TRANSCAT®

Trust in every measure

Quality Assurance Manual

QAC-P01-000
Revision 6.0
September 17, 2020

TRANSCAT

QUALITY ASSURANCE MANUAL

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Approved by: _____
Lee Rudow – President/CEO

Issued by: _____
Ronald Powell - Quality Manager

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1 Scope and Field of Application

1.1 Scope

1.1.1 The scope of this Quality Manual provides an overview of the Quality System in place at all Transcat facilities including Transcat, Inc., Transcat Canada Inc., United Scale & Engineering Corporation (USEC) and Transcat Laboratory Services. All facilities function under the same quality system. It covers all calibration, validation, servicing of analytical equipment, inspection service and repair activities.

1.2 Calibration Laboratories

1.2.1 The Transcat Calibration Laboratories function is that of instrument calibration. The instruments calibrated are used for making precision laboratory, workbench and process measurements. The activity of the laboratories mimics and/or verifies the final calibration activity of measuring and test equipment manufacturers.

1.2.2 Transcat Calibration Laboratories have been audited for accreditation to ISO/IEC 17025:2017 and compliance to ANSI/NCSL Z540-1:1994 and ANSI/NCSL Z540.3-2006. The Joint IAF-ILAC-ISO Communiqué on the Management Systems Requirements of ISO/IEC 17025:2017 is evidence that the Transcat Quality System meets the principles of ISO 9001:2015. Certificates and Scopes of Accreditation and the Joint Communiqué are available on the Transcat web site, www.transcat.com

1.2.3 Transcat maintains compliance to such standards as SCC CAN-P-4, or ANAB MA2100, NQA-1, 10CFR50, 10CFR21, ISO 10012, 21 CFR 820.75 and other applicable standards.

1.3 CMM Laboratories

1.3.1 Transcat CMM Laboratories are an impartial 3rd Party service that offers part inspection, 1st article inspection, Incoming Quality Inspection, PPAP (Production Part Approval Process), Capability Studies and CMM Programming.

1.4 Compliance Services

1.4.1 Transcat Compliance Services (consisting of the Validation and LIS Groups) provides maintenance, calibration, validation, installation and qualification of equipment. Transcat Compliance Services are compliant to ISO 9001:2015 by following Transcat's Quality System.

2 Quality Policy

- Quality and customer service are the guiding principles for Transcat. Quality is providing excellence and continuous improvement in every process to ensure superior customer service. Customer service is knowing and understanding the customer's requirements and meeting or exceeding those requirements. Transcat is committed to the continuous improvement of these principles in order to meet or exceed our customer's requirements and to provide a service every employee can deliver with pride.
- Transcat supports achievement of these goals by implementing a management system that complies with the international standard ISO/IEC 17025 and other applicable standards. Only by providing an outstanding service at the highest quality will we achieve our goals of long term success and sustained improvements.
- Transcat, a supplier of a large variety of test and calibration equipment, serves its customers with accredited calibration services in process calibration services, validation, analytical and remediation consulting services. It is our intention to continue to merit our customers' full

confidence by providing both equipment and instrument services using state-of-the-art equipment, good professional practices, documented procedures and trained personnel, all arrayed to provide prompt service of uncompromised competency and quality.

- The activities ensuring this level of service are the responsibility of the President/CEO, acting through the staff and employees. All personnel within Transcat are responsible for the quality of their work. Transcat provides training and has established systems to assist all personnel to achieve the standards required. All personnel are expected to perform their job functions in furtherance of these goals. Transcat is committed to investigating all customer complaints to resolution and will do our best to put right all justified complaints.
- The policy, organization and procedures necessary to achieve the required standards are described in the Transcat Quality Assurance Manual. Transcat Policies and Procedures are implemented and used in conjunction with, and in support of, the activities documented in the Transcat Quality Assurance Manual. Quality objectives for Transcat are set out in the Quality Planning and Objectives policy. Objectives for individual jobs are to carry out the works to the satisfaction of the customer and in accordance with the contract as agreed with the customer.
- The Quality Manager is responsible for monitoring the quality system and reports regularly to the Transcat Leadership on the system's implementation, status and effectiveness. The Quality Policy is posted in each Transcat office. The Quality Manager is responsible for providing all Transcat offices with current and updated versions of the Quality Policy.

3 General Requirements

3.1 Impartiality and Ethics

3.1.1 Impartiality requirements are covered in the Employee Manual (HR-P01-000).

3.1.2 A service ethics policy is in place, which includes alternative means of reporting issues outside the normal chain of reporting and is documented in the Employee Manual (HR-P01-000).

3.1.3 Departments are managed by responsible personnel in such a manner that their independence of judgment and integrity is maintained at all times.

3.2 Confidentiality

3.2.1 All personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, are responsible for confidentiality. The policy on the confidentiality of all information is documented in the Employee Manual (HR-P01-000).

