

US EPA ARCHIVE DOCUMENT

APPROVAL FORM

Date Submitted: 12/21/98 QTRAK No.: _____

Revision No.: 0 Project Category: Category II

Title: ENVIRONMENTAL TECHNOLOGY VERIFICATION COATINGS
AND COATING EQUIPMENT PROGRAM (ETV CCEP)
QUALITY MANAGEMENT PLAN

Project/Task Officer: Michael Kosusko (MD-61)

EPA/Address/Phone No.: Emissions Characterization and Prevention Branch
National Risk Management Research Laboratory
Air Pollution Prevention and Control Division
Research Triangle Park, NC 27711/919-541-2734

Interagency Agreement No.: DAAE30-98-
C-1050 Task No.: 100/208 Duration _____

Primary Author:

Lynn A. Summerson Lynn A. Summerson 12/21/98
Technical Staff (Laboratory Scientist), CTC Signature Date

APPROVALS

Brian D. Schweitzer Brian D. Schweitzer 12/21/98
CTC Project/Task Manager Signature Date

Jacob E. Molchany Jacob E. Molchany 12/21/98
CTC QA Officer Signature Date

Michael Kosusko Michael Kosusko 12/22/98
NRMRL/APPCD Project/Task Officer Signature Date

Shirley Wasson Shirley Wasson 12/22/98
NRMRL/APPCD QA Officer Signature Date

CTC - Concurrent Technologies Corporation
NRMRL - National Risk Management Research Laboratory
APPCD - Air Pollution Prevention and Control Division

Environmental Technology Verification Coatings and Coating Equipment Program (ETV CCEP)

Quality Management Plan

December 21, 1998

Contract No. DAAE30-98-C-1050
Task No. 100/208

*Prepared by
National Defense Center for Environmental Excellence (NDCEE)*

Operated by Concurrent Technologies Corporation

**ETV CCEP QMP
APPROVAL PAGE**

Primary Author:

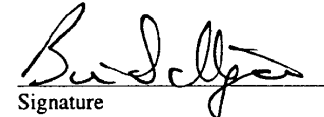
Lynn A. Summerson
Technical Staff (Laboratory Scientist), CTC


Signature

12/21/98
Date

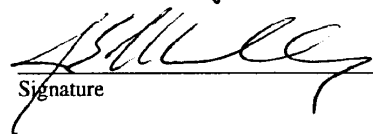
CTC Approval:

Brian D. Schweitzer
CTC Project/Task Manager


Signature

12/21/98
Date

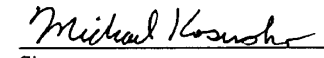
Jacob E. Molchany
CTC QA Officer


Signature

12/21/98
Date

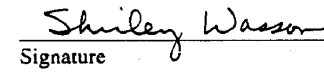
EPA Approval:

Michael Kosusko
NRMRL/APPCD Project/Task Officer


Signature

12/22/98
Date

Shirley Wasson
NRMRL/APPCD QA Officer


Signature

12/22/98
Date

TABLE OF CONTENTS

	Page
1.0 INTRODUCTION.....	1
1.1 Purpose and Content.....	1
1.2 Scope and Applicability	2
1.3 Document Organization	2
1.4 Review and Update	3
2.0 MANAGEMENT SYSTEMS	4
2.1 Management and Organization.....	4
2.2 Quality Systems and Description	7
2.3 Personnel Qualifications and Training	9
2.4 Procurement.....	9
2.5 Documents and Records.....	11
2.5.1 Task Plan, Generic Protocols and TQAPPs	11
2.5.2 Document Control and Distribution.....	12
2.5.3 Laboratory Data and Reports.....	12
2.5.4 Verification Reports and Verification Statements.....	13
2.5.5 Evidentiary Records	13
2.6 Computer Hardware and Software	13
2.6.1 Corporate Computing.....	14
2.6.2 Process Control	14
2.6.3 Data Collection.....	15
2.7 Planning.....	15
2.8 Implement Work Procedures.....	17
2.9 Assessment and Response.....	18
2.9.1 Management Assessments.....	18
2.9.2 Technical Assessments.....	20
2.9.3 Data Quality Assessments	20
2.10 Quality Improvement.....	20
3.0 COLLECTION AND EVALUATION OF ENVIRONMENTAL DATA	22
3.1 Planning and Scope	22
3.1.1 Generic Protocol and TQAPPs.....	23
3.1.2 Waste Disposal and Regulatory Requirements	24
3.2 Design of Data Collection	24
3.2.1 Intended Use of the Data	25
3.2.2 Data Quality Indicators.....	25

