Orifice Laboratory Quality Manual QMOL-02

1 SCOPE -----N/A-----

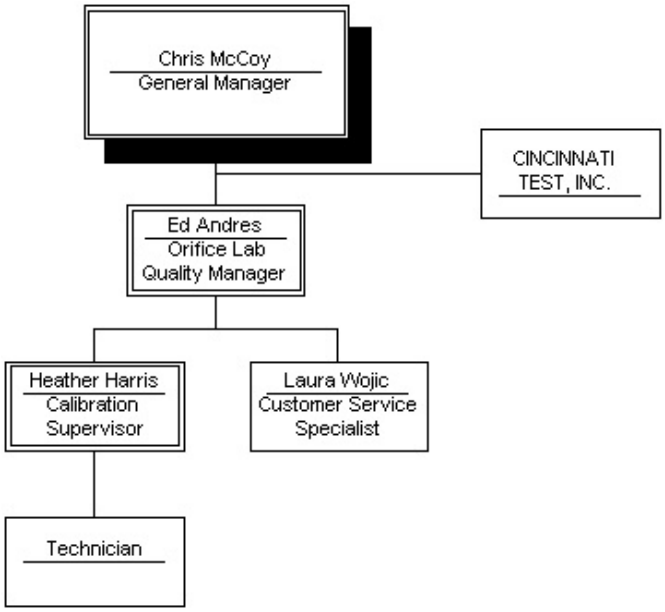
2 NORMATIVE REFERENCES ----N/A---

3 TERMS AND DEFINITIONS -----N/A----

4 MANAGEMENT REQUIREMENTS

4.1 ORGANIZATION

4.1.1 Cincinnati Test Systems is a division of TASI, a Delaware corporation. CTS was founded in 1982 and has operated continuously since its inception. CTS designs, develops, sells and supports its products from its primary offices in Cleves, Ohio. The orifice laboratory resides at these facilities. The Orifice Laboratory Organization Chart is as follows:



4.1.2 The orifice laboratory carries out all testing and calibration activities in compliance with ISO/IEC 17025 and satisfies the needs of the client, the regulatory authorities, and A2LA.

4.1.3 All testing and calibration activities are carried out at the permanent facility in Cleves, Ohio.

4.1.4 The orifice laboratory runs as a team with a designated calibration supervisor. The calibration supervisor and quality manager have the responsibility and authority to ensure that the products and services provided by the orifice laboratory meet the quality standards defined in this manual. No deviations from this policy are permitted without the expressed authority of the General Manager of CTS. The orifice laboratory operates independently from other departments at CTS.

4.1.5 The orifice laboratory:

a) Has designated personnel performing work at an appropriate level based on their level of training. These personnel use proper SPC practices to ensure that the quality of workmanship meets our quality standards. They ensure that all equipment used in the lab is properly maintained and calibrated before it is used to support any production of product or services.

b) Provides products and services that meet or exceed the expectations of our customers and this quality manual. All laboratory personnel are responsible for ensuring that this statement of principle is met. All internal and external work/orders/queries are brought to the calibration supervisor or quality manager for disposition. Either person is responsible to ensure that undue pressures and influences are not brought upon the calibration staff and trainees. Either person shall not bring undue pressures and influences to the calibration staff and trainees. If any laboratory member feels undue pressure or influences have been placed on them, they shall follow the Procedure for Reporting Undue Pressures FMOL-43.

c) Protects CTS's and customer's confidential information from being disclosed to any third party without prior permission. Employees are not to discuss work to unauthorized personnel. All information contained in our electronic files requires appropriate passwords for access. Computers are not left on and unattended in the lab. Client Confidentiality shall be observed in accordance with the Procedure for Client Confidentiality FMOL-44.

d) Ensures that personnel avoid involvement in any activity that would diminish confidence in the competence, impartiality, judgment or operational integrity of any products or services provided by the orifice lab. The laboratory's procedure to ensure this is for the Quality Manager to observe internal and external activities so integrity is not compromised or potentially violated.

e) Maintains the integrity of the lab organization chart as defined in section 4.1.1.

f) Ensures that all technical personnel in the lab understand that it is their individual responsibility to ensure that the products and services provided by the lab meet the quality requirements as defined in this manual. Personnel must immediately alert the appropriate management should they observe or suspect that the CTS quality standards are not being met.

g) Has a Calibration Supervisor who provides adequate supervision of testing and calibration staff, including trainees. This calibration supervisor is familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results.

h) Ensures the Calibration Supervisor has the proper training, experience, and technical support to ensure the lab provides the required quality of products and services.

i) Has a Quality Manager who has the responsibility and authority to ensure that the quality system is implemented and followed at all times. The Quality Manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.

j) Has a technician qualified to the training level of the Calibration Supervisor that is authorized to act as a deputy for the Quality Manager during his/her absence.

k) Has technicians that are involved in management review meetings on a regular basis to review achievements and objectives.

4.1.6 The orifice laboratory team will regularly review Quality Council meeting minutes as an agenda item in the Management Review meeting. The minutes for both the Quality Council Meeting and the Management Review Meeting shall be posted in a prominent place in the lab for technicians to review at any time.

4.2 QUALITY SYSTEM

4.2.1 This quality manual and all associated work instructions, flow charts, forms, checklists,

etc. are the basis of the quality system for the orifice laboratory. All personnel are appropriately trained in the use of the equipment and detail of the quality system. This manual and all subordinate documents are made available to the personnel for their reference. All orifice laboratory personnel are familiar with this quality manual and its associated documents.