4 Structural Requirements

4.1 Responsibilities

4.1.1 The overall responsibility for quality rests with the President/CEO. Implementation of approved policies is the responsibility of his direct reports as well as the directors & managers of individual department and functions.

4.1.2 Any manager has the authority to authorize departures from documented policies and procedures or from standard specifications, per policy Exception Handling (CCS-P04-003). The manager must document the exception to the Quality Manager. The Quality Manager will decide if further corrective/preventative action is required, and/or if additional

Management Review is required.

4.1.3 If deemed necessary, Quality and Metrology management have the authority and responsibility to jointly request a halt to any work or practices felt to be inadequate or unsafe for either customers or employees, subject to further management review.

4.1.4 Specific position descriptions, responsibilities and minimum requirements for each position are detailed in the Position Descriptions maintained by the Human Resources Department. Access and control of these documents is covered by Position Description Policy and Procedure (HR-P02-001).

4.2 Management Representative

4.2.1 The Head of Quality is the ISO/IEC 17025 quality representative. In this capacity, the Head of Quality has the responsibility and authority to ensure the day-to-day implementation and overall effectiveness of the Transcat Quality System. The Head of Quality works directly with the President/CEO and his direct reports as well as the directors & managers of individual department and functions to implement any Quality System modifications necessitated by changing market or operating conditions.

4.2.2 The Head of Metrology is the ISO/IEC 17025 Technical Manager. The Head of Metrology has the overall technical responsibility and oversees the Technical Oversight Committee (TOC). The TOC is comprised of technical and quality staff responsible for recommendations to the senior staff regarding the technical direction of the calibration labs and for decisions on details of the processes employed.

4.2.3 Both the Head of Quality and Head of Metrology have designated deputies by appointment letter, to fulfill necessary functions in their absence.

4.2.4 Jointly, the Head of Metrology and Head of Quality are responsible for compliance to any and all applicable accrediting body requirements.

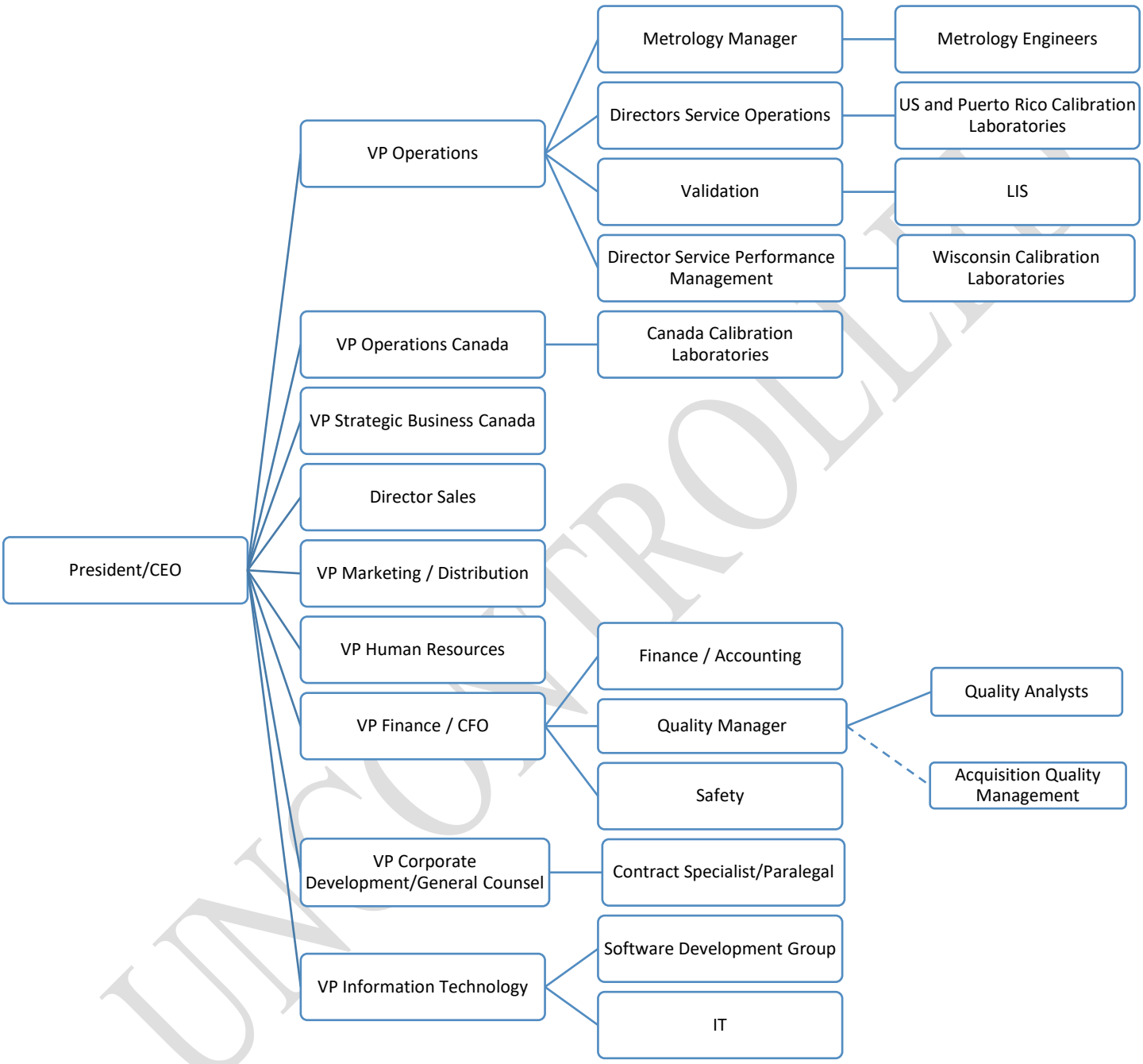
4.2.5 Individuals and organizations performing quality assurance functions shall have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform these functions, including sufficient independence from cost and schedule when opposed to safety function considerations. The quality assurance functions include the following:

- Identifying quality assurance problems;
- Initiating, recommending, or providing solutions to quality problems through designated channels
- Verifying implementation of solutions
- Assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

4.3 Resource Management

4.3.1 It is the responsibility of Transcat management to identify resource requirements. Adequate resources and trained personnel are in place on a full-time basis to provide contract review, contract amendment, inspection of incoming customer equipment, calibration, analytical and validation services and monitoring and verification of final results, as well as handling, packaging and shipping.

TRANSCAT ORGANIZATION CHART



This Organization Chart shows only Senior Management and major functions related to the Quality System. It is representative of the reporting structure at the time of publication and is subject to change. Actual charts are maintained by the HR Department and reflect up-to-date staffing.

5 Quality System

5.1 General

5.1.1 It is the responsibility of the Head of Quality to ensure the continuity and maintain the overall integrity of the Quality System throughout all facilities and departments of the company. This manual is intended to provide the framework and outline of the Transcat Quality System.

5.2 Quality System Procedures

5.2.1 All underlying documentation to the Quality System is implemented and maintained following the information detailed in Section 6 below. The effective implementation of the Quality System is ensured by training of personnel, internal audits - both formal and informal, and customer feedback, as well as audits and continuous assessments by qualified external agencies.

5.2.2 The quality system and related activities comply with the requirements of ISO/IEC 17025, ANSI/NCSL Z540-1, ISO 9001, MIL STD 45662A, and ISO 10012 as applicable.

5.2.3 The quality system meets the applicable requirements of NRC Regulation 10CFR50 Appendix B. Section 3 Design and Section 9 Control of Special Processes for both ASME NQA-1 and NRC Regulation 10CFR50 Appendix B are excluded from these requirements. The reporting of defects and noncompliance per 10CFR21 is covered by procedure Application of Decision Rules for Data Reporting and Adjustments, and TUR's (OPS-P01-002).

6 Document Control

6.1 General

6.1.1 A Master Index is maintained as part of the "Policy and Procedure" SharePoint site and shows the current document version, publish date, review cycle, last reviewed date for each document. Version history is also maintained within the SharePoint site and includes descriptions of any changes.

6.1.2 Documents are defined by a three section alpha numeric document number. The first section is defined as the department or function and may have 2, 3 or 4 characters. The second section is the series and contains an alpha numeric combination as shown below. The last section is the document number. Document numbers are in the format: Department/Function-Series-Document Number "XX(XX)-XXX-XXX". Transcat Canada specific version of document are indicated by "-C" at the end of the number.

The Transcat Quality System documentation includes the following:

• Policies/Procedures	XXX-PXX-XXX
• Forms	XXX-FXX-XXX
• Training Courses/Qualification Exams	XXX-TXX-XXX
• Qualification Documents	XXX-QXX-XXX
• Calibration Procedures (CalTrak Data Sheets)	CAL-CXX-XXX
• Calibration Methodology Documents	XXX-GXX-XXX
• Validation Procedures and Protocols	VAL-PXX-XXX
• LIS Procedures and Protocols	LIS-PXX-XXX
• Validation/LIS Preventative Maintenance and Qualification	PMQ-FXX-XXX
• Position Descriptions	See HR-P02-001

6.1.3 Responsibility for the issuance and control of all Quality System documents resides with the Head of Quality. Responsibility for the maintenance of procedures lies with the departments governed by the procedure. The responsible functions and function owners are documented for each document as part of the Master Index.

