# **CLEAN AIR ENGINEERING** NORTH AMERICAN OPERATIONS

# **QUALITY MANUAL**

# DECEMBER, 2002

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December, 2002	

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# **QUALITY COMMITMENT**

Clean Air Engineering is committed to providing the highest quality services to our clients. Strict quality control procedures are adhered to for all of its programs. The company's goal is to meet or exceed the QA/QC requirements set by USEPA or any other appropriate governmental or private entities and to assure that all data generated are scientifically valid, defensible, comparable and of known acceptable precision and accuracy following the best available testing methods.

This Quality Manual contains Clean Air's quality control procedures applicable to air emission test programs that provide data for the purpose of reporting to the USEPA. As of the latest revision, this manual covers only the operations of Clean Air's U.S. offices. The long-range intent, however, is for these procedures to be adopted as worldwide standards for all Clean Air Engineering operations.

William Walker President Clean Air Engineering 847-991-6200 x2080

jonne E WruzfA

James Wright Quality Administrator 412-787-9130

# SIGNATURE PAGE

The following individuals have read and understand this Quality Manual and agree to uphold the procedures, directives and policies contained herein.

Personnel Name	Division	Corporate Title	Signature/Date	Date
Brent Berridge	Houston	Team Leader, Houston Operations	BurEberry	December 18, 2002
Peter Kaufmann	Palatine Source Testing	Team Leader, Palatine Source	Att Konfun	December 18, 2002
Allen Kephart	Trading Group	Vice President, Trading Group	allen in the hard	December 18, 2002
Doug Rhoades	Analytical	Team Leader, Analytical	( FRC)	December 18, 2002
Mary Ryan	Instrument Rental	Team Leader, Rentals	May Ry-	December 18, 2002
Dan Rybarski	Express	Team Leader, Express	Dar lybourh	December 18, 2002
Tim Rodak	Pittsburgh	Team Leader, Pittsburgh Operations	Timathy D Rodal	December 18, 2002
Jim Wright	Corporate	Vice President, Source Testing Division	Jame E Wrigh	December 18, 2002

# **1.0 Management and Organization**

## 1.1 Background

Clean Air Engineering is a Type-S U.S. corporation headquartered in Palatine, Illinois with operating branch offices located in Pittsburgh, Pennsylvania and Houston, Texas. The company also has an international office located in Marseille, France, as well as several equipment representatives throughout the world.

Clean Air Engineering's primary business is the supply of personnel, equipment and expertise for emissions measurements and related services. This includes source testing, project management, source test instrument sales, rental, maintenance and calibration, consulting and training. The Company responds to Customer demand by tailoring its complementary range of services to meet the individual Customer's requirements.

Clean Air Engineering's aim is to be recognized, worldwide, for providing the highest value products and services for air quality management. Since its founding in 1972 by Mr. William Walker, Clean Air has established a reputation for excellence on projects of all sizes. This reputation stems from our focus on reliability, responsiveness, individual client attention, and pride in our work. The strength of Clean Air's organization is its solid base of professionals dedicated to high-quality technical service.

1.2 Services

Clean Air Engineering's teams work together to provide a number of environmental services including:

- Air Quality Sampling and Monitoring (a.k.a., Stack Testing)
- Instrument Rental
- Equipment Manufacture and Design
- Analytical Services
- Process Consulting and Clean Air Act Compliance
- Permitting
- 1.3 Quality Management Policy

Clean Air Engineering is committed to providing to its customers data of the highest practical quality at all times. The company's goal is that all data will be of known precision and accuracy and within acceptable quality control limits.

This commitment is met through implementation of the following general policies:

- Thoroughly understand the customer's requirements.
- Use only reliable, properly maintained and accurate equipment.
- Apply appropriate testing standards and methods.
- Employ fully trained specialized staff.
- Keep abreast of changes in standards and available methods.
- Participate in regular independent performance audits.

- 1.4 Organizational Structure
  - 1.4.1 Everyone is expected to play a part in maintaining high standards and meeting the overall company quality objectives. Consequently, everyone within Clean Air Engineering is responsible for the quality of the work they perform. Management must make all personnel aware of their responsibility for identifying quality problems and empower them to do something about these problems.
  - 1.4.2 The size of the Company and the range of services offered make it impossible to separate all the functions that are necessary for the successful operation of the company. Deputizing is used frequently to cover absence and great reliance is placed on documented systems and records to maintain continuity of work in progress. The organizational structure in Figure 1 shows the normal operational structure of the company, but not the exclusive one.
  - 1.4.3 The Company's activities are arranged internally, and promoted externally, as separate divisions of Clean Air Engineering. These are:
    - Source Testing air emissions testing and consulting
    - Instrument Rental instrument rental
    - Analytical laboratory services related to emissions testing
    - Express equipment and system sales
    - Trading Group consulting, permitting and regulatory services
  - 1.4.4 The Pittsburgh and Houston offices currently operate under the Source Testing division.
  - 1.4.5 The quality system described in this manual applies to all of these divisions, and is implemented both at corporate and divisional levels. The management-level implementation of the quality system is conducted by a Quality Administrator and several Quality Directors (note the term "director" in this manual is unrelated to Clean Air Engineering's Board of Directors). At the time of this revision, these individuals are as shown in Table 1.

Division	Position	Personnel Name
Corporate	Quality Administrator	Jim Wright
Palatine Source Testing	Director	Peter Kaufmann
Pittsburgh Source Testing	Director	Tim Rodak
Houston Source Testing	Director	Brent Berridge
Instrument Rental	Director	Mary Ryan
Analytical	Director	Doug Rhoades
Express	Director	Dan Rybarski
Trading Group	Director	Allen Kephart

Table 1:Management-Level Quality Personnel

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Figure 1: Clean Air Engineering Organization Chart

#### 1.5 Conflict of Interest

All employees must follow the requirements set forth in Clean Air Engineering's <u>Conflict of Interest Policy</u>. Clean Air Engineering recognizes and respects that employees may take part in legitimate financial, business and other activities outside their jobs. However, those activities must be lawful and free of conflicts with their responsibilities as Clean Air employees. Employees must not misuse Company resources or influence, or discredit Clean Air's name and reputation.

# 1.6 Integrity

- 1.6.1 All Clean Air Engineering employees are expected to strive to be open, trustworthy, honest, truthful and legal in everything they do to the best of their ability. These requirements are expanded upon in Clean Air's <u>Commitment</u> <u>Letter</u>.
- 1.6.2 Clean Air employees should not offer anything of value to obtain any improper advantage in selling goods and services, conducting financial transactions or representing the company's interests to any potential or existing client. The Improper Payments Policy sets forth Clean Air's standards of conduct and practices for certain kinds of payments, entertainment and political contributions. Clean Air must not authorize, involve itself in or tolerate any business practice that does not follow this policy.

# 1.7 Confidentiality

Clean Air Engineering employees must treat all client process data, test data, emission results and process or product specifications as confidential information. Under no circumstances will client information be disclosed to others without a signed directive by the client or a court injunction.

- 1.8 Responsibilities and Authority
  - 1.8.1 The responsibilities and authorities of each group of employees shown in Figure 1 are as described below. Some of the more general job categories are described in terms of the Source Testing division (e.g., field technician). However, similar job responsibilities can be identified for their counterparts in other lines of the company's business.
  - 1.8.2 Quality Administrator the Quality Administrator has the authority and responsibility to ensure that the requirements of this Quality Manual and related operating procedures are implemented and maintained throughout the Company. The Quality Administrator reports directly to the company president, and carries the president's authority for quality-related issues.

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Responsibilities of the Quality Administrator include:

- Establishing, implementing and maintaining the Quality Manual in compliance with the requirements of any applicable standards;
- Documenting and controlling data pertaining to quality systems;
- Overseeing non-conformance and corrective action analysis;
- Responsible for planning, management and effectiveness of internal audits;
- Maintaining the Customer complaints register;
- Maintaining the designated equipment calibration programs.
- 1.8.3 Directors the Directors of the company are high-level management personnel, normally Business Team Leaders. They are personally involved in the daily activities of the company, being in regular contact with customers to assess the suitability of the contents of this manual, and adherence to it, in fulfilling their policy and the requirements of any other applicable standards.

The Directors are responsible for the overall management of quality at an operational level. Although they may report to various senior managers from a business standpoint, their direction for all quality-related issues comes from the Quality Administrator. Their quality-related responsibilities include:

- Defining, implementing and updating the Company's Quality Management Policy;
- Appointing staff and determining their responsibilities, authorities and interrelationships;
- Conducting staff reviews and identifying training needs as required and, as a minimum, annually;
- Regularly reviewing Standard Operating Procedures to ensure their continuing suitability and effectiveness;
- Conducting full management reviews of the quality system annually as in Section 2.5.
- 1.8.4 Project Managers Clean Air Engineering uses Project Managers to oversee individual projects of many varieties and scope. They normally report to a Director, and have the following quality-related responsibilities:
  - Responsible for incorporation of quality procedures into execution of projects;
  - Prepare comprehensive project test plans that are used to disseminate information to test crews pertaining to job-specific quality procedures, job logistics and safety requirements;
  - Oversee data analysis and review procedures;
  - Interface with clients concerning all aspects of project management.