4.2.2 QUALITY POLICY

4.2.2.1 The orifice laboratory is committed to meeting and/or exceeding our customer's expectations for leak standards manufactured and certified by CTS. It is our policy to operate the orifice laboratory in compliance with ISO 17025 and to be American Association of Laboratory Accreditation, A2LA, certification compliant. Good statistical process control techniques are used to demonstrate on-going compliance.

4.2.2.2 It is our policy to maintain compliance with all applicable laws and regulations that govern the operation of the orifice laboratory.

4.2.2.3 Each employee is committed to continuous improvement of our level of on-time performance and the quality of our products and services. Each technician demonstrates familiarity with this quality policy, manual, flow charts, equipment within the laboratory, work instructions, checklist, and documents that relate to their area of responsibility and authority. It is each employee's responsibility to avoid conflicts of interest that compromise the integrity of the orifice laboratory, the quality policy, or Cincinnati Test Systems. Any employee experiencing pressure to compromise the integrity of CTS or its products immediately notifies the Orifice Laboratory Calibration Supervisor or the General Manager for resolution of the conflict.

4.2.2.4 The entire orifice laboratory team must adhere to this Quality Policy, as well as the directives of this manual and its subordinate documents. CTS is committed to ensuring that effective processes, high quality tools, and personnel training are maintained to enable our employees to fulfill this commitment.

4.2.2.5 The orifice laboratory quality manual includes and makes reference to the procedures that the laboratory uses in its everyday function. The structure of the documentation used in the quality system is outlined in this manual. The supporting documentation for this quality manual comes in the form of orifice laboratory work instructions, labeled WIOL-##, flow charts, labeled FCOL-##, forms labeled FMOL-##, and checklists, labeled CLOL-##. Work instructions provide a step-by-step procedure for completing a task. Flow charts provide a process description with decision points. Forms provide documentation and procedures for laboratory use. Checklists are used to ensure that specific details have been completed as part of a task or process. A complete list of supporting documents is included in Section 6.0.

4.2.3 MANAGEMENT RESPONSIBILITY

4.2.3.1 The General Manager has ultimate responsibility for the laboratory's products and services. He appoints the members of the Orifice Laboratory Quality Council. The Orifice Laboratory Calibration Supervisor and the Quality manager for the laboratory are members of the Quality Council. The Quality Council is empowered to review the Orifice Laboratory practices and procedures to ensure compliance with this Quality Policy.

4.2.3.2 It is the responsibility of the quality manager to ensure that the quality system is implemented and followed at all times. The quality manager has direct access to the highest level of management where decisions are made on laboratory policy and resources. The quality manager has the responsibility of Customer relations, quality control, and general management.

4.2.3.3 The Orifice Laboratory Quality Council is comprised of:

4.2.3.3.1 Chris McCoy, General Manager

4.2.3.3.2 Ed Andres, Orifice Lab Quality Manager, Standard Products Manager

4.2.3.3.3 Laura Wojcik, Orifice Product Specialist

4.2.3.3.4 Heather Harris, Orifice Lab Supervisor

4.2.3.3.5 Mike Perkins, Proposal Engineer

4.2.3.4 The Council reviews the SPC data and any other data necessary to ensure the Laboratory maintains control of its processes and maintains an acceptable performance confidence. The Council is responsible for taking immediate action to correct out of control conditions that cannot be resolved by the orifice lab team, such as an irresolvable failure in an SPC.

4.2.3.5 The Council's responsibility, per the referenced ISO 17025 paragraphs, includes:

4.2.3.5.1 Final approval for technician certification, Para 5.2.1.

4.2.3.5.2 Directing internal quality audits, Section 4.13.

4.2.3.5.3 Review all quality documents annually, Para 4.3.2.2b.

4.2.3.5.4 Approve design ECNs to equipment, Para 4.3.2.1 & 4.3.3.1.

4.2.3.5.5 Review customer complaints, Para 4.8.

4.2.3.5.6 Evaluate disposition of non-conforming product, Section 4.9.

4.2.3.6 Quality Council meetings are held annually, or more often as circumstances dictate, to monitor the effectiveness of the Quality System. At minimum, the results of audits and SPC data will be reviewed. The agenda, FMOL-19, will be filled in for each meeting.

4.3 DOCUMENT CONTROL

4.3.1 The Quality manual and the associated work instructions flow charts forms and checklists document the Quality System. The Quality Manual is reviewed and approved by the Quality Council and the General Manager. Changes are documented on the Change Control Sheet and all changes are subject to the same approval process as the original manual. The controlled copy of the manual and all associated documents are maintained on the M drive in the ISO folder in a protected file with the password available only to the Quality Council General Manager and IS Manager.

4.3.2 DOCUMENT APPROVAL AND ISSUE

4.3.2.1 All documents issued to personnel in the laboratory are reviewed and approved by the quality council and the General Manager of CTS. FMOL-86 is the master list of applicable documents for the quality system. The Quality Manager is responsible for ensuring the current manual, forms, work instructions, and flow charts are available to the technicians.

4.3.2.2 The quality manual, stated in section 4.3.3, is approved by the Quality Council to ensure the change is appropriate and will have no unintended consequences on the Orifice Laboratory's overall quality. The Quality Council then submits a recommendation for approval to the General Manager. The quality manual is reviewed as necessary during the Quality Council meetings for any recommended changes.

4.3.2.3 An electronic file is located on the M drive for access by the laboratory personnel. Access to the electronic file is on a "Read Only" basis unless password authorization has been granted. The controlled copy of the quality manual and all supporting documents are maintained in electronic format on this drive. All obsolete documents

are removed from the controlled area and then suitably marked and retained for preservation purposes on the M drive.