6.2 Document Change, Approval and Issue

6.2.1 All documents reside in a secured corporate intranet directory.

6.2.2 The procedure Policies and Procedures – New, Changes, Review and Hard Copies (QAC-P03-001) details generation of new procedures, changes to existing procedures and maintenance of documentation. This procedure also includes the review by affected parties and approval process for documents. This includes the maintenance of change information by the Head of Quality.

6.3 Control of Records

6.3.1 Quality records amendment, storage, retention and disposal and legibility as well as instructions on corrections or amendments to records are detailed in Quality Records Amendment, Storage, Retention and Disposal Policy (QAC-P03-004).

6.4 Record Retention

6.4.1 In general, electronic records relating to the calibration data, inspection reports, validation protocols, and analytical service reports are maintained for ten years.

6.4.2 Transactional records are maintained as required by legal and/or contractual requirements. Where possible, records are maintained on computer, with appropriate backup procedures in place. Older paper copies may be warehoused off-site in a secure facility.

6.5 Record Retrieval

6.5.1 Current records are readily retrievable at each site, or at the corporate offices, depending on the nature of the records. Older records may require notice to retrieve from an off-site facility.

7 Review of Requests, Tenders and Contracts

7.1 Contract Review

The agreed-upon service(s) to be performed are governed by the sales order generated as a result of the contract review with the customer by the Inside Sales/US Sales/Quotes Group with the exception of Validation, Analytical and USEC. The services available are defined in policy Definition of Services Offered (SLS-P01-001).

7.1.1 Calibration of an instrument is performed against the manufacturer's published specifications, unless otherwise specified by the customer, as documented during the contract review process (Order Entry Procedure for Stock Calibrations SLS-P04-001 and Order Entry Procedure for Customer-Owned and Supplied Equipment SLS-P04-002).

7.1.2 Contract review for Validation, Analytical and USEC is performed by the department manager due to the nature of the specific requirements for those areas of business.

7.1.3 USEC-P01-001 covers contract review for USEC.

7.1.4 Each procedure includes the necessary information to ensure that Transcat has the capability and capacity for fulfilling the contract prior to acceptance. Supporting documents include contract definitions and definition of services offered, as well as exception and non-conformance handling procedures.

7.1.5 A web-based pricing and capabilities module is available to all sales representatives for pricing and direction of customer equipment to appropriate facilities.

7.2 Amendment to a Contract

7.2.1 The procedure for amending a contract, whether the amendment is requested by the customer, or required by Transcat, is documented in Calibration Contract Amendment Procedure (SLS-P07-001).

7.3 Records

7.3.1 Record maintenance for contract review and amendment records is covered by the Quality Records Amendment, Storage, Retention and Disposal Policy (QAC-P03-004).

8 Managed Services for Calibrations

8.1 Managed Service Process

8.1.1 Calibration services performed on customer equipment by outside sources are not covered by the scope of the ISO/IEC 17025 accreditations. Customer equipment is only sent to outside sources for calibration when Transcat does not have the technical capability to perform the calibration to the level required by the customer.

8.1.2 The procedures for sending customer equipment to a vendor and receiving it back are detailed in the TMS-PXX series of procedures.

8.2 Vendor Evaluation

8.2.1 Transcat has a program for evaluating and, if necessary, auditing the calibration vendors.

8.2.2 Transcat maintains an approved vendor list. The criteria for approved vendors is detailed in the procedure Approved Vendors (QAC-P08-002).

8.3 Customer Approval

8.3.1 All vendors used for the calibration or repair of customer equipment require customer approval before the instrument can be sent to the vendor for service.

8.3.2 Transcat will present the customer with a viable vendor. The customer has the final authority to approve, reject or request a different vendor for use.

8.4 Return Verification

8.4.1 Upon return, a verification is performed as documented in the TMS-P04 series of procedures. Work sent out for repair only is verified upon return by the calibration performed by Transcat.

8.5 Calibration Witnessing

8.5.1 If, by contract, calibration witnessing is required at the vendor's facility, that requirement will be added to the purchase order and the Lab Manager or designee will make the appropriate arrangements.

9 Purchasing Services and Supplies

9.1 Calibration and Repair Services

9.1.1 Purchasing of calibration and repair services from qualified vendors for Transcat standards is documented in Purchasing Procedure for Test Equipment (Lab Standards) (STD-P04-001).

9.2 Vendor qualification

9.2.1 Vendor qualification is detailed in the procedure Approved Vendors (QAC-P08-002).

9.3 Purchase of consumable, shipping and packaging

9.3.1 The purchase of consumable, shipping and packaging from a vendor is detailed in Procedure for Ordering Laboratory Parts, Consumables, Replacement Units and Packing Material from Vendor (STD-P04-002)

9.3.2 The purchase of consumable, shipping and packaging from a the Transcat Warehouse is Ordering Laboratory Parts, Consumables, Replacement Units and Packing Material from Transcat Warehouses by the Labs (STD-P04-003)

9.4 Incoming inspection and verification requirements

9.4.1 Incoming inspection and verification requirements for Transcat standards are detailed in procedure Verification for Incoming Standards (STD-P01-004).