- 1.8.5 Test Team Leaders these personnel manage the front-line of the quality process. Their positions are generally field-based, and they normally report to a Director. Quality-related responsibilities include:
  - Conducting site tests in accordance with all technical specifications;
  - Overall management of test team activities;
  - Ensuring that site safety requirements are met;
  - Ensuring that all aspects of quality system are adhered to in the field.
- 1.8.6 Sales and Marketing Personnel each operating division uses specific sales and marketing personnel to assist in obtaining orders for work. Since these personnel are often the first persons to contact the Customer, the overall quality process may be viewed as starting with them. They are often involved in customer follow-up, and may receive feedback for the quality of work done in the execution of a project. Their quality-related responsibilities include:
  - Ensuring that bids and proposals meet the technical, quality and safety specifications of both the customer and Clean Air Engineering;
  - Following standard operating procedures for work order creation so that all pertinent information concerning the proposed work is available to the responsible Project Manager;
  - Directing customer feedback to the appropriate mangers or Directors.
- 1.8.7 Workshop Supervisors a large part of quality assurance relies on maintenance and calibration of measurement equipment and instrumentation. These procedures are overseen by the Workshop Supervisors, whose responsibilities include:
  - Repairing, servicing and calibrating equipment;
  - Maintaining equipment inventories and control;
  - Maintaining equipment status records;
  - Arranging external calibration of designated equipment.
- 1.8.8 Report Writers report writers are involved in the production of technical presentations of emissions measurement data. Their responsibilities include the following quality-related procedures:
  - Checking environmental test results for adherence to quality objectives and limits;
  - Maintaining standard electronic files for data analysis and presentation.
- 1.8.9 Technicians the quality of emissions test data begins with the field technician. Their responsibilities include adherence to all standard operating and quality assurance procedures.

# 1.9 Quality Training

- 1.9.1 Everyone at Clean Air Engineering is expected to know and understand the contents of this manual and any referenced procedures that are applicable to their work function. This manual and all referenced operating procedures are available at all times on the Clean Air Engineering intranet.
- 1.9.2 Quality Directors will ensure that new employees are introduced to this manual and understand its major elements. Any employee with a question concerning this manual or any referenced procedure should consult a Director.
- 1.9.3 Specific training on any topic within this manual may be done on an as-needed basis, either to individual employees or groups. The selection of training topics, materials, trainees and presentation content will be up to the discretion of each Director, and must be cleared with the Quality Administrator. The Quality Administrator may also choose specific training agendas for one or more employees as necessary.

#### 1.10 Records

- 1.10.1 The Directors shall ensure that personnel and organizational records are maintained in accordance with documented procedures.
- 1.10.2 Either paper or electronic copies of this Quality Manual shall be supplied to all work areas, including mobile facilities such as field laboratories, CEM trailers, etc.

# 1.11 Referenced Standard Operating Procedures

The following policies are referenced in this section. These are all available on the Clean Air Intranet under the stated web addresses.

- Commitment Letter <u>http://209.125.143.203/interns/Commitment\_Letter.html</u>
- Improper Payments Policy <u>http://209.125.143.203/interns/Sections/improperpayments.html</u>
- Confidentiality Policy <u>http://209.125.143.203/interns/Sections/protectingclientdata.html</u>
- Conflict of Interest Policy <u>http://209.125.143.203/interns/Sections/conflictsinterest.html</u>

# 2.0 Quality System Description

2.1 Purpose

This section describes the key components of Clean Air Engineering's quality system and how it is used to meet the quality policy defined in Section 1.3.

# 2.2 Scope

This section applies to all projects executed by Clean Air Engineering.

#### 2.3 Responsibilities

- 2.3.1 The Quality Administrator is responsible for ensuring that the operational processes of the company are consistent with the requirements of this section.
- 2.3.2 Each managing Quality Director is responsible for ensuring that the requirements of this section are complied with and that standard operating procedures are followed at all times during project execution.
- 2.3.3 All affected staff are expected to follow standard operating procedures.

#### 2.4 Quality Objectives

There are five main objectives of the Quality System:

- To continually monitor the accuracy and precision of data being generated for projects involving air pollution monitoring.
- To implement measures designed to control the accuracy and precision of data generated for such measurements.
- To continually improve the quality of data generated for such measurements.
- To provide a permanent record of quality control data generated for such measurements.
- To identify, correct and document all system-related problems exposed through this quality control program.

#### 2.5 Management Review

The Directors shall carry out a review of the quality system as described in this manual at least annually to consider its continuing suitability and effectiveness in pursuit of Clean Air's business aims. This review will be overseen by the Quality Administrator.

The agenda shall include, as a minimum, the following topics:

- Changes in Company structure
- Safety issues
- Personnel changes
- Economic changes

- New legislation
- New technology
- New methods
- Previous management reviews and their effectiveness
- Analysis of Customer feedback
- Internal & external audit and non-conformance reports since the last review and their analysis together with previous analyses
- The progress made towards previously set Company objectives
- The effectiveness and continued suitability of Company documentation
- Training plans, achievements, effectiveness and improvements
- Desirable improvements
- Company objectives

# 2.6 Incorporated Directives

The Quality System includes the following operational directives:

- All tests shall be performed to agreed standards.
- A Project Job Plan shall be prepared for each test undertaken.
- Whenever possible, equipment required for tests shall be obtained from Clean Air's own stock, including Source, Rentals and Express.
- Only items from Clean Air's rental stock shall be offered for rent to the Customer.
- All equipment shall be inspected, serviced and calibrated prior to use.
- All Customer calls are documented and the purpose of the call is recorded.
- Weekly divisional meetings will be used to communicate important current and upcoming projects, resource shortages (and plans to relieve those shortages), problems and resolutions from the previous week, and important team and company directives.
- All technicians will be trained to operate and/or maintain the equipment with which they work. Cross training between divisions will be done periodically by sharing personnel on a project or timeframe basis (e.g., Rental technician participating on a field project for Source.)
- Test results shall be presented to the Customer in a written report that has been reviewed and certified by a senior company representative.
- Periodic Audits will be used to assess the quality system and identify areas of nonconformance.
- Quality improvements will be made through corrective action and preventative analysis systems.
- 2.7 Inquiry Processing
  - 2.7.1 In response to a Customer inquiry, a Director shall oversee the preparation of a quotation for the proposed test work. The quotation will be prepared in accordance with the <u>Opportunity Assessment</u>, <u>Proposal Preparation</u> and <u>Cost</u>

Estimation procedures contained in the <u>Sales Handbook</u>. Divisional-specific procedures may also be employed in the sales quotation or proposal generation process. Normally, in addition to the Director, one or more sales personnel will be involved in this process.

- 2.7.2 In preparing a quotation for repeat tests at an existing Customer's site, details of the requirements may be obtained from previous Customer records. In cases involving new Customers or different test methods, the Director shall consider the benefit of visiting the Customer's site to ascertain the testing requirements.
- 2.8 Order Processing

On receipt or confirmation of the Customer's order, full details of the project requirements shall be translated onto an internal Job Release (usually by the sales staff) and verified by a Director before being issued to the Test Team to process. At this time, the Accounting department will issue a unique project number that will be used from that point on to identify the project.

- 2.9 Project Management
  - 2.9.1 The Project Manager shall prepare a Project Job Plan in line with the specifications outlined in the <u>Test Planning Procedure</u> contained in the <u>Project Manager Handbook</u>.
  - 2.9.2 The Project Manager shall consider the need to visit a site to establish direct contact with the Customer and to discuss the preliminary Job Plan requirements.
  - 2.9.3 All paper records will be kept in the Project File in accordance with the <u>Project</u> <u>File Procedure</u> contained in the <u>Administrative Handbook</u>.
- 2.10 Equipment Resources

The corresponding Packing List produced by the Test Planning Procedure shall be used by the Workshop Supervisor to assemble and pack the items. The applicable Workshop Supervisor shall examine the Packing List against the available equipment to identify any items that would require servicing or calibration before expiration of the proposed period of use. Any such items shall be routed to the Workshop for checking prior to dispatch.

2.11 Staffing

Staffing assignments will be made by the applicable managing Director. The Director will consider the Job Plan and project budget in determining the manpower quantity and skill-level requirements. The Director will ensure that the project is staffed appropriately, regardless of budget constraints or schedule conflicts. Consultation with other Directors will be necessary in cases that require manpower sharing across different divisions.

# 2.12 Pre-Test Briefing

Prior to departing for the tests, the Project Manager shall hold a pre-test briefing with the Field Test Leader and Report Writer to discuss the Job Plan and review the final arrangements.

# 2.13 On-Site Work

- 2.13.1 All staff involved with the tests shall comply with the requirements of the Job Plan and applicable internal procedures and external reference documents. When applicable, the testing will be conducted using specific procedures from the <u>Clean Air Engineering Manual of Standard Operating Procedures Source Testing Division</u>. Other Quality Assurance requirements will be derived from the <u>Source Testing Quality Assurance and Quality Control Procedures</u>, the USEPA <u>Quality Assurance Handbook for Air Pollution Measurement Systems: Volume III, Stationary Source-Specific Methods (EPA/600/R-94/038c) and in Clean Air Engineering's <u>Manual of Method Clarifications</u>.</u>
- 2.13.2 All staff shall comply with Clean Air Engineering's <u>Occupational Health and</u> <u>Safety Program</u> requirements and those imposed by the Customer.
- 2.13.3 During the tests, the Team Leader shall be responsible for execution of the Job Plan and may effect minor changes in order to comply with site requirements. Any large deviations from the Plan, or additional Customer requests, shall be approved by the Project Manager before implementation.

# 2.14 Equipment Return

- 2.14.1 All returning equipment shall be checked in by the Workshop Supervisor(s) against the Packing List and placed in the designated area awaiting inspection. Any missing items or obvious damage shall be recorded on the Packing List and a Non-conformance report filed.
- 2.14.2 Depending on the state of the equipment, the Workshop Supervisor will decide whether it requires repair, maintenance or recalibration before it is returned to inventory. Any necessary calibrations or repair to the equipment will be performed by the Workshop staff in accordance with standard procedures.
- 2.15 Results Processing

On completion of the tests, and acquisition of any laboratory analyses, the Report Writer shall compile all the relevant data sheets, field logs, etc. and prepare a final report in accordance with the <u>Clean Air Engineering Report Manual</u>. The report shall be checked and authorized by the Project Manager and the overseeing Director for the project before being issued to the Customer.

