Revision	ECN	DESCRIPTION OF CHANGE	CHANGE BY	DATE
A	-	Original Issue to ISO/IEC 17025:2005	S. Nichol	08/23/07
B	8892	Updated Section 4.6 Purchasing Services and Supplies, Section 4.8 Complaints, Section 4.9 Control of Non-Conforming testing and/ or Calibration Work. Section 5.2 Personnel, Section 5.8 Handling of test and Calibration Items, 5.10 Reporting the Results	M. Lampron	07/20/12
C	14985	Updated to include “Print Name” front page and section 3 Quality Objectives	J. Noriega	03/25/19
D	15927	Major Rewrite for ISO 17025:2015	M. Johnson	2/1/2020
E	15989	Updated section 6.4.13 to include: Records are retained in accordance with DP07-0902 Measurement Traceability Section 8.0 Records, and the “Calibration Equipment Recall Log”.	J. Noriega	11/04/20
F	16765	Added: Watermark: “WEBSITE DOCUMENT” Add to footer: *Marketing must be notified of any changes. Updated formatting	B. Allmer	05/27/22
G	17173	Section 3 Updated Quality Policy	M. McAllister	05/23/23
H	17236	Section 2 Scope and Application Updated	M. McAllister	07/31/23

ISO/IEC 17025:2017 Quality Management System Manual

Dytran Instruments, Inc.
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(818) 700-7818

Signature: _____ _____

Print Name: _____ _____
President/ General Manager Management Representative

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SECTION 1

INTRODUCTION

Dytran Instruments, Inc. (Dytran) was established in 1980 by company Nicholas D. Change, in Buffalo NY. Mr. Change applied his vast knowledge of piezoelectric sensors to start Dytran (the name comes from the combination of the words **Dy**namic and **tran**sducer).

Dytran is an industry leader in the development, manufacturing, and calibration of piezoelectric sensors for dynamic measurements. Our products include accelerometers, force transducers, pressure sensors, impulse hammers and smart sensors, to name a few. Dytran also provides calibration and repair services for our products.

Mission Statement: Our Mission at Dytran is to create innovative sensor solutions to meet the test and measurement challenges of our customers. For over thirty-nine years the following four principles have provided guidance and direction for the continued growth of Dytran:

- We learn from our customers
- We educate our customers
- We provide solutions to our customers
- We build lasting relationships with our customers

SECTION 2

SCOPE AND APPLICATION

The Quality Manual contains the Quality System used by Dytran Instruments, Inc. (Dytran). Its purpose is to provide the controls necessary to:

- Achieve the highest possible quality standards for all services provided by Dytran Instruments, Inc.
- To recognize and implement all customer and statutory requirements.
- Motivate and control the management, technical and human resources that affect and impact quality for the purpose of identifying, reducing, and ultimately preventing all quality deficiencies.

The Quality System contained in this manual is based on the requirements of ISO/IEC 17025:2017. The Scope of Accreditation for the laboratory is contained in the appendix to this manual as document DP07-0104. Dytran is claiming exceptions to the following clauses based on the company's current business practices: Clause 7.3, Sampling and 6.6, Externally Provided Products and Services.

SECTION 3

QUALITY POLICY

Dytran Instruments, Inc. strives to be a leading sensor company. We are committed to achieving our quality objectives through continual improvement of our people, products, procedures and customer satisfaction, while meeting applicable requirements.

QUALITY OBJECTIVE

Dytran's approved quality objectives are documented as part of the management review process. These objectives are documented and maintained as part of the record of the management review meeting.

Signature: _____ _____

Print Name: _____ _____

President/ General Manager Quality Assurance

REFERENCES

ISO/IEC 17025: *Quality Systems – General Requirements for the Competence of Testing and Calibration laboratories*

ISO 5725-1 through 4: *Accuracy (trueness and precision) of measurement methods and results*

ISO/IEC 9001: *Quality Management Systems – Requirements*

AS9100: *Aerospace Quality Management System Standard*

ISO 10012: *Measurement Management Systems-Requirements for measurement processes and measuring equipment*

ISO/IEC Guide 43-1,2: *Proficiency testing by Interlaboratory comparisons-Part 1: Development and operation of proficiency testing schemes, and Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies.*