10 Service to the Client

10.1 Facility Visits

10.1.1 Transcat is always willing to have customers visit any of its facilities for formal or informal audits, to witness their calibrations, or for any other assistance or information that may be required. Confidentiality is always maintained, per section 6.04 Confidentiality Information Policy as written in the Employee Manual (HR-P01-000).

10.2 Contract Amendment

10.2.1 Any changes in status or delays in delivery are addressed through contract amendment per Calibration Contract Amendment Procedure (SLS-P07-001).

10.3 Customer Feedback

10.3.1 Customer feedback is always welcome and is logged. If it is determined that corrective action is required the information in entered in the Customer Care System, see Section 11 below.

10.3.2 Transcat periodically conducts surveys of various segments of the customer base. The results of these surveys are tabulated and reviewed by senior management, either in a formal Management Review Meeting, or in a separate forum specifically addressing the survey results. Corrective or preventive action(s) resulting from the review of the information is also tracked in the Customer Care System.

11 Customer Care (Corrective Action, Feedback, Complaint, OFI)

11.1 Customer Care Policy

11.1.1 All feedback, complaints, corrective and preventive actions are entered into the Transcat Customer Care System as “Issues”. In general, the Head of Quality in conjunction with the Head of Metrology are responsible for ensuring that the appropriate level of corrective

action is taken to prevent reoccurrence of issues.

11.1.2 Verification of effectiveness is performed under the direction of the Head of Quality by internal auditors, or in special cases, by other qualified individuals.

11.1.3 Where necessary, corrective actions may be reported to senior management, including the CEO and the Vice-President, Lab Operations by the Head of Quality or the Head of Metrology as soon as they are noted.

11.2 Customer Issue (Feedback and Complaints)

11.2.1 Employees are required to document feedback, positive and negative, when received from customers. Customer feedback and complaints are entered into the Customer Care System per Customer Issues – Feedback and Complaints (CCS-P05-001).

11.3 Audits (Accreditation, Customer, Internal and Vendor)

11.3.1 Corrective actions are generated by customer and internal feedback, by internal, customer and accreditation audits. The procedure Audits (Accreditation, Customer, Internal and Vendor) (CCS-P03-001) details the feedback, corrective and preventive action process, while the procedure NOD (Notices of Deviation) (CCS-P04-001) contains the corrective action process initiated when an issue involving the integrity of Lab processes is involved, such as out-of-tolerance standards or environmental issues.

11.4 NOD (Notice of Deviation and Quality Action Notices)

11.4.1 When a Transcat standard or process is found to be outside of its established parameters, a Notice of Deviation (non-conformance) is completed by the Lab per NOD (Notices of Deviation) (CCS-P04-001), detailing the extent of the condition, and any possible impact on calibrations (customer and/or internal) performed since the last verifiable in-control condition. Any customers whose equipment may have been impacted are notified by the Lab and advised as to the extent of the potential problem. The Recall Analysis and Reporting Procedure (CCS-P04-002) provides guidance on the recall analysis process.

11.5 Internal (Preventive Action and OFI)

11.5.1 Preventive Action and Opportunity for Improvements requirements are generally initiated through feedback, Management Review or audits. These are documented through the Customer Care System, as described in Preventive Action and OFI Policy (CCS-P02-001).

11.6 Vendor Issues

11.6.1 Vendor Issues are generally initiated through feedback from the Transcat Calibration Laboratories. The procedure Vendor Issues (Product and Service) (CCS-P06-001) details the process to enter, manage and generate vendor corrective actions.

12 Control of Non-Conforming Work

12.1 Transcat Standards

12.1.1 Out of Tolerance Transcat standards or process deviations are documented following the NOD process described in Section 11.4 of this quality manual.

12.2 Customer Equipment

12.2.1 Disposition of customer-owned equipment that cannot be brought into calibration is detailed in Application of Decision Rules for Data Reporting, Adjustments, and TUR's (OPS-P01-

002).

12.2.2 Customer equipment being returned due to an inability to repair or adjust is outlined in Handling Customer Units Beyond Economical Repair Procedure (OPS-P08-004).

12.3 Stock Calibrations

12.3.1 New Transcat stock that is out-of-tolerance is returned to a designated location in the warehouse for return to the manufacturer for repair and re-calibration and then returned to inventory upon its return from the vendor per procedure Handling Defective Stock Calibrations (OPS-P04-008).

13 Internal Audits

13.1 Responsibility

13.1.1 Internal audits of the Quality System and its procedural implementation at all sites are the responsibility of the Head of Quality.

13.1.2 Internal technical audits to ensure technical competency and compliance with the technical requirements of the calibration program are the responsibility of the Head of Metrology.