- 2.16.1 Overall System The quality system assessment described in Section 9.0 will be followed.
- 2.16.2 Field Data Collection Field data collection will be assessed by continuous monitoring of method-specific quality control criteria such as isokinetic sampling percentage, minimum sample volume requirements, adherence to component temperature set-points, leak-checks, etc. Instrumental test methods will be evaluated using calibration error and bias measurements. These assessments will be made on-site for every test run performed. Tests failing to meet any of these criteria will be subject to invalidation and, in such cases, will be repeated. These evaluations will be the responsibility of the on-site Test Leader.
- 2.16.3 Report Review Additional quality control measures will be made during the <u>Report Review</u> process to confirm the validity of the field measurements. Each test run field-validated according to Section 2.16.2 will be reconfirmed by the Report Writer or Project Manager. Discrepancies between the field validation and the report evaluation will be brought to the attention of the managing Director for resolution.
- 2.16.4 Rental Equipment Quality monitoring will be accomplished using Weekly Meetings, the Call Documentation Sheet feedback system, and the Green Dot/Red Dot order coding systems as prescribed in the <u>Rental Division's Team Quality</u> <u>Program</u>.
- 2.17 Technical Assessments
  - 2.17.1 Clean Air Engineering participates in the USEPA Stationary Source Compliance Audit Program (SSCAP) administered by the Emission Measurement Center (EMC). This participation is on a job-specific basis as dictated by compliance with state agency requirements.
  - 2.17.2 Clean Air Engineering also participates in the Louisiana DEQ semiannual proficiency test (PT) program for continuous monitoring methods, as described at <a href="http://www.deq.state.la.us/laboratory/ptsamples.htm">http://www.deq.state.la.us/laboratory/ptsamples.htm</a>.
- 2.18 Quality Improvements

The quality system improvement systems described in Section 10.0 shall be followed.

- 2.19 Records
  - 2.19.1 All documents and folders (electronic and paper) pertaining to the project will be coded with the Project Number.
  - 2.19.2 The final test report, together with the test plan, field logs, records of equipment used, etc., shall be retained for a period of 20 years after completion of the tests.

- 2.19.3 All paper records will be compiled in the Project Folder according to standard administrative procedures.
- 2.19.4 Electronic files will be stored on the file server at the Palatine facility in accordance with the <u>Computer Document Control Procedure</u>.
- 2.19.5 All physical operations shall be documented through the use of appropriate Field, Laboratory or Instrument Logbooks.
- 2.19.6 The documented report of the Management Review described in Section 2.5 shall be copied to the Directors for action and the master record copy retained by the Quality Administrator for a period of 10 years. A copy of the report, or nonconfidential extracts from it, may be released to other staff at the Directors' discretion.

#### 2.20 Referenced Standard Operating Procedures

All standard operating procedures are available on the Clean Air Intranet under the Standard Procedures link. Those procedures or groups of procedures referenced in this section are:

- Sales Handbook
- Project Manager Handbook, Revision 3, November 1995
  - Test Planning Procedure
  - Report Review
- Administrative Handbook
  - Project File Procedure
- Manual of Standard Operating Procedures Source Testing Division, Draft 2000-1, July 2000
- Source Testing Quality Assurance and Quality Control Procedures, Revision 3, January 2000
- USEPA Quality Assurance Handbook for Air Pollution Measurement Systems: Volume III, Stationary Source-Specific Methods (EPA/600/R-94/038c)
- Manual of Method Clarifications
- Occupational Health and Safety Program
- Report Manual, Revision 5.1, April 2001
- Computer Document Control Procedure, September 2001
- Rental Division Team Quality Program

# 3.0 Personnel

3.1 Purpose

The purpose of this section is to ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.

3.2 Scope

This section applies to all technical personnel working for Clean Air Engineering, including subcontracted laborers.

- 3.3 Responsibilities
  - 3.3.1 Each managing Director is responsible for the implementation of this section on a divisional basis.
  - 3.3.2 The Quality Administrator shall maintain a list of all technical personnel and their skill grades consistent with this section.
- 3.4 Staff Requirements
  - 3.4.1 Each managing Director shall ensure that personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.
  - 3.4.2 Each managing Director shall ensure that appropriate supervision is provided whenever using staff that is undergoing training.
- 3.5 Subcontractors
  - 3.5.1 As much as possible, Clean Air Engineering will only use personnel who are directly employed by the company.
  - 3.5.2 Where contracted technical support personnel are necessary, the managing Director shall ensure that such personnel are supervised by Clean Air Engineering personnel, are competent and work in accordance with this quality system.
- 3.6 Training
  - 3.6.1 The managing Directors must ensure that the following training is provided to all new employees prior to their first job assignment:
    - Health and Safety Requirements
    - Company Orientation
    - Employee Handbook
    - Computer Basics

- 3.6.2 Additional training is specific to the employee's job function. The managing Director must ensure that the employee is provided with the minimum training requirements as specified in Section 3.7.
- 3.6.3 Source testing personnel must demonstrate a minimum level of proficiency before being allowed to perform any test method that is used to demonstrate compliance with federal, state or local regulations, performance guarantees, international regulations, or any other type of enforceable requirements.
- 3.6.4 Training records will be maintained for all personnel, listing their formal and work training (e.g., college degrees, specific EPA methods, special certifications, etc.) Managing Directors are responsible for maintaining these records for all employees that report directly to them. A master copy of these records will reside with Human Resources.
- 3.6.5 A large element of Clean Air Engineering's training program is on-the-job training. The managing Director must ensure that adequate personnel and time are available to facilitate this process, particularly within the first three months of the employee's service, without sacrificing safety or quality.
- 3.7 Qualifications

Technical personnel are classified according to six skill grades, ranging from Grade T3 through E1. This section describes each grade and its qualifications.

- 3.7.1 Skill Grade T3
  - 3.7.1.1 General Description A technician or equivalent that assists in field activities related to air emissions testing under the supervision of a higherlevel technician or engineer. They may also work in the office, shop or warehouse performing a wide variety of tasks under the supervision of higher level personnel. Field-related tasks include:
    - equipment packing and unpacking
    - equipment set-up
    - sample train leak-checks
    - meter operation
    - sample train recovery

# 3.7.1.2 Minimum Qualifications

- Two or four-year college degree. Technical degree preferred.
- Demonstrate ability to use scientific calculator.
- Experience in laboratory environment (college lab course acceptable).
- Able to lift 50 lbs.
- Able to climb ladders (if intended for possible field use).

3.7.1.3 Advancement Criteria – Not applicable. This is an entry level position.

# 3.7.2 Skill Grade T2

3.7.2.1 General Description – A technician or equivalent capable of conducting sampling at a single test location with minimal direct supervision. May oversee one or more level T3 personnel.

# 3.7.2.2 Minimum Qualifications

- Able to use Clean Air Express programmable calculator to determine K-factor and post-test parameters (e.g., isokinetics, flowrate, meter volume).
- Knowledgeable of what variables go into the K-factor and how changes in these variables affect isokinetic sampling.
- Familiar with the <u>CAE Field Handbook</u> and its use.
- Able to perform all aspects of USEPA Method 5 sample recovery.
- Able to measure up and downstream disturbance distances and calculate number and location of traverse points for particulate tests.
- Familiar with Method 1 cyclonic flow evaluation measurements.
- Able to assemble CEM sampling probe components (probe, filter, heaters, etc.)
- Able to fix a thermocouple plug.
- Knowledgeable of proper packing and unpacking procedures for meters.
- Able to perform critical orifice calibration of meter and do related calculations.
- Able to perform Orsat analysis.
- Able to set up Unistrut.

# 3.7.2.3 Advancement Criteria (T3⇒T2)

- Six months experience working as T3.
- Proficiency Test

# 3.7.3 Skill Grade T1

- 3.7.3.1 General Description Technician or equivalent capable of conducting sampling at a single test location with minimal direct supervision, and also able to operate CEM equipment, run a field lab, or conduct advanced test procedures such as 3D Probe Traverses, PM<sub>10</sub>, VOST, etc. May oversee one or more level T2 or T3 personnel.
- 3.7.3.2 Minimum Qualifications Same as T2 with addition of at least one of the following sub-categories of qualifications:
  - 3.7.3.2.1 CEM Technician

- Knowledgeable of QA/QC requirements of EPA Methods 3A, 6C, 7E, 10, 20 and 25A.
- Able to assemble, calibrate and operate a monitoring system consisting of multiple gas analyzers.
- Familiar with LabTech software and associated Excel CEM workbook.
- Able to troubleshoot, diagnose problems and fix CEM sampling systems.
- Able to perform rudimentary troubleshooting and maintenance of individual gas analyzers.

3.7.3.2.2 Field Laboratory Technician

- Knowledgeable of sample train set-up and recovery procedures for EPA Methods 5, 6, 8, 12, 13B, 23, 26(A), 29 and SW846 0010, 0011 and 0013.
- Familiar with on-site analytical techniques, such as gravimetric procedures (EPA 5, 202) chloride and sulfate titrations, and ammonia electrode analysis.
- Able to package and ship samples in accordance with Clean Air Engineering and IATA requirements.
- Familiar with proper Chain of Custody procedures for samples.