ANSI/NCSL Z-540-I: *Calibration Laboratories and Measuring and Test Equipment-General Requirements*

APLAC TC 005: *Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing*

NIST Technical Note 1297: *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*

Dytran Instruments, Inc. AS9100 Quality Management System Documentation

SECTION 4

GENERAL REQUIREMENTS

Section 4.1: Impartiality

4.1.1 Laboratory activities at Dytran are undertaken impartially and structured and managed to safeguard impartiality***.***

4.1.2 Laboratory Management is committed to impartiality.

4.1.3 Dytran is responsible for the impartiality of its laboratory activities and does not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 Dytran identifies risks to its impartiality on an on-going basis. This includes those risks that arise from our activities, from our relationships, or from the relationships of our personnel.

4.1.5 If a risk to impartiality is identified, Dytran takes appropriate measures to demonstrate how it eliminates or minimizes such risk.

Section 4.2: Confidentiality

4.2.1 Dytran is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. Dytran informs the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between Dytran and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and is regarded as confidential.

4.2.2 When Dytran is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) is confidential between the customer and Dytran. The provider (source) of this information shall be confidential to Dytran and shall not be shared with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the Dytran's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

SECTION 5

STRUCTURAL REQUIREMENTS

5.1 Dytran Instruments, Inc. is a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

5.2 Dytran has identified management that has overall responsibility for the laboratory.

5.3 Dytran defines and documents the range of laboratory activities for which it conforms with this document. Dytran only claims conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

5.4 Laboratory activities are carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This includes laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5.5 Dytran has:

a) defined the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;
b) specified the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
c) documented its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.6 Dytran has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;
b) identification of deviations from the management system or from the procedures for performing laboratory activities;
c) initiation of actions to prevent or minimize such deviations;
d) reporting to laboratory management on the performance of the management system and any need for improvement;
e) ensuring the effectiveness of laboratory activities.

5.7 Dytran management ensures that:

a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;

b) the integrity of the management system is maintained when changes to the management system are planned and implemented.

SECTION 6

RESOURCE REQUIREMENTS

6.1 Dytran maintains the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

6.2 Personnel

6.2.1 Dytran personnel, either internal or external, that could influence the laboratory activities act impartially, are competent and work in accordance with the laboratory's management system.

6.2.2 Dytran documents the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

6.2.3 Dytran ensures that personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

6.2.4 The management of the laboratory communicates to personnel their duties, responsibilities and authorities.

6.2.5 Dytran maintains procedure(s) and retain records for:

a) determining the competence requirements;
b) selection of personnel;
c) training of personnel;
d) supervision of personnel;
e) authorization of personnel;
f) monitoring competence of personnel.

6.2.6 Dytran authorizes personnel to perform specific laboratory activities, including but not limited to:

a) development, modification, verification and validation of methods;
b) analysis of results, including statements of conformity or opinions and interpretations;
c) report, review and authorization of results.

6.3 Facilities and Environmental Conditions

6.3.1 Dytran facilities and environmental conditions are suitable for laboratory activities and do not adversely affect the validity of results.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities are documented.

6.3.3 Dytran monitors, controls and records environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

6.3.4 Measures to control facilities are implemented, monitored and periodically reviewed and include, but is not be limited to:

a) access to and use of areas affecting laboratory activities;
b) prevention of contamination, interference or adverse influences on laboratory activities;
c) effective separation between areas with incompatible laboratory activities.

6.3.5 When Dytran performs laboratory activities at sites or facilities outside its permanent control, it ensures that the requirements related to facilities and environmental conditions of this document are met.

6.4 Equipment

6.4.1 Dytran has access to necessary equipment that is required for the correct performance of laboratory activities and that can influence the results.

6.4.2 If Dytran uses equipment outside its permanent control, we ensure that the requirements for equipment of this document are met.

6.4.3 Dytran has a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

6.4.4 Dytran verifies that equipment conforms to specified requirements before being placed or returned into service.

6.4.5 The equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6 Measuring equipment is be calibrated when:

a) the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or

b) calibration of the equipment is required to establish the metrological traceability of the reported results.

6.4.7 Dytran has established a calibration program, which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4.8 All equipment requiring calibration, or which has a defined period of validity, is labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.4.9 Equipment at Dytran that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, is taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. Dytran examines the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks are carried out according to Dytran procedure(s).