13.2 Scheduling

13.2.1 Internal audits are scheduled based on a minimum of one audit per year for each site or department, or as indicated by open corrective action, or based on prior audit results. They may be scheduled or unannounced.

13.2.2 As a minimum, all sections of the QA Manual relevant to the site, and the measurement parameters covered by the site's Scope of Accreditation are covered at least once a year. The procedure Internal Audits (QAC-P02-003) includes details on the audit requirements and their reporting.

13.3 Corrective Action Tracking

13.3.1 Issues requiring corrective action are tracked via the Customer Care System and verified for effective implementation, as appropriate, per Audits (Accreditation, Customer, Internal and Vendor) (CCS-P03-001).

14 Management Review

14.1 Frequency

14.1.1 Management Review occurs on a regular basis, per Management Review Procedure (QAC-P01-006), which addresses frequency, attendees and topics to be covered. The Head of Quality is responsible for documentation and record maintenance from these meetings, as well as verification of any action to be taken. Any action items generated by these meetings are documented as Internal (Preventive Action and OFI) and logged into the system for planning, implementation and verification of effective action.

14.2 Quality Planning

14.2.1 Quality planning per Quality Planning and Objectives (QAC-P01-002) is an integral part of the Management Review process. As such, a specific area or areas are targeted for process improvement. Input is solicited from appropriate departments and personnel. Formal

objectives are established for key individuals and are tracked by Management.

15 Training

15.1 Goal

15.1.1 It is the goal of Transcat to provide and encourage as broad a base of technical skills and customer knowledge as possible. In keeping with this, a wide range of in-house training is offered, and employees are also assisted with outside training courses to enhance their overall customer service and/or technical abilities.

15.1.2 Employee training and qualification records are maintained, as detailed in Quality Records Amendment, Storage, Retention and Disposal Policy (QAC-P03-004).

15.2 General Training

15.2.1 General Training requirements are created as a guideline for the initial training of personnel per the Training Policy (TRN-P01-001).

General Training for Calibration Technicians	TEC-T01-006
General Training for United Scale Technicians	TEC-T01-007
General Training for Validation Technicians	VAL-T01-001
Analytical Field Service Engineers Training	LIS-T01-002
Internal Auditor Training and Certification	QAC-T02-043
Training Requirements for Inside Sales	SLS-T01-001

15.2.2 This training may be required if the personnel are unfamiliar with a specific process or instrument type. Qualification and re-qualification of personnel are performed as necessary to maintain stated proficiencies.

15.3 Position Descriptions

15.3.1 Position Descriptions for each job classification are the responsibility of the Human Resources Department. The control, issuance, review and change authority are detailed in Position Description Policy and Procedures (HR-P02-001).

16 Environmental Conditions

16.1 Environment

16.1.1 Environmental conditions and housekeeping requirements are detailed in Environment and Housekeeping (OPS-P02-002).

16.2 ESD

16.2.1 The policy on ESD control is documented in Electrostatic Discharge Control Procedure (OPS-P02-001).

17 Calibration

17.1 Categories

17.1.1 The instruments calibrated belong to one of three categories:

- New instruments being purchased from Transcat, where a calibration is purchased with the instrument;
- Customer-owned equipment being calibrated at the Transcat facility;
- Customer-owned equipment being calibrated at the customer's site.

17.2 Calibration Process

17.2.1 The calibration process itself is identical for all categories. However, some variations exist in the transaction processing. New instruments, never having been in service, do not require "as found" data readings, which are of importance on instruments which have been in use by a customer. Additionally, no repair issues are involved with new stock calibrations, but may be required on customer equipment, and can cause changes to the initial contract if the need for repair was unknown to the customer prior to its return for calibration.

17.2.2 Customer equipment received at the Transcat Lab requires incoming handling procedures to ensure proper tracking of that particular instrument throughout its processing.

17.2.3 Calibrations performed at a customer's facility require additional precautions taken for the standards used in performing the calibration. Repair work cannot generally be done at a customer's site, and units found to be out-of-tolerance are usually returned to the lab for further work prior to completion of the calibration.

17.2.4 The calibration process actually consists of two components: the verification of readings for the unit under test, and the adjustment of the unit if it has out of tolerance readings (or, if requested by the customer, to optimize or zero the readings). Calibration procedures include such information as appropriate standard(s) to use, calibration test points, proper verification methodology, and expected results (as appropriate to the unit).

17.3 Calibration Methodologies and Data Reporting

17.3.1 The calibration methodologies used are defined in the Calibration Policy (OPS-P01-001) and subsidiary documents. The data readings to be taken for each model of instrument, and the acceptable results for that instrument, are detailed in the Calibration Procedure (CalTrak Data Sheet) for the instrument, including any limitations to the performance of a full calibration.