3.7.3.2.3 Advanced Sampling Technician

• Experienced in equipment set-up, operation, and QA/QC procedures for a specific advanced test method.

# 3.7.3.3 Advancement Criteria (T2⇒T1)

- Six months experience working as T2.
- Four projects working under supervision in specific sub-category.
- Proficiency Test

# 3.7.4 Skill Grade E3

- 3.7.4.1 General Description Job Leader able to manage people and activities of one test location. May oversee one to three technicians in the field.
- 3.7.4.2 Minimum Qualifications Same as T1 with additional requirements of:
  - Able to perform on-site data reduction (e.g., flow rates, pollutant emission calculations, RATA calculations, etc.)
  - Able to interface with the client contact regarding test schedule, general oversight, process operation, safety requirements, access issues, etc.
  - Knowledgeable of administrative duties such as completion of Field Time Sheets and Work Change Orders.

- Capable of overseeing job-related field purchases (hardware store, ice, etc.)
- 3.7.4.3 Advancement Criteria (T1⇒E3)
  - Six months experience working as T1.
  - Advanced Technical Training (Clean Air Engineering course or equivalent)
- 3.7.5 Skill Grade E2
  - 3.7.5.1 General Description This level is a management position that may involve field and/or office responsibilities:
    - 3.7.5.1.1 Field Manager: Manages large projects involving multiple test locations and/or test methods. May oversee activities of several test crews.
    - 3.7.5.1.2 Project Manager: Performs all aspects of project management as defined in Clean Air Engineering Project Manager Handbook.
  - 3.7.5.2 Minimum Qualifications This level requires an overall knowledge of Clean Air Engineering operations, with the following specific experiences based on the type of position involved:

3.7.5.2.1 Field Manager

- Experienced with managing other job leaders and coordinating activities of multiple crews.
- Able to perform all aspects of field-generated data analysis.
- Able to interact with clients, EPA or agency representatives, and other consultants.
- Familiar with sales and marketing relationships with specific clients.
- Have a general understanding of engineering and operating aspects of specific processes.

3.7.5.2.2 Project Manager

- Able to manage entire projects, from initial sales lead through reporting and invoicing.
- Knowledge of regulations and familiar with permit language and interpretation.
- Able to write reports.
- Thorough understanding of engineering and operating aspects of specific processes, including market relationships.
- Proficient at managing multiple projects simultaneously.

- 3.7.5.3 Advancement Criteria (E3⇒E2)
  - Three years of overall experience that includes at least one year of experience at an E3 level.
  - Four-year engineering degree or equivalent.
  - Clean Air Engineering Report Training
  - Formalized Personnel Management training (for Field Managers)
  - Formalized Project Management training (for Project Managers)

#### 3.7.6 Skill Grade E1

3.7.6.1 General Description – This level is used for office managers or high-level senior personnel.

### 3.7.6.2 Minimum Qualifications

- Able to manage entire business operations or large customer accounts.
- Is an active force in the industry, i.e., attends conferences, publishes papers, works for industry groups, etc.
- Actively involved in Clean Air Engineering policy-making.
- Champions process improvement and implementation of quality systems within Clean Air Engineering.

## 3.7.6.3 Additional Job Requirements for Office Managers

- Responsible for profitability of the department.
- Prepares Business Development and Management Plan ("Business Plan") for department and ensures that all operations of the business are performed consistently with this plan.
- Responsible for maintaining proper staffing requirements. Develops and maintains a department staffing plan that meets the requirements of the Business Plan.
- Ensures that staff is adequately and properly trained for their job functions.
- Oversees the development and maintenance of the quality program for office and ensures that operations are consistent with this program.
- Oversees the development and maintenance of the safety program for office and ensures that operations are consistent with this program.
- Serves as overall quality manager for office.
- Makes and enforces office policies (e.g., work-hours, dress codes, information management, communications control, etc.)
- Actively involved in career development of managed staff. This includes creating and maintaining employee development plans for entire staff.
- Oversees accounts payable and receivable functions.

- Maintains business sales and activity projections for department.
- Maintains personnel and resource allocation schedules for department.
- Active in at least one industry-related technical conference or trade show annually (session chair, presenter, company booth representative, etc.)

# 3.7.6.4 Advancement Criteria (E2⇒E1)

- At least 8 years experience in stack testing industry, including 3 years or more in a project-management or similar capacity.
- Published in a technical journal or proceedings. In lieu of this, successful completion of MBA degree or PE registration is also acceptable.
- Demonstrated ability of leadership amongst peers.

# 3.8 Records

- 3.8.1 The following personnel records shall be maintained for all technical personnel, including contracted personnel:
  - employment history, including positions held within Clean Air Engineering
  - educational and professional qualifications
  - in-house training
  - outside training or workshops
  - relevant authorizations(s)
  - competence
  - skills and experience in specific methods or processes
- 3.8.2 This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.
- 3.8.3 The Quality Administrator shall maintain these records.

# **4.0 Procurement of Services**

4.1 Purpose

The purpose of this section is to ensure that Clean Air Engineering's purchased products and services conform to specified requirements. The quality of Clean Air's purchased products and services ultimately reflects in the products and services supplied to the Customer.

4.2 Scope

This section applies to all products and services purchased to meet Customers' requirements.

- 4.3 Responsibilities
  - 4.3.1 Each managing Director is responsible for the control of purchasing and the evaluation of suppliers for their particular operating division.
  - 4.3.2 All staff requesting goods or services are responsible for ensuring that the specifications are clear and complete on the relevant purchasing documents, and for observing the correct purchasing procedures.
- 4.4 Purchasing Requirements
  - 4.4.1 The managing Director shall ensure that the established purchasing records system and procedures are maintained and complied with as directed in the <u>Purchasing Procedure</u>.
  - 4.4.2 The managing Director shall authorize all purchase orders of \$2,000 or less. Purchases exceeding \$2000 must be authorized by the Chief Financial Officer.
  - 4.4.3 Only products or services that satisfy Customer requirements and meet those set by Clean Air Engineering or the applicable standards, shall be purchased. All purchases shall be made from approved suppliers.
- 4.5 Approved Suppliers
  - 4.5.1 The Directors shall maintain a list of approved suppliers and their agents and record performance in meeting the requirements of each order against set criteria. Appropriate action shall be taken should a supplier's performance deteriorate. The approved supplier list shall be maintained together with evaluation data as directed in the <u>Supplier Evaluation Procedure</u>.
  - 4.5.2 This requirement shall not preclude the use of suppliers not already identified on the list to meet emergency situations, provided effective controls are established.

#### 4.6 Subcontractors

- 4.6.1 The Directors shall approve the engagement and selection of subcontractors from the list of approved suppliers. Subcontractors shall comply with the requirements of Clean Air's quality system.
- 4.6.2 Subcontracted laboratories must be accredited by the applicable agency if the results are being submitted to an agency that accepts data only from a certified laboratory.
- 4.6.3 Clean Air Engineering will notify a Customer in writing if and what subcontractors are used to perform a portion of the test program, including analytical work.
- 4.7 Records

Purchase orders, supplier delivery notes and other related purchasing records shall be retained for a period of 10 years as directed in the <u>Purchasing Procedure</u>.

4.8 Referenced Standard Operating Procedures

All standard operating procedures are available on the Clean Air Intranet under the Standard Procedures link. Those procedures or groups of procedures referenced in this section are:

- Supplier Evaluation Procedure
- Purchasing Procedure

# **5.0 Documentation and Records**

5.1 Purpose

The purpose of this section is to describe the documentation processes that are used to ensure that only documents and data which are correct, workable and of the correct revision are made available to staff at their workplace when needed.

5.2 Scope

This section applies to all documents and data essential to the effective functioning of the quality system.

- 5.3 Responsibilities
  - 5.3.1 The Quality Administrator is responsible for ensuring that procedural documents and templates of the correct issue are available for use.
  - 5.3.2 The Directors are responsible for authorizing all internally produced documents and their amendments.
  - 5.3.3 The Directors shall ensure that all employees have access to this Quality Manual, all Standard Operating Procedures, published standards, product manuals, and any other standards or documents required to conduct their work and meet the directives described herein.
  - 5.3.4 All staff engaged in acquiring, producing, modifying, authorizing and using listed documents are responsible for observing the correct procedures.
- 5.4 Quality System Documentation
  - 5.4.1 Scope This Quality Manual, together with the referenced Procedures, Work Instructions, Forms and Templates, specifies the requirements and provisions adopted by Clean Air Engineering for its Quality Management System.
  - 5.4.2 Issue Numbers These documents will be uniquely identified by an Issue Number that specifies the date and revision of the document.
  - 5.4.3 Review These documents shall be reviewed annually subsequent to the Management Review and whenever deemed necessary due to reports of non-conformance or changes in mandatory or guidance documentation.
  - 5.4.4 Master Copies The Quality Administrator shall retain the Master Copies of the Quality Manual and all related Procedures, Work Instructions, Forms and Templates. The Quality Administrator shall be the only person with access to make changes to the Master Copies of these documents.
  - 5.4.5 Uncontrolled Copies Unchangeable versions of these documents will be available to all staff on the Clean Air Intranet.