6.4.11 When calibration and reference material data include reference values or correction factors, Dytran ensures the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4.12 Dytran takes practicable measures to prevent unintended adjustments of equipment from invalidating results.

6.4.13 Records are retained for equipment which can influence laboratory activities. Records are retained in accordance with DP07-0902 Measurement Traceability Section 8.0 Records, and the "Calibration Equipment Recall Log". The records shall include the following, where applicable:

a) the identity of equipment, including software and firmware version.
b) the manufacturer's name, type identification, and serial number or other unique identification.
c) evidence of verification that equipment conforms with specified requirements.
d) the current location.
e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
h) details of any damage, malfunction, modification to, or repair of, the equipment.

6.5 Metrological Traceability

6.5.1 Dytran has established and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

6.5.2 Dytran ensures that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or
b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or
c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

6.5.3 When metrological traceability to the SI units is not technically possible, Dytran demonstrates metrological traceability to an appropriate reference, e.g.:

a) certified values of certified reference materials provided by a competent producer;
b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as

providing measurement results fit for their intended use and ensured by suitable comparison.

6.6 Externally Provided Products and Services

6.6.1 Dytran ensures that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

a) are intended for incorporation into the Dytran's own activities;
b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
c) are used to support the operation of the laboratory.

6.6.2 Dytran maintains procedures and retain records for:

a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;
b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
c) ensuring that externally provided products and services conform to the Dytran's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3 Dytran communicates its requirements to external providers for:

a) the products and services to be provided;
b) the acceptance criteria;
c) competence, including any required qualification of personnel;
d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

SECTION 7

PROCESS REQUIREMENTS

7.1 Review of Requests, Tenders and Contracts

7.1.1 Dytran maintains a procedure for the review of requests, tenders and contracts. This procedure ensures that:

a) the requirements are adequately defined, documented and understood;

b) the laboratory has the capability and resources to meet the requirements;

c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;

d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

7.1.2 Dytran informs the customer when the method requested by the customer is considered to be inappropriate or out of date.

7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule are clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

7.1.4 Any differences between the request or tender and the contract are resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.

7.1.5 The customer is informed of any deviation from the contract.

7.1.6 If a contract is amended after work has commenced, the contract review is repeated and any amendments are communicated to all affected personnel.

7.1.7 Dytran cooperates with customers, or their representatives, in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

7.1.8 Records of reviews, including any significant changes, are retained. Records are also retained of pertinent discussions with a customer

relating to the customer's requirements or the results of laboratory activities.

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and verification of methods

7.2.1.1 Dytran uses appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, are kept up to date and made readily available to personnel.

7.2.1.3 Dytran ensures that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application.

7.2.1.4 When the customer does not specify the method to be used, Dytran selects an appropriate method and informs the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods may also be used.

7.2.1.5 Dytran verifies that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification is repeated to the extent necessary.

7.2.1.6 When method development is required, it is a planned activity and is assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review is carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan are approved and authorized.

7.2.1.7 Deviations from methods for all laboratory activities occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

7.2.2 Validation of Methods

7.2.2.1 Dytran validates non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation is as extensive as is necessary to meet the needs of the given application or field of application.

7.2.2.2 When changes are made to a validated method, the influence of such changes is determined and where they are found to affect the original validation, a new method validation is performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, are relevant to the customers' needs and consistent with specified requirements.

7.2.2.4 The laboratory retains the following records of validation:

a) the validation procedure used;
b) specification of the requirements
c) determination of the performance characteristics of the method;
d) results obtained;
e) a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.1 Dytran has a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method addresses the factors to be controlled to ensures the validity of subsequent testing or calibration results. The sampling plan and method are available at the site where sampling is undertaken. Sampling plans are, whenever reasonable, be based on appropriate statistical methods.

7.3.2 The sampling method describes:

a) the selection of samples or sites;
b) the sampling plan;
c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.