4.3.2.4 The quality manual and all related documents contain a unique identification, revision level, revision date, page number, and total number of pages.

4.3.3 DOCUMENT CHANGES

4.3.3.1 The Quality Council reviews and recommends for approval any changes to the quality manual and supporting documentation.

4.3.3.2 A brief description of any change is included in the revision history sheet at the end of all documents except for Forms. A historical record of Forms is maintained.

4.3.3.3 The laboratory quality manager is authorized to make amendments to the quality manual and any supporting documentation. The changes will be clearly marked and initialed and will be reviewed at the next quality council meeting. Approval will be given by the quality council and the appropriate revision level and date will be assigned and the document given to the General Manager for final approval.

4.3.3.4 An electronic master file of the current quality manual and all supporting documentation is maintained on the orifice laboratory network drive. All documents are password controlled for access and modification. This password is different from the password that is used to access the CTS network. The master file does contain copies of obsolete documents.

4.4 CUSTOMER PURCHASE ORDER REVIEW

4.4.1 The Quality Manager, or designee, is responsible for assuring the customer's contract (PO) is complete before any fabrication or calibration work commences. The purchase order (PO) is the complete agreement with the customer as to the scope, nature, and specifics of the project. Work is not to begin until all conflicts are resolved with the customer. The purchase order review is to ensure that the following conditions are met:

4.4.1.1 The purchase order adequately defines the product or service to be supplied.

4.4.1.2 The laboratory has the capability and resources to meet the requirements.

4.4.1.3 All administrative items are adequately defined to allow successful completion of the contract.

4.4.2 Form # FMOL-26 is reviewed to ensure the order is complete. Any discrepancies in the purchase order are to be referred to the customer for resolution. Purchase orders are to be acknowledged using form # FMOL-26 if the customer requests written confirmation of the order.

4.4.3 CTS will not subcontract fabrication of leak standards or calibration services.

4.4.4 The customer is to be informed and agree in advance should any deviation from the contract be required using an updated FMOL-26 form.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

4.5 SUBCONTRACTING OF TESTS AND CALIBRATIONS

4.5.1 CTS will not subcontract fabrication of leak standards or calibration services.

4.6 PURCHASING SERVICES AND SUPPLIES

4.6.1 The orifice laboratory Calibration Supervisor and/or Quality Manager is responsible for

identifying all purchased services and supplies that affect the quality of the leak standards manufactured, or calibration services provided, by Cincinnati Test Systems. A vendor list, FMOL-24 is maintained detailing the specific supplies or services provided. A vendor is defined as a supplier of services or product to Cincinnati Test Systems that have an effect on either the flow standards or calibration measurement equipment. The team leader is responsible for ensuring that the products and services provided by the vendors on the above list are satisfactory. All items used in the orifice lab must be located within the lab 24 hours prior to their use. The orifice laboratory Calibration Supervisor is responsible for scheduling, handling, and storage of customer supplied items.

4.6.2 SPC's will be conducted each time that a lab instrument returns from being calibrated to verify proper operation. A visual inspection of the following items will be conducted before use to ensure compliance. A Non Conformance form FMOL-17 will be filled out if parts are bad.

4.6.2.1 Orifice Holders

4.6.2.2 Orifice Seals

4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release by the Technical Manager by initialing it. The calibration certificates received from the vendor are initialed by the Technical Manager to insure that the proper information is present.. Non-conformances are also documented per non- conforming material and are not to be used. The supplier is to be notified per failure to comply with the specification.

4.6.4 Critical vendors will be evaluated based on their quality and demonstrated capabilities. The Quality Council shall evaluate these vendors in accordance with the Procedure for Evaluation of Vendors FMOL-45. Records of these evaluations will be maintained and the approved vendors will be listed in FMOL-24.

4.7 SERVICE TO THE CUSTOMER

4.7.1 Customers may have the opportunity to witness testing or calibrations done in the lab by having approval of the orifice lab Calibration Supervisor. The customer can review the needed documents to verify compliance with this quality manual and its related documents. An uncontrolled copy of the quality manual may be provided for the customer's retention. Copies of work instructions, flow charts, or technician training documents may not be given to the customer without prior approval of the General Manager. No photographs may be taken without the expressed approval of the General Manager. Customers will be notified of any change or problem with their order. Any question that arises about an order will result in the customer being contacted.

4.7.2 A survey is sent to customers with each order, Form FMOL-01, soliciting feedback on the Orifice Laboratory's service and quality. Any survey with negative feedback is recorded in FMOL-17 as a nonconformance / preventative action item and is made part of the Quality Council's regular review. The Quality Manager compiles an evaluation of the responses. The Quality Council reviews the survey responses as part of the Quality Council Meeting agenda.

4.8 COMPLAINTS

4.8.1 The Quality Manager is responsible for dealing with customer complaints. Form FMOL-17, Non-Conformance, Preventive Action and Communication Log, is completed for each complaint. A resolution for each complaint is documented on form FMOL-17. A record of all complaints is maintained including disposition. The Quality

Council reviews all complaints and resolutions. The Quality Council may determine if a preventative action routine is necessary and documents it on FMOL-17. The Quality Council shall assure that all resolutions are completed in a timely manner via internal audits of these complaints. Any unresolved complaint is presented to the General Manager for review and resolution.

4.9 CONTROL OF NON-CONFORMING WORK

4.9.1 The Orifice Laboratory Calibration Supervisor and Quality Manager are responsible for ensuring that all outgoing work has been made to specification and is within the tolerance limits. This check is to verify that the work is properly documented and procedures were properly followed. If a problem is identified, the Quality Manager should complete form FMOL-17 and investigate why the deviation occurred and if the deviation indicates that non-conforming work has potentially been shipped to a customer. If the failure is of such a nature that defective product could be shipped, then the Calibration Supervisor has the authority to halt production and follow the Corrective Action Procedure (FMOL-46). Where necessary, the client is notified and work is recalled.