## 5.4.6 Revision Control

- 5.4.6.1 When amendments are required, the Quality Administrator shall make the revisions and complete a document history record form identifying the reason for the change.
- 5.4.6.2 The amendments shall take the form of a complete replacement document together with any other documents affected by the changes, e.g., Procedures, Work Instructions, etc. All revised documents shall be identified by new Issue Numbers.
- 5.4.6.3 The Quality Representative shall arrange for all uncontrolled copies that have been superseded to be recalled and replaced by the revised issues.
- 5.4.6.4 Revisions shall not be deemed necessary only to correct typographical errors unless such errors could lead to a major failure.
- 5.4.7 Externally Distributed Copies Uncontrolled copies of the Manual may be issued to existing or potential Customers and suppliers, but only when authorized by the Quality Administrator. These copies shall be clearly marked "Uncontrolled" on the front cover and will not be maintained.
- 5.5 Internally Produced Submission Documents
  - 5.5.1 Scope Internally produced submission documents are those produced in-house by Clean Air Engineering or those produced on Clean Air's behalf by external agencies over which Clean Air has direct control of the contents. Examples include reports, proposals, protocols, letters, etc.
  - 5.5.2 Issue Numbers These documents will be uniquely identified by an Issue Number in accordance with the <u>Computer Document Control Procedure</u>.
  - 5.5.3 Review These documents shall be reviewed in accordance with the applicable procedures specific to the type of document being submitted.
  - 5.5.4 Master Copy A Master Copy of the document shall be filed in accordance with the applicable procedures specific to the type of document being submitted.
  - 5.5.5 Revision Control When amendments are required, the managing Director shall oversee the revisions and completion of a document history record form identifying the reason for the change. The amendments shall take the form of a complete replacement document together with any other documents affected by the changes. All revised documents shall be identified by new Issue Numbers in accordance with the <u>Computer Document Control Procedure</u>.
  - 5.5.6 Document Retention Reports, proposals, protocols, letters, etc. will be retained for a period of not less than 20 years. All such documents company-wide will be archived at the Palatine facility.

# 5.6 Standards

- 5.6.1 The nature of Clean Air Engineering's activities relies heavily on working to various standards, codes of practice and other legislative documents.
- 5.6.2 The Directors shall ensure that a master copy of each appropriately identified reference standard is maintained at the correct issue. Superseded standards shall be retained in an archive to satisfy possible Customer inquiries or the occasions when the Customer requires testing to these standards.
- 5.6.3 The Quality Administrator shall ensure that all working copies are to the same revision.
- 5.6.4 The appropriate standards necessary to perform a job function shall be made available to all employees by ensuring that either paper or electronic copies of these documents are supplied to the work areas, including mobile facilities such as field laboratories, CEM trailers, etc.

#### 5.7 Product Manuals

- 5.7.1 The Directors shall ensure that a master copy of the product manual for each item of equipment used internally, or available to a Customer, is maintained at the correct issue. Copies of manuals relating to obsolete equipment shall be retained to satisfy maintenance demands or Customer inquiries.
- 5.7.2 The appropriate product manuals necessary to perform a job function shall be supplied to the work areas, including mobile facilities such as field laboratories, CEM trailers, etc.
- 5.8 Externally Produced Documents

Externally produced documents are those produced by external agencies over which Clean Air Engineering has no control of the contents. All working copies shall be controlled according to best office work practices.

#### 5.9 Logbooks

- 5.9.1 Laboratory logbooks, instrument logbooks and field logbooks shall consist only of bound notebooks with ruled paper and pages sequentially numbered by the manufacturer.
- 5.9.2 The managing Director will assign the logbook to an individual, area or instrument. The assignment and date shall be written into the first page of the logbook.
- 5.9.3 The managing Director will oversee control of all logbooks and ensure that completed logbooks are archived in the division's library.

# 5.10 Records

- 5.10.1 Lists of Procedures, Work Instructions, Templates, product manuals, external standards and other documents shall be maintained by the Quality Administrator.
- 5.10.2 Lists of Reports, Protocols and Proposals will be maintained in the Clean Air Engineering 4D database according to standard administrative procedures.
- 5.10.3 All project records will be maintained for a minimum of 10 years in the Palatine Archival Center. The records retained in this system includes all original observations, calculations and derived data (i.e., results), calibration records, the COC of any samples, the analytical method, the analyst performing the analysis, the date of the test, and a complete copy of any test report generated. Such records collected after January, 2004 will also be maintained in electronic image format on the Palatine Computer Server and its back-up system(s).
- 5.10.4 The managing Director will maintain a list of all logbooks and their assignments.
- 5.11 Referenced Standard Operating Procedures

All standard operating procedures are available on the Clean Air Intranet under the Standard Procedures link. Those procedures or groups of procedures referenced in this section are:

- Computer Document Control Procedure
- Administrative Handbook

# 6.0 Equipment

6.1 Purpose

The purpose of this section is to ensure that all measurements made in meeting Customers' requirements are done to the level of accuracy commensurate with the requirements using approved equipment having calibrations traceable to accepted Standards.

# 6.2 Scope

This section applies to all equipment and computer software used to demonstrate the conformance of a product or service supplied to the Customer.

# 6.3 Responsibilities

- 6.3.1 Each managing Director is responsible for ensuring that the requirements of this section are complied with and that the designated equipment is maintained and calibrated according to this program and that the appropriate records are maintained.
- 6.3.2 The Workshop Supervisor is responsible for undertaking the maintenance and calibration of the designated equipment as required in standard procedures. This includes arranging external services when required.
- 6.3.3 All staff are responsible for selecting the correct equipment for the application, using it in accordance with the relevant work instructions and ensuring that the calibration status is valid.
- 6.3.4 All staff, when using the equipment, are responsible for reporting any defects found or suspicious readings obtained.
- 6.3.5 All staff are responsible for using, handling and storing the equipment correctly and in a manner that will not impair its calibration or functionality.
- 6.3.6 The Information Systems Management team leader is responsible for tracking all computer software in use by Clean Air Engineering. They will assure that all computer software is legally licensed, and that appropriately updated versions are in use to ensure compatibility within the organization and with the needs of Customers and Suppliers.
- 6.4 Equipment Requirements
  - 6.4.1 All designated equipment shall be maintained and calibrated according to the requirements of the appropriate equipment control procedure.
  - 6.4.2 Each managing Director shall maintain the list of designated equipment, adding new items as and when required. For each device, the Quality Administrator shall

determine its purpose, position in traceability hierarchy, method and frequency of calibration, accuracy and calibration uncertainty.

- 6.4.3 Each new device shall be assigned a unique identification number to aid its identification as designated equipment and correlation with the maintenance and calibration records. A label shall be affixed to each device to indicate its calibration status (e.g., "for indication only", "calibrate before use", "do not use after date", etc.)
- 6.4.4 Each managing Director shall maintain records of the designated equipment service and calibrations and review their histories to identify trends for the purpose of improving the uncertainty, altering the calibration interval or justifying replacement.
- 6.4.5 Each managing Director shall assess the validity of previous test results should any shifts in calibrations be found. This shall include advising Customers that have rented equipment.
- 6.4.6 The Workshop Supervisor shall arrange for the service or calibrations of designated equipment, either in-house or through an external laboratory, as scheduled in the appropriate calibration procedure, test method, work instructions and/or product manuals.
- 6.4.7 Service and calibration of all equipment will follow <u>Standard Equipment</u> <u>Maintenance Procedures</u> as contained on the Clean Air Intranet.
- 6.4.8 Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials (e.g., only EPA Protocol gases shall be used for CEM calibrations).
- 6.4.9 Internal reference materials shall be checked as far as is technically and economically practicable against a certified reference material.
- 6.4.10 Designated equipment shall be calibrated and used only by trained staff in accordance with the requirements of the applicable calibration procedure, test method, work instructions and/or product manuals. Attention shall be paid to its calibration status, limitations of use, accuracy and uncertainty.
- 6.4.11 Unless authorized by the managing Director, designated equipment shall not be adjusted, modified or treated in any way that would impair its functionality or calibration.
- 6.5 Computer Software Requirements
  - 6.5.1 The Information Systems (IS) Management team will compile a list of computer software in use company-wide. Only software with appropriate licensing agreements in place will be allowed to be used.
  - 6.5.2 The IS Management team will evaluate software revision status on an annual (minimum) basis to ensure that the software is of the appropriate version to effectively satisfy the requirements of the work being performed. They will also

evaluate the compatibility of the software within the company as well as externally.

6.5.3 The IS Management team will recommend computer hardware and software upgrades when they deem it appropriate. However, decisions to upgrade hardware or software will rest within the group of Directors and Quality Administrator, and will require consideration of economic impacts, operational effects and training requirements.

# 6.6 Records

- 6.6.1 Each managing Director shall maintain a list of the designated equipment and records of the calibration program as specified in the appropriate equipment control procedure. Equipment records shall be maintained containing details of any faults, repairs, modifications or adjustments together with calibration certificates.
- 6.6.2 All records shall be retained for a period of not less than 10 years.
- 6.6.3 Each managing Director will cooperate with the Information Systems Management team to ensure that all computer software is accounted for and that appropriate licensing agreements are in place.
- 6.7 Referenced Standard Operating Procedures

All standard operating procedures are available on the Clean Air Intranet under the Standard Procedures link. Those procedures or groups of procedures referenced in this section are:

- Standard Equipment Maintenance Procedures
  - Clean Air Rentals Equipment Check-Out Procedures
  - Manual of Standard Operating Procedures Source Testing Division, Draft 2000-1, July 2000 – Equipment Calibration

# 7.0 Planning

7.1 Purpose

The purpose of this section is to ensure that appropriate and adequate planning measures are taken to ensure that the quality objectives are met for every project.

7.2 Scope

This section applies to all projects executed by Clean Air Engineering.