17.3.2 The application of decision rules for data reporting, adjustments and TUR (test uncertainty ratio) are detailed in Application of Decision Rules for Data Reporting, Adjustments, and TUR's (OPS-P01-002). Special or limited calibrations are only performed with permission from the customer.

17.3.3 Proficiency Testing

17.3.3.1 Proficiency Testing requirements are set forth in Proficiency Testing Policy (QAC-P07-001).

17.3.3.2 At a minimum all major parameters covered the scope of accreditation will be covered in a four year period.

17.3.3.3 The proficiency testing plan is maintained by the Metrology Department.

17.3.4 Special Process or Non-Standard Methodology

17.3.4.1 The only instances where a special process or non-standard methodology shall be used is under specific request from a customer, negotiated through a detailed contract. This would be documented through the contract review process, and shall include all agreed-upon criteria for the process, including test and verification of results.

17.3.4.2 When changes are made to a non-standard validated method, the influence of such changes shall be evaluated and where they are found to affect the original validation, a

new validation shall be performed per Method Validation (QAC-P04-002).

17.3.5 Data Reporting, Adjustment, and Repair

17.3.5.1 The standards and methods used in the calibration process are selected to target at least a 4:1 test uncertainty ratio (TUR) to the unit under test. Where this is not possible for any reason, the actual TUR noted in the appropriate area on the Supplemental Data Sheet. The fully operational condition of an instrument is the prerequisite to calibration. The calibration activity is in part dependent on an instrument repair activity to meet this prerequisite. The repair activity is not part of the scope of any registration or accreditation.

NOTE: The repair activity is referred to here because it is part of the overall process. If a customer chooses this alternative, an additional calibration is performed following the repair, and a set of in-tolerance readings provides verification of the effectiveness of the repair process.

17.3.5.2 The technician performs a preliminary inspection to ascertain that customer equipment is operable prior to starting the calibration. Calibration adjustments are made, as necessary, to out-of-tolerance units only after all as-received readings are completed. When a unit cannot be brought into tolerance by the recommended adjustments, a repair may be required and the customer is notified of the available course(s) of action, per Calibration Contract Amendment Procedure (SLS-P07-001). These include a repair of the equipment, or if beyond economical repair, the replacement or return of the equipment. Any subsequent action is based solely on the customer's request.

17.4 Calibration Cycles

17.4.1 Calibration cycles for customer units are based solely on the customer's determination. The customer must determine their actual calibration cycle, based on their own history, and the criticality of the instrument within their own process. These are documented in the order as part of the initial contract review. When the customer does not provide a calibration interval, the due date is set per the Transcat Terms and Conditions (MKT-P01-001). The Terms and Conditions can be found on www.transcat.com.

17.5 Data Review

17.5.1 Random verifications of completed calibrations are performed in accordance with procedure Certificate Data Review Process (QAC-P05-002). The certificate and any associated documentation are reviewed by a qualified and appointed signatory, and the certificate is electronically signed by that person as evidence of the review. The Lab Manager's name is always printed on the certificate as the final responsibility for the adequacy of the calibration process within that facility. Note that the digital signature process has been validated for compliance to the applicable sections of 21CFR11.

17.6 Adjustment tamper proofing

17.6.1 Wherever allowable by the equipment design, access to calibration adjustment circuitry is covered by a "CAL VOID" sticker. If a customer unit has a broken or damaged sticker, the technician will note the condition in the Cert Comments in the order. Where use of the sticker is not feasible, other precautions, such as sealing the adjustment pots, are taken where appropriate.

NOTE: Breaking or damaging the sticker may void any warranty or guarantee that is in

force at the time.

18 Compliance Services

18.1.1 Customer-owned equipment is maintained, installed, calibrated, qualified and validated by the Transcat Compliance Services. General Protocols written for compliance services are controlled documents that go through document control process per Document Control Policies and Procedures (QAC-P03-001). Custom protocols are approved by the individual customer. Labels (including asset#, service date and due date) indicating the performed service are placed on each piece of equipment after successful completion of the service. Standards used for compliance services are covered in Section 19 below. The customer will receive the data collected for the compliance service but not a certificate unless a calibration was performed as part of the validation or analytical service.

19 Control of Inspection, Measuring and Test Equipment

19.1 Standards (IM&TE)

19.1.1 Transcat maintains and controls its inspection, measuring and test equipment (IM&TE) using documented procedures. Standards shall not be used for calibrations, validation or analytical services if they are not within their valid calibration period. The laboratory is equipped with all items required to perform the required calibrations. As part of their training, technicians are instructed in the proper use, maintenance, handling and storage of Transcat standards.

19.2 Non-permanent Standards

19.2.1 When equipment (leased, borrowed, etc.) acquired from outside the laboratory's permanent control is put into service, it is treated as if it is a permanent standard with all applicable controls in place. These include, but are not limited to: a current calibration, verification of calibration results, physical examination, cross checks and maintenance, as applicable.