4.9.2 The Quality Manager and/or Calibration Supervisor are authorized to stop calibrations and shipments should the deviation affect the accuracy or quality of the product or service provided to our customer. The Calibration Supervisor shall follow the Corrective Action Procedure (FMOL-46). The Calibration Supervisor must have the concurrence of the quality council that the issue has been properly resolved before calibrations may be resumed.

4.10 IMPROVEMENT

4.10.1 The Orifice Laboratory is committed to continually improving the effectiveness of it's systems through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management review.

4.11 CORRECTIVE ACTION

4.11.1 It is the Quality Manager's responsibility to develop the required changes in policy or practice needed to eliminate the cause for deviations or to prevent the effect of the cause from impacting the quality of products or services. These changes are to be approved by Quality Council. The Procedure for Corrective Action is FMOL-46.

4.11.2 The Quality Manager determines the root cause of the deviation and takes the appropriate steps to reduce the probability of a reoccurrence. The sequence of review is Process, Equipment, Materials, Training and Personnel.

4.11.3 The Quality Manager is to meet as soon as possible with the Calibration Supervisor after any work stoppage caused by a failure in the quality system. He is responsible for reviewing and approving any interim and permanent changes, ensuring the corrective actions are appropriate, and establishing a schedule for implementation of any permanent changes.

4.11.4 The Quality Manager is to determine what methods or information should be monitored to ensure the corrective action is effective. The Calibration Supervisor is to report at the next scheduled Quality Council meeting on the effectiveness and appropriateness of the implemented changes and compliance with any scheduled permanent changes in procedures or processes.

4.11.5 The Quality Council determines if unscheduled audits or additional SPC tests are to be conducted to ensure that the corrective actions are effective.

4.12 PREVENTIVE ACTION

4.12.1 The Quality Council may determine that preventative action is necessary to improve the quality of the lab. In this case, the Quality Council shall complete FMOL-17. Quality Council shall develop a preventative action plan including schedule for implementation. This plan shall be monitored in its implementation by the Quality Council to reduce the likelihood of the occurrence of non-conformances and to take advantage of the opportunities for improvement.

4.12.2 CTS is committed to continuous improvement of our processes and procedures. The goal is to improve quality, profitability and service to our customers. The Quality Manager along with the Quality Council will require controlled experiments be conducted that may identify weaknesses or productive changes that should be made in our quality system or processes. The Quality Council meetings should include discussions about possible initiatives that can improve the performance of the orifice laboratory.

4.12.3 Procedures for preventative actions shall include the initiation of actions and application of controls to ensure that they are effective. These shall be noted on form FMOL-17.

4.13 CONTROL OF RECORDS

4.13.1 GENERAL

4.13.1.1 Controlled Copies of SPC data, the Quality Manual, internal audit reports, Quality Council reports, and procedures for laboratory operation are contained within the Orifice Laboratory.

4.13.1.2 Records associated with the administration and operation of the Orifice Laboratory is maintained for up to ten years. Records maintained include but are not limited to:

4.13.1.2.1 Orifice calibration reports, (7 years)

4.13.1.2.2 Customer records associated with the orifice, (7 years)

4.13.1.2.3 Technician certification reports, (employment + 5 years)

4.13.1.2.4 Calibration reports for critical laboratory equipment, (7 years)

4.13.1.2.5 Internal Audit Reports, (3 years)

4.13.1.2.6 Customer Complaint & Resolution, (3 years)

4.13.1.2.7 SPC data, (7 years)

4.13.1.3 All records associated with the operation of the Orifice Laboratory are maintained securely inside of CTS's facilities and access is restricted to those personnel needed to operate or manage the facility to maintain confidentiality. The Quality Council will approve all disposal requests prior to destruction of the records.

4.13.1.4 Electronic records are maintained on the company network to ensure that backup procedures are followed and that access is password controlled.

4.13.2 TECHNICAL RECORDS

4.13.2.1 The orifice laboratory retains electrical copies of the orifice calibration reports per paragraph 4.13.1.2. These reports, forms FMOL-61, 62 & 63, include the necessary data to identify the test conditions, the equipment used, and the technician performing the test in order to be able to repeat the test.

4.13.2.2 Observations, data and calculations are recorded at the time they are made and recorded on the appropriate forms.

4.13.2.3 When mistakes occur in records, the Calibration Supervisor is notified and moves that record from the record database table to the error record database table. The

Calibration Supervisor then initials the record and records the reason for the error. The technician completes the new record with the correct data.

4.14 INTERNAL AUDITS

4.14.1.1 Internal audits are the responsibility of the Quality Council. Management and technical personnel who are not directly involved with the day-to-day operation of the laboratory perform the audits in accordance to a predetermined schedule and procedure. The audits are comprehensive. The complete audit may be done in phases provided everything is covered within the defined time frame. Internal audits are conducted according to CLOL-05. They may be scheduled without prior warning. All procedures must be audited once per year. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel, who are independent of the activity to be audited.

4.14.1.2 FMOL-17 is completed for all major findings. Any remedial actions taken will follow the same procedures as defined in Section 4.9, Control of Non-Conforming Work, and Section 4.10, Corrective Action.

4.14.1.3 An audit report is generated that details the different elements audited, any discrepancies discovered, and recommended corrective actions issued. A copy of the report is placed in the file for reference. The Quality Council reviews the audit report with the auditors.