- 7.3 Responsibilities
  - 7.3.1 Each managing Director is responsible for ensuring that the requirements of this section are complied with and that adequate planning is conducted on every project.
  - 7.3.2 Each managing Director is responsible for preparing technical proposals that meet the requirements of the Customer, USEPA and applicable agencies while citing appropriate test methods and analytical procedures. They must also ensure that the quotations provide adequate resources of manpower, equipment and time to allow the accomplishment of the proposed project without compromise of safety or quality.
  - 7.3.3 Project Managers are responsible for overseeing and, to a large extent conducting the primary planning elements during project execution, including preparation of Test Protocols, project Job Plans, etc.
  - 7.3.4 All affected staff are expected to follow the requirements set forth in project Job Plans, Quality Assurance Project Plans, and any other planning documents.
- 7.4 Proposal Requirements
  - 7.4.1 Adequate project planning must be accomplished during the proposal stage prior to award of the project to ensure that technical and quality objectives can be met within the budgetary constraints of the work. Managing Directors, along with sales staff and Project Managers, will see that the following items, at a minimum, are defined during the proposal stage:
    - detailed scope of work
    - applicable regulations
    - permit and/or guarantee limits
    - list of pollutants and/or parameters to be measured
    - description of test locations (e.g., accessibility, size, orientation, etc.)
    - number, size and orientation of test ports
    - gas stream conditions at test points (e.g., temperature, pressure, dust loading, etc.)

- process operation characteristics expected during testing •
- detailed schedule of activities •
- sampling and analytical methodology •
- number and types of personnel required •
- major equipment resources required
- major consumable items required •
- identification of any unusual safety issues •
- 7.4.2 Proposals will be prepared in accordance with the Opportunity Assessment, Proposal Preparation and Cost Estimation procedures contained in the Sales Handbook.
- 7.4.3 Proposals must be reviewed and approved by the managing Director prior to submittal to the potential Customer.
- 7.5 Project Management
  - 7.5.1 After project award, the managing Director will assign a Project Manager to oversee the planning and execution of the project.
  - 7.5.2 The Project Manager shall prepare a Project Job Plan in line with the specifications outlined in the Test Planning Procedure contained in the Project Manager Handbook. The Job Plan will contain the following information:
    - objectives and summary of test program
    - description of the source and process to be tested •
    - description of the test matrix •
    - sampling locations •
    - test methods to be used •
    - process data to be collected •
    - specific QA procedures and audits •
    - required laboratory analysis ٠
    - subcontractor laboratories •
    - reporting format and other requirements •
    - plant entry and safety requirements •
    - responsibilities of test personnel •
    - detailed test schedule •
    - directions to job-site •
    - travel and living arrangements .
  - 7.5.3 In some cases, a more detailed Test Protocol or Quality Assurance Project Plan (QAPP) may be required, depending upon agency or Customer requirements. In such cases, the Project Manager will prepare the documents in accordance with applicable USEPA or agency requirements, e.g., "Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans" (QAMS-005/80),

or "Preparation and Review of Site-Specific Emission Test Plans" (USEPA GD-042).

- 7.5.4 If the preparation of documents as listed in Section 7.5.3 is required, such documents must be approved by the managing Director prior to submittal to the Customer or agency.
- 7.5.5 The Project Manager shall consider the need to visit a site to establish direct contact with the Customer and to discuss the preliminary Job Plan requirements.
- 7.5.6 A copy (electronic or paper) of the Job Plan will be provided to each member of the field test team prior to their participation in the project.
- 7.5.7 Prior to field execution, the Project Manager will meet with the Field Test Leader to discuss the project. They will review the proposal, Job Plan, Test Protocol (if applicable), and QAPP (if applicable).
- 7.5.8 The contents of the Job Plan shall be communicated by the Field Test Leader to all personnel participating in the test project prior to the start of the project.
- 7.5.9 Deviation from the Job Plan shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client and any regulatory agency (if appropriate).
- 7.6 Test Method Selection
  - 7.6.1 Clean Air Engineering shall use test methods which meet the needs of the Customer and which are appropriate for the tests it undertakes. Methods published in national (e.g., USEPA), international (e.g., ISO) or regional standards shall preferably be used.
  - 7.6.2 Clean Air Engineering shall use the latest valid edition of a standard unless it is not appropriated or possible to do so. The standard shall be supplemented with additional details to ensure consistent application, as defined in the <u>Source</u> <u>Testing Standard Operating Procedures</u> and the <u>Manual of Method Clarifications</u>.
  - 7.6.3 When it is necessary to use methods not covered by standard methods, these shall be performed only after the Customer has agreed to this approach. The agreement will include a clear specification of the Customer's requirements and the purpose of the test program.
  - 7.6.4 When it is necessary to perform test methods that Clean Air Engineering has not performed previously, but which are established, published, or validated test methods, the Project Manager must take appropriate actions to ensure that the applicable requirements of this practice are properly addressed before and during the performance of the new method.

# 7.7 Records

7.7.1 All paper records will be kept in the Project File in accordance with the <u>Project</u> <u>File Procedure</u> contained in the <u>Administrative Handbook</u>. 7.7.2 All electronic files will be kept on the Palatine File Server in accordance with the <u>Computer Document Control Procedure</u>.

# 7.8 Referenced Standard Operating Procedures

All standard operating procedures are available on the Clean Air Intranet under the Standard Procedures link. Those procedures or groups of procedures referenced in this section are:

- Sales Handbook
  - Opportunity Assessment
  - Proposal Preparation
  - Cost Estimation
- Project Manager Handbook, Revision 3, November 1995
  - Test Planning Procedure
- USEPA
  - "Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans" (QAMS-005/80)
  - "Preparation and Review of Site-Specific Emission Test Plans" (USEPA GD-042)
- Manual of Standard Operating Procedures Source Testing Division, Draft 2000-1, July 2000
- Manual of Method Clarifications
- Administrative Handbook, October 2001
  - Computer Document Control Procedure
    - Project File Procedure

# 8.0 Implementation of Work Processes

## 8.1 Purpose

The purpose of this section is to describe each of the major processes implemented within the organization and how these processes are designed to meet the overall quality objectives.

# 8.2 Scope

This section applies to all projects executed by Clean Air Engineering.

#### 8.3 Responsibilities

- 8.3.1 The Quality Administrator is responsible for ensuring that the operational processes of the company are consistent with the requirements of this manual.
- 8.3.2 Each managing Director is responsible for ensuring that the requirements of this section are complied with and that standard operating procedures are followed at all times during project execution.
- 8.3.3 All affected staff are expected to follow standard operating procedures.

## 8.4 Communication

- 8.4.1 Operating Procedures Review and Update Standard operating procedures will be reviewed periodically for accuracy, completeness and relevancy. These reviews will be overseen by the Quality Administrator with the help of the appropriate technical support staff. If appropriate, the procedures will be updated, revised, eliminated or replaced as necessary to be consistent with the current standard practices while satisfying the objectives of the operations. All procedures will undergo this review and update process at least biannually, or more often if evidence suggests that a more frequent schedule is necessary.
- 8.4.2 Standard Operating Procedure Accessibility The most current revisions of all Standard Operating Procedures will be accessible on the Clean Air Engineering Intranet site, which can be accessed worldwide through the internet. All employees will be issued a username and password for this purpose. The Quality Administrator will oversee the organization and posting on this site.
- 8.4.3 Job Plans The Project Manager will post Job Plans on the Palatine File Server under the corresponding project folder in the <u>Project Work Folders</u> directory. This site can be accessed worldwide through the internet using the employee's username and password. Paper copies of the Job Plan will also be provided to each member of the field team.
- 8.4.4 Staff Meetings Each operating division will hold regularly schedule staff briefing meetings on a weekly (minimum) basis. The agenda of these meetings

may vary, but must include time allotted to discuss quality issues observed both at the office and in the field. The managing Director will oversee these meetings.

- 8.4.5 All-Company Meetings An all-company meeting will be held at the Palatine office on a semi-annual basis, or more frequently if circumstances require. Outer offices will attend via teleconference. The meeting will include time allocated to present any major changes to operational procedures. The company president will preside over this meeting.
- 8.4.6 Technical Update Bulletin Major technical issues that require wide-spread dissemination will be addressed in the Technical Update Bulletin (TUB) on an asneeded basis. The Quality Administrator will oversee this process. Copies of the TUB are archived on the Palatine File Server under the <u>Corporate Archives</u> directory.
- 8.4.7 Field Communications All field test leaders will be assigned cell telephones and personal computers with email capability. During a field project, the Field Test Leader will report to the office either by phone or email on a daily basis.
- 8.5 Field Measurements
  - 8.5.1 Customer Interaction The Field Test Leader will serve as the single contact with the Customer representative while on-site.
  - 8.5.2 Field Accommodations Field work normally involves working in industrial environments that are less than ideal. The following approaches will be taken on all projects to ensure that environmental conditions do not invalidate the results or adversely affect the required quality of any measurement:
    - 8.5.2.1 The Field Test Leader shall document any environmental conditions that can affect the results of tests and calibrations.
    - 8.5.2.2 The Field Test Leader shall inform the Customer or regulatory authority of the possible effects of environmental conditions on data quality. If the conditions pose a safety threat to personnel performing the test, the Field Test Leader shall abort the test.
    - 8.5.2.3 Whenever possible, environmentally controlled shelters shall be used for sample apparatus preparation and sample recovery operations. To the extent practical, there shall be effective separation between neighboring areas in which there are incompatible activities.
    - 8.5.2.4 Sample recovery areas will be clean and protected from any environmental conditions (e.g., wind, fugitive emissions) that could possibly contaminate or cause loss of the sample.
    - 8.5.2.5 Continuous analyzers shall only be used inside well-lit, properly ventilated environmentally controlled shelters in which the air temperature can be maintained to 75°F±10°F.