7.3.3 Dytran retains records of sampling data that forms part of the testing or calibration that is undertaken. These records include, where relevant:

a) reference to the sampling method used;
b) date and time of sampling;
c) data to identify and describe the sample (e.g. number, amount, name);
d) identification of the personnel performing sampling;
e) identification of the equipment used;
f) environmental or transport conditions;
g) diagrams or other equivalent means to identify the sampling location, when appropriate;
h) deviations, additions to or exclusions from the sampling method and sampling plan

7.4 Handling of Test or Calibration Items

7.4.1 Dytran maintains a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of Dytran and the customer. Precautions are taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item are followed.

7.4.2 Dytran maintains a system for the unambiguous identification of test or calibration items. The identification is retained while the item is under the responsibility of the laboratory. The system ensures that items will not be confused physically or when referred to in records or other documents. The system, if required, can accommodate a sub-division of an item or groups of items and the transfer of items.

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions are recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, Dytran consults the customer for further instructions before proceeding and records the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, Dytran includes a disclaimer in the report indicating which results may be affected by the deviation.

7.4.4 When items need to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored and recorded.

7.5 Technical Records

7.5.1 Dytran ensures that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations are recorded at the time they are made and are identifiable with the specific task.

7.5.2 The laboratory ensures that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.6 Evaluation of measurement uncertainty

7.6.1 Dytran identifies the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, are taken into account using appropriate methods of analysis.

7.6.2 When Dytran performs calibrations, including of its own equipment, the measurement uncertainty for all calibrations.is evaluated.

7.6.3 Dytran evaluates measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation is made based on an understanding of the theoretical principles or practical experience of the performance of the method.

7.7 Ensuring the Validity of Results

7.7.1 Dytran maintains a procedure for monitoring the validity of results. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques may be applied to review the results. This monitoring is planned and reviewed and includes, where appropriate, but not be limited to:

a) use of reference materials or quality control material
b) use of alternative instrumentation that has been calibrated to provide traceable results;
c) functional check(s) of measuring and testing equipment;

d) use of check or working standards with control charts, where applicable;
e) intermediate checks on measuring equipment;
f) replicate tests or calibrations using the same or different methods;
g) retesting or recalibration of retained items;
h) correlation of results for different characteristics of an item;
i) review of reported results
j) interlaboratory comparisons.
k) testing of blind sample(s).

7.7.2 Dytran monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned and reviewed and includes, but not be limited to, either or both of the following:
a) participation in proficiency testing.
b) participation in interlaboratory comparisons other than proficiency testing.

7.7.3 Data from monitoring activities is analyzed, used to control and, if applicable, improve Dytran's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action is taken to prevent incorrect results from being reported.

7.8 Reporting of Results

7.8.1 General

7.8.1.1 Results are reviewed and authorized prior to release.

7.8.1.2 The results are provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports are retained as technical records.

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

7.8.2 Common Requirements for Reports (test, calibration or sampling)

7.8.2.1 Each report includes at least the following information, unless there are valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:
a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling");

b) the name and address of the laboratory;
c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
e) the name and contact information of the customer;
f) identification of the method used;
g) a description, unambiguous identification, and, when necessary, the condition of the item;
h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
i) the date(s) of performance of the laboratory activity;
j) the date of issue of the report;
k) reference to the sampling plan and sampling method used by Dytran or other bodies where these are relevant to the validity or application of the results;
l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;
m) the results with, where appropriate, the units of measurement;
n) additions to, deviations, or exclusions from the method;
o) identification of the person(s) authorizing the report;
p) clear identification when results are from external providers.

7.8.2.2 Dytran is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer is clearly identified. In addition, a disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results. Where Dytran has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

7.8.3 Specific Requirements for Test Reports

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports, where necessary for the interpretation of the test results, include the following:

a) information on specific test conditions, such as environmental conditions;
b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
— it is relevant to the validity or application of the test results;
— a customer's instruction so requires, or
— the measurement uncertainty affects conformity to a specification limit;
d) where appropriate, opinions and interpretations (see 7. 8 .7);
e) additional information that may be required by specific methods, authorities, customers or groups of customers.

7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

7.8.4 Specific requirements for Calibration Certificates

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates include the following:
a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);
b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
c) a statement identifying how the measurements are metrologically traceable;
d) the results before and after any adjustment or repair, if available;
e) where relevant, a statement of conformity with requirements or specifications (see 7. 8 . 6);
f) where appropriate, opinions and interpretations (see 7. 8 .7).