4.14.1.4 Items requiring corrective action have a formal response presented to the Quality Council within one calendar quarter or the next council meeting, whichever occurs first. The Quality Council reviews and concurs with any corrective actions. The corrective actions are examined at the next internal audit to verify the effectiveness of the action.

4.15 MANAGEMENT REVIEWS

4.15.1 The General Manager participates in the annual Quality Council review that includes the result of the internal audit. The review also includes the overall business climate and any future plans that may impact the Orifice Laboratory's operation and a summary of the prior year's Quality Council meetings. The meeting includes but is not be limited to:

4.15.1.1 Suitability of existing policies and procedures.

4.15.1.2 Report from the orifice laboratory Calibration Supervisor and Quality Manager.

4.15.1.3 Results of any internal audits.

4.15.1.4 Corrective and preventive actions.

4.15.1.5 Results of any external audits.

4.15.1.6 Results of any laboratory comparisons.

4.15.1.7 Changes in laboratory volume.

4.15.1.8 Customer feedback.

4.15.1.9 Other relevant factors.

4.15.1.10 Complaints

4.15.1.11 Recommendations for improvement.

4.15.2 Any findings from the management review and action items are to be documented and

an agreed schedule for correction or implementation is to be completed as part of the meeting. The next management review will ensure that the action item list has been completed.

5 TECHNICAL REQUIREMENTS

5.1 GENERAL

5.1.1 Many factors determine the correctness and reliability of the calibrations performed by the orifice laboratory. These include contributions from:

5.1.1.1 Human factors.

5.1.1.2 Laboratory environmental conditions.

5.1.1.3 Test and calibration methods and validation.

5.1.1.4 Equipment.

5.1.1.5 Measurement trace ability.

5.1.1.6 Sampling.

5.1.1.7 Handling of test and calibration equipment.

5.1.2 The orifice laboratory team leader and quality manager take into account human factors during test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment used in the laboratory.

5.2 PERSONNEL

5.2.1 The Calibration Supervisor and Quality Manager have an understanding of the manufacturing process, are knowledgeable of statistical process control techniques as they relate to the operation of the lab, and are responsible for ensuring compliance with the quality policy and laboratory procedures. The orifice calibration supervisor and quality manager are responsible for proper training of new personnel. While any staff member is undergoing training, appropriate supervision will be provided.

5.2.2 The Calibration Supervisor defines the skill requirements, checklist CLOL-03, for laboratory personnel and ensures these requirements are met before a technician is certified. All technicians demonstrate the ability to correctly interpret a specification, fabricate and assemble a flow standard, run a calibration test, perform the required mathematics, and complete the required paperwork. Upon meeting these requirements, each technician is presented with a certificate, form # FMOL-07, recognizing that all of the required training has been completed and a copy is placed in the personnel file. To ensure the effectiveness of the training process, all technicians shall complete a yearly evaluation, FMOL-85 and results shall be analyzed to improve the training process.

5.2.3 The Orifice Laboratory technicians are employed by CTS, and are assigned to the orifice laboratory. The Calibration Supervisor monitors the performance of the technicians and any technical personnel in the laboratory to ensure that proficiency is maintained and that the procedures are followed.

5.2.4 All current job descriptions for all positions related to the orifice laboratory is approved by the quality council and maintained by the CTS Human Resources Manager. These job descriptions are listed in form FMOL-25. The job descriptions as a minimum are to include the following responsibilities or qualifications:

5.2.4.1 Performing calibrations.

5.2.4.2 Planning and evaluation of calibrations and results.

5.2.4.3 Reporting results and interpretations of results.

5.2.4.4 Method for modification to, and development of new, methods.

5.2.4.5 Experience required for the job.

5.2.4.6 Qualifications and training required.

5.2.4.7 Managerial duties.

5.2.5 The General Manager authorizes specific personnel to perform calibrations, quality test, issuing test results and calibration certificates. Records of authorizations, competence, qualifications, training, skills, and experience of technical personnel are maintained in the Orifice laboratory. These records contain the date for when the authorization is confirmed.

5.3 LABORATORY ENVIRONMENT

5.3.1 The Orifice Laboratory is enclosed in an area in the building to minimize fluctuations in pressure and temperature. The temperature is maintained at 72, +/- 5 degrees Fahrenheit. The Calibration Supervisor is immediately notified should the environmental conditions exceed these limits and corrective action will be taken. The door to the laboratory remains closed during testing and calibration. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility.

5.3.2 The laboratory environmental conditions are monitored and recorded as required by flow chart # FCOL-03 automatically by the lab software. Temperature and Barometric Pressure in the laboratory are recorded during calibration and entered into a database table without operator intervention. Due care is taken to control dust in the laboratory area. Test and calibrations shall be stopped when the environmental conditions jeopardize the results of the test and/or calibration.

5.3.3 No activities are conducted that are incompatible with the existing manufacturing and calibration of the leak standards certified in the orifice laboratory.

5.3.4 Entrance and exit from the laboratory is prohibited during a calibration cycle to prevent pressure fluctuations from corrupting the measurements. A “DO NOT ENTER” light is installed outside the laboratory and is illuminated during the calibration cycle by the technician as a warning to not enter the laborator during critical times. Only authorized personnel are permitted in the lab without the consent of the orifice calibration supervisor.

5.3.5 All materials used to make Laboratory products are kept put away until needed to keep clean and dust free. Test Gas and Dry Cal test equipment “soak” in the laboratory for 24 hours before use. The Procedure for good housekeeping is FMOL-48.

