan*.

Audits are planned such that all elements of the quality system, including the calibration activities are audited at least once per year. It is the responsibility of the **Quality Manager** to plan and organize audits as required by the *Internal Audit Plan* and as requested by management. Wherever possible, the audits are carried out by trained and qualified staff that is independent of the activities being audited. The audits are based on the A2LA “Assessor Checklist for Calibration Labs” and are designed to determine:

- Whether procedures described in the quality system are being followed;
- Whether quality system objectives are being achieved;
- Whether designated duties are being carried out satisfactorily; and
- Whether there are opportunities for improvement.

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of HN Calibration Laboratories’ calibration results, HN Calibration Laboratories will take timely corrective action, and notify clients in writing if investigations show that the laboratory results may have been affected.

Completed audits are documented in the *Audit Documentation File*. The documentation includes the area of activity audited, the audit findings and corrective actions that arise from them.

Corrective action requests initiated as a result of the audits are documented in the *Corrective Action Log*. Follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken.

4.14 Management reviews

A management review of the quality system is conducted once every year to ensure that the quality system continues to be suitable and effective and to introduce any necessary changes or improvements.

The management reviews follow a set agenda, see *Management Review Agenda*.

The minutes of completed management reviews are documented in the *Management Review File*.



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Corrective action requests initiated as a result of the management reviews are documented in the *Corrective Action Log*. Follow-up audit activities verify and record the implementation of the corrective action within an appropriate and agreed timescale, as well as the effectiveness of the corrective action taken.

References

POL-01 Quality Policy
POL-02 Confidentiality Policy
POL-03 Gifts and Gratuities Policy
POL-04 Internal Complaint Policy
POL-05 External Complaint Policy
POL-08 Use of Outside Support Services and Supplies Policy
POL-09 Acceptable Activities Policy
POL-10 Nonconforming Calibration Work Policy
POL-11 Corrective Action Policy
PRO-01 Quality Documentation Maintenance and Distribution Procedure
PRO-03 Work Flow Procedure
PRO-05 Feedback and Corrective Action Procedure
PRO-06 Complaint Procedure
PRO-13 Data Protection and Backup Procedure
PRO-14 Consumable Material Procedure
PRO-15 Electronic Transmission Procedure
PRO-16 Activity Evaluation Procedure
PRO-17 Externally Generated Quality Documentation Maintenance and Distribution Procedure
PRO-18 Maintenance of Electronic Documents Procedure
PRO-19 Preventive Action Procedure
PRO-20 Record Control Procedure
Technical Manager Job Description
Quality Manager Job Description
Technician Job Description
Administrative Assistant Job Description
Confidentiality Agreement
Internal Audit Plan
Management Review Agenda
New Hire Introduction Agenda
Quality System Training Form
Quality Documentation Update Form
Quality Document Master List
Outside Support Services and Supplies List
Corrective Action Log
Technical Manager Personnel File
Quality Manager Personnel File
Obsolete Documents File
Work Order File
Sub-contractor File
Outside Supplier File
Audit Documentation File

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