19.3 Standards Records

19.3.1 Records of the Transcat standards' calibrations are maintained per Quality Records Amendment, Storage, Retention and Disposal Policy (QAC-P03-004). The records include calibration certificates and data, as well as maintenance records and any other pertinent historical information for the standard. In addition, the current information regarding last calibration and next calibration due dates is maintained within CalTrak.

19.4 Calibration and Preventative Maintenance of Standards

19.4.1 Standards used in the calibrations, validation and analytical services are themselves calibrated on a regular basis, traceable to physical representations of the SI units through NIST, NRC or other National Metrology Institutes, or through ILAC-MRA accredited laboratories for the parameters being calibrated.

19.4.2 Calibration Cycle

19.4.2.1 The calibration cycle of each standard is determined by the manufacturer's recommendation, originally, and subsequently based on calibration history, periodic cross checks, frequency of use, and/or any failures or equipment stress. The guidelines for establishing/adjusting calibration intervals for Transcat standards are detailed in

Guidelines for Establishing Calibration Intervals (STD-P01-006).

19.4.3 OOT (out-of-tolerance) Standards

19.4.3.1 See Section 12 of this manual.

19.4.4 Preventative Maintenance

19.4.4.1 Preservation of the standards to assure continuous process capability is through periodic preventive maintenance, as recommended by the manufacturer and Transcat's experience with the assets. Specific preventive maintenance details are included in Lab Standard Maintenance and Labelling Procedure (STD-P03-015).

19.5 Standards Labeling

19.5.1 All Transcat standards have both their asset number and their most recent calibration sticker affixed to them (size permitting).

19.5.2 Test equipment used for function check only is indicated by a tag stating such.

19.5.3 Failed or out of tolerance equipment is prominently labeled with a Failed Equipment Tag to indicate rejection and is generally removed from the work area.

19.5.4 Wherever allowable by the equipment design access to calibration adjustment circuitry is covered by a "CAL VOID" sticker. A broken or damaged sticker indicates the possibility of tampering and voids the calibration.

20 IT and Software Validation

20.1 IT information is maintained by the IT department and is covered in Transcat IT Policy (IT-P01-000).

20.2 Software developed by Transcat for performing calibrations, automated calibrations, adjustments or evaluation/calculation of calibration results is validated per Lab Software Validation (STW-P05-001).

20.3 The CalTrak software has been validated in accordance with 21CFR Part 820.75, with further validation of the electronic signatures to 21CFR Part 11. Records of the original validation, as well as validation of subsequent revisions are maintained in Rochester, and can be made available for review upon request.

20.4 Commercial, off-the-shelf and/or OEM software is considered to be validated, however verification to a reasonable level is performed where technically feasible.

21 Uncertainty Determination

21.1 Uncertainty determination is performed per the procedure Uncertainty Determination (QAC-P06-001) for calibration and CMM-11-01-H for inspection. Uncertainties are reported with a coverage factor k=2, providing a level of confidence of approximately 95%.

22 Handling, Storage, Packaging, Preservation and Delivery

22.1 Handling

22.1.1 Proper handling, packaging and storage of customer equipment is detailed in procedure Handling and Packaging of Equipment (OPS-P08-002). All employees who may have occasion to handle customer equipment are instructed in its proper handling in OPS-P08-

002, including ESD procedure OPS-P02-001.

22.2 Receiving

22.2.1 Each unit is tagged prior to entry into the Transcat system with a unique identifying number. Tagging instructions are included in Receiving and/or Transferring Customer Equipment for Repair and/or Recal (OPS-P07-002). This identifier stays with the unit throughout its processing, and is recorded on all associated paperwork, as well as the unit's calibration label (size permitting).

22.3 Shipping

22.3.1 The conclusion of the final inspection of the order is performed by personnel in accordance with Receiving and/or Transferring Customer Equipment for Repair and/or Recalibration (OPS-P08-007). This inspection includes checking the unit against both the pick ticket, and the Certificate (and Data, if ordered). Completed calibrations ready for shipment are staged in a designated area suitable for its protection while paperwork is processed.

22.3.2 Delivery is by the carrier designated by the customer during contract review. Transcat also offers limited pickup and delivery service. The customer equipment is wrapped, packed and/or placed in tote bins and secured from movement during this process.

23 Statistical Techniques

23.1 Feedback and complaints are monitored on a routine basis for repetitive problems, as well as for the effectiveness of applicable corrective action(s).

23.2 Random sampling of individual calibrations is per Certificate and Data Review Process (QAC-P05-002), under the direction of the Head of Metrology.

24 Risks and Opportunities

24.1 Risk Management is covered in detail in policy Risk Management (QAC-P10-001).

25 Safety

25.1 Safety is covered in the “SAF” series of procedures.