5.4 TEST AND CALIBRATION METHODS

5.4.1 The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

5.4.2 The laboratory shall have instructions on the use and operation of all relevant equipment , and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference date relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel.

Deviation from test and calibration methods shall occur only if the deviation has been documented technically justified, authorized, and accepted by the client.

5.4.3 The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

5.4.4 When the client does not specify the method to be used, the laboratory shall select appropriate methods that have been 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. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.

5.4.5 The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out of date.

5.4.6 LABORATORY-DEVELOPED METHODS

5.4.6.1 The introduction of test and calibration methods developed by the laboratory fo its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

5.4.7 NON-STANDARD METHODS

5.4.7.1 At present CTS does not employ non-standard methods of testing or calibrating leak standards.

5.4.8 VALIDATION OF METHODS

5.4.8.1 Validation is the confirmation by examination and the provision of objective evidence the particular requirements for a specific intended use are fulfilled.

5.4.8.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

5.4.8.3 The range and accuracy of the values obtained from the methods of production are assessed to ensure that the values are relevant to the client's needs.

5.4.9 ESTIMATION OF UNCERTAINTY OF MEASUREMENT

5.4.9.1 The Quality Manager is responsible for ensuring that SPC data has been completed for the Orifice Laboratory. The Form FMOL-11 is the procedure for estimating the uncertainty of measurement for all calibrations done in the laboratory.

5.4.9.2 The orifice laboratory is a fabrication and calibration laboratory, not a testing laboratory.

5.4.9.3 All uncertainty components of importance are defined and taken into account using appropriate methods of analysis. Form FMOL-11, Uncertainty Calculation, is completed and current. The uncertainty measurement is reviewed or confirmed at each Quality Council meeting and the approved measurement is used on the Calibration Certificates.

5.4.10 CONTROL OF DATA

5.4.10.1 The technician performs the calibration calculations using a program created for orifice calibration. The formulas within the program have been validated by performing identical calculations by two different people using a hand calculator and comparing the results. The correction factor calculation is done within the program, and is also included on the certification certificates.

5.4.10.2 Data generated from the testing and calibration of orifices in the Standards Lab of Cincinnati Test Systems, Inc. is recorded in a database stored on the Company's Database Server via an Internal Ethernet network. The data is secured using user permissions and user authentication. The data is archived to tape on a daily basis in a weekly rotation. Each weekend the data is archived to a tape, which is stored off site and never reused. The Database Server is protected from damage by electrical anomalies by the use of an isolated electrical circuit for all data processing equipment and an Uninterruptible Power Supply, which constantly regulates the current to the server and will initiate an orderly shutdown of the server if power is lost for an extended period of time. Computer software developed by Cincinnati Test Systems is documented in sufficient detail and is suitably validated as be adequate for use.

5.5 EQUIPMENT

5.5.1 All equipment needed to perform the calibration of the leak standards is contained in the orifice laboratory and is readily accessible by the technicians.

5.5.2 All orifice laboratory equipment used for calibration is capable of supporting the advertised accuracy as demonstrated in the estimation of uncertainty of measurement, section 5.4.6. CTS maintains and controls the orifice laboratory test equipment. An equipment calibration summary, form # FMOL-12, is maintained for all test equipment that affects the accuracy or NIST trace ability of calibrations. All such equipment is calibrated according to the Procedure for Equipment Calibration FMOL-12 before being put into service. SPC data is taken for each station and monitored weekly. If any data looks questionable, the equipment is checked out for any problems that might exist. Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

5.5.3 Equipment is operated by authorized personnel. Operating manuals are stored in the Orifice Laboratory and are available for reference as needed. Only authorized technicians can operate the equipment unsupervised.

5.5.4 The Calibration Supervisor and Quality Manager are responsible for maintaining all designated equipment in good working order and valid and current calibration documentation. Equipment is tracked by manufacturer's serial number.

5.5.5 The Quality Manager maintains records of the equipment that includes but is not limited to:

5.5.5.1 Identity by type and serial number

5.5.5.2 Manufacturer

5.5.5.3 Manufacturer's recommended calibration cycle

5.5.5.4 Operating manuals

5.5.5.5 Dates, results and copies of calibration reports.

5.5.5.6 Records of any scheduled or unscheduled maintenance.

5.5.5.7 Special handling requirements.

5.5.5.8 Damage or repair of equipment.

5.5.6 The equipment used to perform the calibration is handled in a safe manner to ensure no damage occurs that would impact the equipment's performance. The team leader is notified anytime test equipment is suspected of providing inaccurate readings or has potentially been damaged by improper operation or handling.

5.5.7 Equipment that is suspected of improper operation or has potentially been damaged is removed from service and placed in Quarantined Equipment storage until proper operation has been verified. Equipment is clearly labeled as not usable if it is not practical to place the equipment in Quarantined Equipment storage. FMOL-17, the Nonconformance Communication Preventive Action Log is completed. An investigation shall be conducted to determine the effects on previous tests. After verification that the equipment is not functional, equipment is sent out to the manufacturer for repair. All documentation is available for customer review on request.

5.5.8 Test equipment is recalibrated based on the manufacturer's recommendations. No test equipment is used without a valid and current calibration label, form FMOL-13.

5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.10 The overall performance of the equipment is monitored through the daily SPC checks, FCOL-03 and data stored in the SPC SQL database.

5.5.11 Equipment correction factors are incorporated into the orifice lab. The use of correction factors procedure may be found in document FMOL-71.

5.5.12 The test equipment has tamper proof seals in the appropriate areas to prevent or identify if the equipment has had unauthorized repairs. All software programs are password protected to prevent unauthorized modifications that could invalidate the calculations or the revision level control of documents.