- 8.5.2.6 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled by means of doors and signage. The Field Test Leader shall see that this control is enforced and maintained.
- 8.5.2.7 The Field Test Leader shall ensure that good housekeeping procedures are followed in all areas that testing or analysis activities are conducted.

# 8.5.3 Data Collection and Recording

- 8.5.3.1 Handwritten data will be recorded on standardized data sheets in accordance with <u>Source Testing Standard Operating Procedures</u>.
- 8.5.3.2 Electronically generated instrument data will be recorded using a standard data acquisition system in accordance with <u>Source Testing Standard</u> <u>Operating Procedures</u>.
- 8.5.3.3 When mistakes occur in written records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.
- 8.5.3.4 The technician recording the data will check the datasheet or computer file in the field for completeness and accuracy. Initialing the sheet (or printout) in the bottom right-hand corner will indicate that this check was done.
- 8.5.3.5 The Field Test Leader will evaluate data quality in the field by verifying that certain quality control limits are being met on a run-by-run basis. These items include percent isokinetics, minimum sample volume, temperature set-points, calibration error and bias, instrument response time, leak-checks, and volume meter calibrations.
- 8.5.3.6 The decision to invalidate any test run that fails to meet the field QC criteria will be made by discussions between the Field Test Leader, Project Manager, Customer and agency representative.
- 8.5.3.7 The Test Leader will photocopy all written datasheets prior to return to the office. The copies will be kept separately from the originals. Similarly, the Test Leader will store a copy of all electronic files onto CD-ROM or magnetic disc prior to leaving the job-site.
- 8.5.4 Equipment Handling and Use
  - 8.5.4.1 The managing Directors will ensure that all technicians will be trained on the use and operation of all relevant equipment, and on the handling 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 calibration.

- 8.5.4.2 The managing Directors will ensure that all instruction, standards, manuals and reference data relevant to the work shall be kept up to date and shall be made readily available to all applicable personnel.
- 8.5.4.3 Only equipment that has been properly calibrated and maintained will be used to collect test data. Workshop Managers shall tag all equipment that is sent on a project to indicate that the equipment has been checked out and calibrated in accordance with standard procedures.
- 8.5.4.4 Technicians shall place appropriate "Service-Required" tags on any equipment that is found to be defective or out of calibration in the field.
- 8.5.4.5 Workshop Managers shall provide for the safe handling, transport and storage of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.
- 8.5.4.6 Workshop Managers will ensure that hard-copy records of the most recent calibration or certification will be packed with every field project.
- 8.5.5 Waste Disposal Field Test Leaders shall ensure that all wastes generated on-site shall be disposed of in accordance with <u>Source Testing Standard Operating</u> <u>Procedures</u> and any Customer-specific industrial hygiene requirements.
- 8.6 Sample Handling
  - 8.6.1 All Clean Air Engineering personnel shall follow <u>Source Testing Standard</u> <u>Operating Procedures</u> for the transportation, receipt, handling, protection, storage, retention and disposal of samples, sampling media and calibration materials.
  - 8.6.2 Storage Containers The managing Director shall ensure that only new containers are used for sample storage. Choice of container will follow the specifications provided in the <u>Source Testing Standard Operating Procedures</u>. Glass storage containers will be pre-cleaned and QC-certified by the manufacturer.
  - 8.6.3 Sample Numbering All samples shall be uniquely identified with a standard Clean Air Engineering sample label. This label will be produced and provided by the Project Manager using the <u>Samplelabel.xls</u> workbook, available on the Palatine File Server. The label will include the following information:
    - Job Number
    - Customer Name
    - Project Site
    - Test Method
    - Source Name
    - Run Number
    - Date
    - Recovery Technician initials

- 8.6.4 Chain of Custody The Field Test Leader shall ensure that all samples are recorded on the Clean Air Engineering Chain of Custody form in accordance with <u>Source Testing Standard Operating Procedures</u>. Samples will be stored in a secure, locked area while on-site, and a copy of the Chain of Custody must be with the samples at all times.
- 8.6.5 Preservation All samples must be stored in such a way as to prevent deterioration, loss or damage to the sample. The Field Test Leader must ensure that these conditions shall be maintained, monitored and recorded while on-site.
- 8.6.6 Shipping The Field Test Leader shall ensure that all samples are properly packaged and shipped in accordance with <u>Source Testing Standard Operating</u> <u>Procedures</u>. These procedures provide conformance with FAA, DOT and IATA shipping regulations, and prevent deterioration, loss or damage to the sample.
- 8.7 Field Quality Assurance
  - 8.7.1 General All personnel will follow the procedures listed in the <u>Source Testing</u> <u>Quality Assurance and Quality Control Procedures</u>, the USEPA <u>Quality</u> <u>Assurance Handbook for Air Pollution Measurement Systems: Volume III,</u> <u>Stationary Source-Specific Methods (EPA/600/R-94/038c)</u> and in Clean Air Engineering's <u>Manual of Method Clarifications</u>.
  - 8.7.2 Field Blanks and Spikes The Project Manager shall designate in the Job Plan the appropriate field and trip blanks and spiked samples to be collected. This procedure will be in accordance with the specifications of the test method, protocol and/or Customer or agency requirements being followed.
  - 8.7.3 Calibrations
    - 8.7.3.1 The Field Test Leader shall ensure that all necessary on-site calibrations are performed in accordance with the <u>Source Testing Quality Assurance</u> <u>and Quality Control Procedures</u>, the <u>USEPA Quality Assurance Handbook</u> <u>for Air Pollution Measurement Systems: Volume III, Stationary Source-</u> <u>Specific Methods (EPA/600/R-94/038c)</u> and in Clean Air Engineering's <u>Manual of Method Clarifications</u>.
    - 8.7.3.2 The decision to invalidate any test run that fails to meet the field QC criteria will be made by discussions between the Field Test Leader, Project Manager, Customer and agency representative.
- 8.8 Laboratory Interaction
  - 8.8.1 Sample Receipt All laboratories, both internal and subcontracted, shall submit a sample receipt form to the Project Manager that indicates the identification, condition and date of samples received at the laboratory.

- 8.8.2 Tracking The Project Manager will interface with the laboratory contact to coordinate the sample analysis and ensure that all analytical, quality and schedule objectives are being met.
- 8.8.3 Data Package
  - 8.8.3.1 All laboratories, both internal and subcontracted, shall submit a full data package electronically.
  - 8.8.3.2 The data package must be authenticated and signed by a managing representative of the laboratory.
  - 8.8.3.3 The results shall be in Microsoft Excel workbook format and arranged in such a way that it can be readily integrated into standard Clean Air Engineering data processing workbooks.
  - 8.8.3.4 The data package will also include all applicable QA/QC data, supporting instrument data (e.g., chromatograms, strip charts, etc), sample calculations, chain of custody and hold-time information, and all other intermediary information necessary to calculate the reported results from the raw instrument data. This information must be in Adobe Acrobat or equivalent standard viewing software.

# 8.9 Reporting

- 8.9.1 Preparation Each Emission Test Report shall be prepared in accordance with the <u>Clean Air Engineering Report Manual</u>. The Project Manager shall oversee the preparation of the report.
- 8.9.2 Content Each Emission Test Report will contain the following information:
  - Certification of Accuracy and Completeness
  - Project Overview
  - Key Project Participants
  - Dates and times of all tests
  - Summary of Results
  - Detailed Presentation of Results
  - Facility or Process Description
  - Source Description
  - Description of Test Methods
  - Sample Calculations
  - Detailed Sampling, Analytical and Emissions Parameters
  - Calibrations and Certifications
  - Quality Control Summary
  - Processed Field Data
  - Raw Field Data
  - Laboratory Reports
  - Process Data

- 8.9.3 Software Reports will be prepared using Microsoft Word, Microsoft Excel, Deneba Canvas, and Adobe Acrobat. The Quality Administrator shall ensure that appropriate versions of each software package are available and used in report preparation.
- 8.9.4 Templates All reports will be prepared using standard and Director-approved templates, available on the Palatine File Server under the <u>Standard Files</u> directory. The Quality Administrator will ensure that the most recent versions of all report templates are posted.

# 8.9.5 Review and Certification

- 8.9.5.1 A managing Director, technical leader, or equivalent senior company representative will review and certify as accurate and complete each test report.
- 8.9.5.2 The person certifying the report must have the following qualifications:
  - possess training, experience and satisfactory knowledge of the testing carried out;
  - understand the process being tested;
  - possess knowledge of the general requirements expressed in the applicable legislation or general standards;
  - understand the significance of the deviations found with regard to the normal use of the items, materials, products, etc. concerned.
- 8.9.5.3 The Project Manager or Field Test Leader will also sign off on the certification.
- 8.9.5.4 In some cases, a Professional Engineer may be required to certify the report, depending on Customer or agency requirements.
- 8.9.5.5 Human Resources will maintain a list of signatures and initials of all personnel with authority to approve data or reports.
- 8.9.6 Draft Reports In some circumstances, for the purposes of review, a Draft report may be issued without certification. In these cases, every page of the report must be stamped with a "DRAFT" watermark.
- 8.9.7 Revisions A revision to a report is required if any information contained in the original document requires modification or correction, excluding non-consequential typographical or grammatical changes. A revision shall consist of a complete copy of the report document, be uniquely identified and shall contain a reference to the original that it replaces.
- 8.9.8 Amendments An amendment to a report consists of information that was not included in the original document. The amendment will include a Title Page and shall include the statement: "Amendment to Test Report, Job Number ... [or as otherwise identified]", or an equivalent form of wording.