7.8.4.2 Where Dytran is responsible for the sampling activity, calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

7.8.4.3 A calibration certificate or calibration label does not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

7.8.5 Reporting Sampling – Specific Requirements

Where Dytran is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports include the following, where necessary for the interpretation of results:

a) the date of sampling;
b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);
c) the location of sampling, including any diagrams, sketches or photographs;
d) a reference to the sampling plan and sampling method;
e) details of any environmental conditions during sampling that affect the interpretation of the results;
f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, Dytran documents the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

7.8.6.2 Dytran reports on the statement of conformity, such that the statement clearly identifies:

a) to which results the statement of conformity applies;
b) which specifications, standards or parts thereof are met or not met;
c) the decision rule applied (unless it is inherent in the requested specification or standard).

7.8.7 Reporting Opinions and Interpretations

7.8.7.1 When opinions and interpretations are expressed, Dytran ensures that only personnel authorized for the expression of opinions and interpretations release the respective statement. Dytran documents the basis upon which the opinions and interpretations have been made.

7.8.7.2 The opinions and interpretations expressed in reports are based on the results obtained from the tested or calibrated item and are clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue is retained.

7.8.8 Amendments to Reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information is clearly identified and, where appropriate, the reason for the change included in the report.

7.8.8.2 Amendments to a report after issue are made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number... [or as otherwise identified]", or an equivalent form of wording. Such amendments will meet all the requirements of this document.

7.8.8.3 When it is necessary to issue a complete new report, the new report is uniquely identified and contains a reference to the original that it replaces.

7.9 Complaints

7.9.1 Dytran maintains a documented process to receive, evaluate and make decisions on complaints.

7.9.2 A description of the handling process for complaints is available to any interested party on request. Upon receipt of a complaint, Dytran confirms whether the complaint relates to laboratory activities that it is responsible for and, if so, deals with it. Dytran is responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints includes at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
b) tracking and recording complaints, including actions undertaken to resolve them;
c) ensuring that any appropriate action is taken.

7.9.4 When a complaint is received, Dytran is responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the Dytran acknowledges receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the complainant are made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.9.7 Whenever possible, Dytran gives formal notice of the end of the complaint handling to the complainant.

7.10 Nonconforming Work

7.10.1 Dytran maintains a procedure that is implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). This procedure ensures that:

a) the responsibilities and authorities for the management of nonconforming work are defined;
b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
d) a decision is taken on the acceptability of the nonconforming work;
e) where necessary, the customer is notified and work is recalled;
f) the responsibility for authorizing the resumption of work is defined.

7.10.2 Dytran retains records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity Dytran's operations with its own management system, Dytran shall implement corrective action

7.11 Control of Data and Information Management

7.11.1 Dytran has access to the data and information needed to perform laboratory activities.

7.11.2 Dytran's information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data is validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they are authorized, documented and validated before implementation.

7.11.3 Dytran's information management system(s) is:

a) protected from unauthorized access;
b) safeguarded against tampering and loss;
c) operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
d) maintained in a manner that ensures the integrity of the data and information;
e) includes recording system failures and the appropriate immediate and corrective actions.

7.11.4 In the event that Dytran chooses to utilize a laboratory information management system that is managed and maintained off-site or through an external provider, Dytran ensures that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 Dytran ensures that instructions, manuals and reference data relevant to Dytran's information management system(s) are made readily available to personnel.

7.11.6 Calculations and data transfers are checked in an appropriate and systematic manner.

SECTION 8

MANAGEMENT SYSTEM REQUIREMENTS

8.1 Dytran Instruments, Inc. maintains a quality management system that is registered to ISO:9001 and AS9001 standards by an independent registrar body. Dytran Instruments, Inc. utilizes Section 8, Option B for demonstrating compliance to management system requirements as defined in ISO:17025, Management System Requirements

8.1.1 The calibration laboratory at Dytran has an established and documented management system that is capable of supporting and demonstrating the consistent achievement of requirements of ISO:17025, ISO:9001, AS9100 and AS9101.

8.1.2 The quality management systems at Dytran address management system documentation, control of management system documents, control of records, actions to address risks and opportunities, improvement, corrective actions, internal audits and management reviews.