5.6 MEASUREMENT TRACEABILITY

5.6.1 GENERAL

5.6.1.1 Measurement equipment is recalibrated based on the Procedure for Equipment Calibration FMOL-12. No test equipment is used without a valid and current calibration label, form FMOL-13.

5.6.2 SPECIFIC REQUIREMENTS

5.6.2.1 CALBRIATION

5.6.2.1.1 All test equipment used in the calibration of flow standards has trace ability to NIST, or SI recognized laboratories, either directly or through the company that performs calibrations on the equipment. The certifying company demonstrates competence, measurement capability and trace ability. Any calibration work performed by a laboratory that has a third party accreditation with an appropriately internationally recognized organization for compliance with ISO/IEC 17025 is considered in compliance. The certificates contain the measurement results, including the measurement uncertainty.

5.6.2.1.2 All Cincinnati Test Systems measurements are traceable to SI, therefore this section does not comply.

5.6.2.2 TESTING

5.6.2.2.1 CTS does not provide testing services in the orifice laboratory.

5.6.3 REFERENCE STANDARDS AND REFERENCE MATERIALS

5.6.3.1 The orifice laboratory uses a common set of leak standards for tracking the SPC performance of the calibration stations. These leak standards are not calibration standards for the stations. The leak standards are not adjustable. The SPC tracking of the laboratory demonstrates out of control problems that may develop with the leak standards.

5.6.3.2 Reference material, where possible, is certified reference material.

5.6.3.3 Intermediate checks will be carried out to maintain confidence in the calibration status of the working standards. Such checks are SPC tracking, referencing WIOL-02 and internal audits.

5.6.3.4 The laboratory follows 5.8.1 for safe handling, transport, storage, and use of reference standards and materials to prevent contamination or deterioration.

5.7 SAMPLING

5.7.1 The leak standards manufactured and calibrated by the orifice laboratory are 100 percent tested and not subject to a sampling process.

5.8 HANDLING OF TEST AND CALIBRATION ITEMS

5.8.1 Received items are recorded by serial number and corresponding client. The items are placed in zip lock bags and transferred to the laboratory. The items remain in bags until calibration is conducted.

5.8.2 The majority of items are serialized. Those that are not serialized are associated with the customer in the zip lock bags. Items without serial numbers are give one upon calibration.

5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded on the certification under technical remarks. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the discussion.

5.8.4 The laboratory procedure for handling is to place all items in zip lock bags upon receipt unless handling instructions are provided with the item, in which case, those will be followed. When items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored, and recorded. Where a test or calibration item or portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned to the customer specifications. When an item is to be disposed, CTS will thrown it away unless otherwise specified by the customer, in which case, those instructions will be followed.

5.9 ASSURING THE QUALITY OF CALIBRATION RESULTS

5.9.1 The Orifice Laboratory makes use of SPC practices to monitor the quality of the calibration procedures. The SPC procedure is defined in flowchart FCOL-03. This is

done to validate the overall operation of the laboratory. The third party calibration of the test orifices meets the requirements of an inter-laboratory validation.

5.10 CALIBRATION REPORTS

5.10.1 GENERAL

5.10.1.1 The results of each calibration are reported using any approved certification (FMOL-61). Each of these forms must include all information necessary for interpreting the results and the method used for the test. The same forms are provided regardless if the customer is an internal CTS organization or an external customer. The results of each test shall be reported accurately, clearly, unambiguously, and objectively and in accordance with any specific instructions in the test or calibration methods.

5.10.1.2 All manufactured or recalibrated orifices have a properly completed calibration certificate, FMOL-61. Calibrated orifices have an appropriate label, FMOL-06, affixed to the standard as defined in the appropriate work instructions, WIOL-08/09/10. FMOL-50 Determines technician qualifications including which technicians are qualified to handle customer relations and to sign certification reports. All certificates contain the following:

5.10.1.2.1 A title

5.10.1.2.2 The name and address of laboratory, location where tests and/or calibrations were carried our, if different from the address of the laboratory.

5.10.1.2.3 Unique identification of the test report or calibration certificate, such as serial number, and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, a clear end of the test report or calibration certificate.

5.10.1.2.4 Identification of method used.

5.10.1.2.5 Description of, condition of, identification of the item calibrated.

5.10.1.2.6 Date of receipt of calibration item.

5.10.1.2.7 Reference to procedure used by laboratory

5.10.1.2.8 Test or calibration results with, where appropriate, the units of measurement.

5.10.1.2.9 Name, function, signature or identification of person authorizing the calibration certificate.

5.10.2 TEST REPORTS. ----N/A-----

5.10.3 CALIBRATION CERTIFICATES

5.10.3.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

5.10.3.1.1 The conditions under which the calibrations were made that have an influence on the measurement results

5.10.3.1.2 The uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof

5.10.3.1.3 Evidence that the measurements are traceable

5.10.3.2 The calibration certificates relate only to the results of the functional test performed by the technician. When statements of compliance are made the uncertainty of measurement shall be taken into account.

5.10.3.3 Re-calibration certificates include the calibrated performance of the leak standard at its last calibration, provided CTS performed the last calibration.

5.10.3.4 A Calibration certificate (or label) shall not contain any recommendations on the calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations.

5.10.4 OPINIONS AND INTERPRETATIONS -----N/A-----

5.10.5 TESTING AND CALIBRATION RESULTS OBTAINED FROM SUBCONTRACTORS. -----N/A-----

5.10.6 ELECTRONIC TRANSMISSION OF CERTIFICATES

5.10.6.1 Any certificates or documents transmitted by facsimile are in full compliance with this quality manual and the procedure for Client Confidentiality FMOL-44.