## 8.10 Method Validation

- 8.10.1 Whenever possible, testing will be performed using agency-approved methodologies, such as USEPA reference methods.
- 8.10.2 These methodologies shall be available either electronically or in hard-copy format to the staff performing the tests in the field.
- 8.10.3 Any variance from agency-approved methodology is acceptable only with prior written confirmation by the agency and client.
- 8.10.4 When an approved method or an appropriate modification is not available, a method validation package must be prepared. This package must include, at a minimum, the following items:
  - origin of method;
  - deviations from standard, if applicable;
  - reason for deviations;
  - effects of deviations; and
  - when applicable, comparison with the agency-approved methods replaced, with documentation indicating results achieved from the modified method are equal to or better than the original method.
- 8.11 Referenced Standard Operating Procedures

All standard operating procedures are available on the Clean Air Intranet under the Standard Procedures link. Those procedures or groups of procedures referenced in this section are:

- Manual of Standard Operating Procedures Source Testing Division, Draft 2000-1, July 2000
- Source Testing Quality Assurance and Quality Control Procedures, Revision 3, January 2000
- USEPA Quality Assurance Handbook for Air Pollution Measurement Systems: Volume III, Stationary Source-Specific Methods (EPA/600/R-94/038c)
- Manual of Method Clarifications.
- Report Manual, Revision 5.1, April 2001

# 9.0 Assessment and Response

9.1 Purpose

The purpose of this section is to provide processes to assess ongoing quality efforts and to identify and document non-conforming work.

9.2 Scope

This section covers how and by whom assessments of programs are planned, conducted, and evaluated.

- 9.3 Responsibilities
  - 9.3.1 The Quality Administrator is responsible for the following tasks relative to this section:
    - Coordinating response to and maintaining records of all customer complaints, non-conformances and their status.
    - Maintaining records and analyzing trends of quality problems reported via non-conformances.
    - Producing a comprehensive Internal Audit program.
    - Selecting auditors to perform Internal Audits.
    - Maintaining copies of all Internal Audit reports.
    - Completing the Internal Audit program to schedule.
  - 9.3.2 The managing Directors are responsible for the following tasks relative to this section:
    - Reviewing all non-conformance reports.
    - Reviewing the results of Internal Audits.
  - 9.3.3 Appointed Internal Auditors are responsible for the following activities:
    - Preparing Internal Audit checklists.
    - Performing Internal Audits to the agreed program.
    - Preparing Internal Audit reports.
    - Confirming completion (closing out) of non-compliances.
  - 9.3.4 All staff are responsible for the following tasks relative to this section:
    - Recording and reporting non-conformances or deviations from the proposed or documented operations of the Company.
    - Cooperating with Internal Auditors.

#### 9.4 Non-Conformances

- 9.4.1 Identification of non-conforming work originates with performance feedback from various sources including the Customer, regulatory authorities, and internal audits and reviews. Feedback can come in many forms observations, telephone conversations, emails, faxes, letters or any other forms of communications.
- 9.4.2 In any instance, as soon as a non-conformance is suspected, the employee shall notify their managing Director.
- 9.4.3 For Proficiency Test (PT) sample audits in which a non-conformance is detected, corrective action must be performed for every failed analyte in the PT study and a copy of the action must be sent to the applicable Accrediting Authority.
- 9.4.4 Formal Customer complaints shall be dealt with quickly and courteously in a written reply from the managing Director.
- 9.4.5 The managing Director shall establish a paper documentation file. The timeline of events should be established, and the file organized chronologically as well as possible.
- 9.4.6 Using the information available, the managing Director shall make an evaluation of the significance of the non-conforming work.
- 9.4.7 Depending on the significance of the non-conformance, the Director may:
  - Temporarily halt the work progress until corrective action can be taken.
  - Withhold test reports or data, as necessary, until the work is corrected.
  - Where necessary, notify the Customer and halt or re-do the work.
  - Notify the Quality Administrator.
- 9.4.8 The managing Director must ensure that corrective actions are taken within an appropriate time period, together with any decision about the acceptability of the nonconforming work.
- 9.4.9 If the identification of non-conformances or departures casts doubts on Clean Air Engineering's compliance with its own policies and procedures, or on its compliance with this practice, the Quality Administrator shall ensure that the appropriate areas of activity are audited in accordance with Section 9.5 of this practice as soon as possible.
- 9.4.10 Where the evaluation indicates that the non-conforming work could recur or that there is doubt about the compliance of the division's operations with its own policies and procedures, the corrective action procedures given in Section 10.4 shall be followed.
- 9.4.11 In cases that there is reason to believe that the implications are severe enough to threaten the image of the company or affected parties, then the procedures contained in the <u>Standard Operating Procedure For Handling Negative Feedback</u>, shall be followed.

- 9.5 Internal Quality Audits
  - 9.5.1 Internal Quality Audits serve three main purposes:
    - To verify whether the Quality activities comply with the objectives as specified in this Manual and the associated Procedures and Work Instructions.
    - To provide knowledge, evidence and motivation for effecting improvement.
    - To provide evidence for examination by a third party assessor or a Customer where quality assurance surveillance is required.
  - 9.5.2 The Quality Administrator shall schedule a systematic review of the Quality Management System's effectiveness such that a full program is completed every year. The program shall be sufficiently flexible for it to respond to:
    - Changes in the time elapsed since the last audit.
    - Any problems that might have arisen within the workings of a Division.
    - Recent or impending changes to the Procedures.
    - New products or services offered.
  - 9.5.3 The Quality Administrator shall select an Auditor who is independent of the Division to be audited.
  - 9.5.4 The Auditor shall prepare a check list and assessment form prior to the audit.
  - 9.5.5 The date of the audit shall be mutually agreed with the managing Director responsible for the division being audited and the general areas of examination made known.
  - 9.5.6 At the time of the audit, the Auditor shall complete an audit report and include all findings discovered to which the Auditee shall sign as being a true record.
  - 9.5.7 The Auditee shall prepare a corrective action program to rectify all noncompliances found, proposing dates for implementation of each corrective action.
  - 9.5.8 The Auditor shall verify that the corrective actions have been implemented by the proposed dates, closing out the actions on the audit report accordingly.
  - 9.5.9 The results of internal audits, and their timely completion, shall be reviewed by the Directors as part of their quarterly and annual review meetings.
- 9.6 Records
  - 9.6.1 All non-conformance reports, Customer complaints and suggestions for improvement shall be retained for a period of 10 years.
  - 9.6.2 The Quality Administrator shall retain the audit reports, transferring them from "Outstanding" to "Completed" as appropriate.
  - 9.6.3 The Quality Administrator shall update and maintain the master copy of the Internal Audit program schedule as audits are completed.

9.7 Referenced Standard Operating Procedures

All standard operating procedures are available on the Clean Air Intranet under the Standard Procedures link. Those procedures or groups of procedures referenced in this section are:

• Standard Operating Procedure For Handling Negative Feedback, Revision 2, September, 2001

# 10.0 Quality Improvement

10.1 Purpose

The purpose of this section is to provide processes to correct quality problems and to ensure that all actual or potential quality problems are dealt with quickly and effectively.

# 10.2 Scope

This section addresses systematic problems related to potential flaws in the quality system. These processes are not intended to address common causes attributable to random variation in any system.

# 10.3 Responsibilities

- 10.3.1 The Quality Administrator is responsible for maintaining records of corrective actions and quality improvement suggestions.
- 10.3.2 The managing Directors are responsible for analyzing the causes of poor quality, recording their findings, recommending appropriate corrective actions, authorizing their implementation and monitoring their effectiveness.
- 10.3.3 All staff are responsible for suggesting quality improvements and following any corrective actions that are implemented.

# 10.4 Corrective Action

- 10.4.1 The managing Director involved in a non-conformance that requires corrective action shall oversee an investigation to determine the root cause(s) of the problem.
- 10.4.2 Where corrective action is needed, the managing Director shall identify potential corrective actions. Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.
- 10.4.3 The managing Director shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Proposals for suitable corrective action shall involve discussion between the Quality Administrator, the managing Director and, if necessary, additional members of senior management.
- 10.4.4 The managing Director shall document and implement any required changes resulting from corrective action investigations.
- 10.4.5 The managing Director shall monitor the results to ensure that the corrective actions taken have been effective.
- 10.4.6 If the corrective action affects procedures that cross divisional lines, then the Quality Administrator will oversee the larger-scale implementation of the changes.

- 10.5 Preventative Action Analysis
  - 10.5.1 Preventative Analysis is intended to analyze actual or potential quality problems and trends in order to discover their root cause so that action may be taken to prevent recurrence.
  - 10.5.2 The Quality Administrator shall collate and analyze information received from the following sources:
    - Internal audits
    - Customer complaints
    - Non-conformance reports
    - Quality improvement suggestions
  - 10.5.3 At six monthly intervals, the Quality Administrator shall prepare a summary of the information gathered in a Corrective Action Analysis report for discussion with the Directors.
  - 10.5.4 The Directors, in conjunction with the Quality Administrator, shall examine the report to identify any trends, root causes of poor quality and effectiveness of any corrective actions. Consideration will be given to the following:
    - Effectiveness of previous corrective actions.
    - Whether problems can be traced to deficiencies in communication, documentation, training, motivation, materials, tools or equipment.
    - Whether any particular product or service is causing excessive quality problems.
    - Improvement or deterioration in the overall quality system.
  - 10.5.5 Following the review, the Directors shall authorize implementation of any desirable preventative actions at the earliest opportunity. Where this would involve changes to Standard Operating Procedures or Work Instructions, then these shall be made and authorized accordingly.

# 10.6 Records

10.6.1 The Corrective Action Analysis report, together with the findings and recommendations of the review meetings, shall be retained by the Quality Representative for a period of 10 years.

# **END OF DOCUMENT**