5.10.7 FORMAT OF CERTIFICATES

5.10.7.1 All certificates are reviewed and approved for use by the Quality Council. The Quality Council ensures that the certificates are in compliance with ISO/IEC 17025 and any additional CTS or customer requirements.

5.10.8 AMENDMENTS TO CALIBRATION CERTIFICATES

5.10.8.1 Material amendments to a calibration certificate include the following wording:

5.10.8.1.1 “Supplement to calibration certificate for orifice serial number _____, dated _____.”

5.10.8.2 Additional copies of an existing calibration certificate are sequentially numbered and include the following wording:

5.10.8.2.1 “Copy number _____of calibration certificate for orifice serial number _____, dated _____.”

REVISION LEVEL HISTORY

Rev Level	Date	Description of Revision	Originator	Approved by
0	10-09-01	Initial Release	Christina Greene	Quality Council
A	01/22/02	Changed wording in 4.9.2 from "shipments can" to "calibrations may" in the last sentence.	Chris McCoy	Quality Council
B	05/17/02	4.1.1- Changed Quality Manager from Christina Greene to Chris McCoy. 4.6.2-Removed "Gage R&R" wording from the first sentence. Instruments will be checked via the SPC process upon receipt from calibrations. 5.9.1-Changed the Gage R&R process to annually unless calibrations become suspect due to SPC. Was every quarter or when instruments come back from calibration or repair. 5.10.1.1- Changed the certifications to the current forms. Forms were FMOL-4, -5, -32, -14, -09 5.10.2- Changed the certifications to the current forms. Forms were FMOL-4, -5, -32, -14, -09	Chris McCoy	Quality Council
C	08/23/02	Updated Footer to proper Revision Added "must" to the last sentence in 4.1.5(f) Added quality manager responsibility in 4.1.5(i) Changed Christina Greene to Chris McCoy in 4.2.4.3 Added sentence on amended contracts in 4.4.5 Added purchasing references in 4.13.1	Chris McCoy	Quality Coucnil
D	09/06/02	4.3.2.2 Removed sentence stating backup disk shall be held in Presidents office. The documents are stored on the network drives, which are backed up daily. 5.5.10 Changed FCOL-05 to FCOL-03. Added statement that the SPC data is stored in the SQL database. 4.1.1 Removed Wanda Smith from the organization structure 4.3.2.1 Changed Lab Manager to Quality Manager for current document responsibility	Chris McCoy	Quality Council
E	10/22/02	5.10.1.1 Updated the calibration certificate to FMOL-61 5.10.2 Updated the calibration certificate to FMOL-61	Chris McCoy	Quality Council

F	11/29/02	Added the procedures to sections 4.14.1 and 5.5..11	Chris McCoy	Quality Council
G	8/21/03	Revised personnel changes	Laura Wojcik	Quality Council
H	10/31/03	Revised personnel titles; corrected typing errors; modified 5.4	Laura Wojcik	Quality Council
I	11/21/03	Added FMOL-79 and modified 5.5.7 to show this form	Laura Wojcik	Quality Council
J	3/1/04	Added FMOL-80	Laura Wojcik	Quality Council
K	3/31/04	Modified 4.1.5, 4.6.3, 4.8, 4.11, 4.13, 5.3.1, 5.3.2, 5.8; Revised FMOL-78, FMOL-46, FMOL-17, FMOL-12, FMOL-11; Obsolete FMOL-49, FMOL-47, FMOL-35, FMOL-36, FMOL-37, FMOL-38, FMOL-39, FMOL-40, FMOL-41, FMOL-42, FMOL-47, FMOL-66, FMOL-67, FMOL-68, FMOL-69, FMOL-70, FMOL-74, FMOL-75, FMOL-76, FMOL-79, FMOL-80.	Laura Wojcik	Quality Council
L	5/10/04	Modified section 5.8.4 to include disposal of calibrated items	Laura Wojcik	Quality Council
M	8/10/05	Revised 4.1.1 organizational chart, corrected typographical errors; added FMOL-82; added FMOL-82 and FMOL-83.	Laura Wojcik	Quality Council
N	12/10/05	Revised 4.2.4.6 changing quality council meetings from quarterly to annually, 4.14.1 management review annually with quality council meeting, 5.3.2 stating barometric pressure being recorded during calibration instead of throughout the day; Modified FMOL-81, FMOL-61, FMOL-62, FMOL-63, CLOL-05, obsoleted FMOL-34	Laura Wojcik	Quality Council
O	12/4/2006	Updated Cover with new logo Reformatted entire document Removed Document list at end Replace every occurrence of President to General Manager. Revised 4.1 to add Ed Andres as Quality Manager 4.1.1 Updated Org Chart 4.1.3 Added word Permanent 4.1.4 Added Independent statement 4.1.5 Added K line 4.1.6 Added entire line 4.2.3.3 Added Ed Andres to Quality Council and removed Vern Rebsch 4.3.2.1 Revised section for separate document list 4.3.2.3 Added electronic format as controlled copy 4.7.2 Added section to cover negative feedback 4.10 & 4.10.1 Added thia section and improvement statement 4.13.1.3 Added security and confidentiality statements 4.13.2.1 Fixed reference to documents 4.15.1.11 Added Recommendation for improvement 5.2.2 Added yearly evaluations FMOL-85 5.3.1 removed central to 5.3.2 removed FMOL-03 and added recorded automatically 5.3.4 Added reference to “DO Not Enter” light 5.6.3.3 Added referencing WIOL-02	Ed Andres	Quality Council