TABLE OF CONTENTS (continued)

	Page
3.2.3 Performance Characteristics	25
3.2.4 Specifications	26
3.2.5 Factory Equipment	26
3.2.6 Laboratory Equipment	27
3.2.7 Sample Handling Procedures	28
3.2.8 Laboratory Data Handling, Validation, and Reporting	29
3.2.9 Data Reporting and Archival	31
3.3 Implementation	32
3.3.1 Control of Test Plans, TQAPPs, and Methods	32
3.3.2 Work Procedures and Work Instructions	33
3.3.3 Verification of Equipment Operation Prior to Testing	33
3.3.4 Procedures for Data Validation	33
3.4 Assessment and Response Implementation	34
3.4.1 Maintenance and Calibration Frequency	34
3.4.2 Analysis of Known Samples/Standards	35
3.4.3 Internal and External Audits	35
3.4.4 Assessment of Data Usability	36
3.5 Reporting	37

FIGURE

Figure 1 ETV Project Management and Its Relationship to Other Organizations	5
Figure 2 Data Review Flow Chart	30

APPENDICES

A Quality Planning Checklist	
1 Approval Form	
2 ISO 9001 v ANSI/E4 Crosswalk	
3 Environmental Technology Verification (ETV) QA/QC Data Forms	

1.0 INTRODUCTION

The Environmental Technology Verification Coatings and Coating Equipment Program (ETV CCEP) is a joint venture between *Concurrent Technologies Corporation (CTC)* and the US Environmental Protection Agency (EPA). EPA's role in this joint venture is to manage the verification process by providing guidance and oversight to the partner organizations and providing meaningful data to technology users through the use of approved protocols and reviewed and audited data. *CTC's* role in this project is to operate a center to identify and test technologies that claim to be effective in preventing or controlling pollution. The ETV CCEP was established as part of the Environmental Technology Verification Program (ETV) administered by the EPA to solicit and test products from vendors of these pollution prevention technologies. *CTC* will provide unbiased test data for these technologies, using approved test and quality assurance protocols, to technology providers and developers, end users, and regulators.

The goal of this Quality Management Plan is to document quality procedures followed within the ETV CCEP for meeting *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, ANSI/ASQC E4-1994 and the ETV Quality and Management Plan (ETV QMP). The ANSI/ASQC E4 standard and ETV QMP have been established as the guidelines for the ETV CCEP. This *CTC* Quality Management Plan details the system of management and team infrastructure to ensure that data resulting from the execution of this project are 1) valid and defensible and 2) meet project quality and environmental quality objectives.

CTC's Quality Assurance and Quality Control (QA/QC) program is accepted and supported across all levels of the organization.

- The quality system is maintained to ensure that established quality guidelines are followed
- Verifications are performed according to approved test plans and protocols
- Appropriate assessments, reviews and audits are conducted to provide sufficient data to support verification statements.

Each individual involved in verification testing activities is committed to meeting the quality objectives.

1.1 Purpose and Content

The ETV CCEP is a unique organization which requires a detailed system of quality management to fulfill the verification and data collection mission. The purpose of this document is to serve as an overall guide to the quality system and the management organization areas that have key roles in the oversight of the ETV CCEP. The Quality Management Plan contains information concerning the planning, implementation, and assessment of the quality system.

- Personnel directly involved with the execution of verifications have the responsibility and authority for quality control and quality assurance activities.
- The Project Manager is responsible for oversight of the ETV CCEP
- The Project Manager and Quality Assurance Officer (QA Officer) are independent entities, both reporting directly to the Program Manager for the National Defense Center for Environmental Excellence (NDCEE).

1.2 Scope and Applicability

Management and data collection activities of the ETV CCEP are for performance assessment of environmental technologies used for pollution prevention. A primary goal of the ETV CCEP will be to assess the environmental emissions of these technologies that are expected to provide pollution prevention. The Quality Assurance and Quality Control functions are a vital part of the ETV CCEP operations and are applicable to all levels of the project. All levels of project personnel are individually responsible for QA and QC functions. A QA Officer, independent of the Project Manager for the ETV CCEP, is responsible for managing and addressing Quality Assurance activities. Review of verification data and reports occurs across multiple levels of management.

1.3 Document Organization

The Quality Management Plan is organized according to the quality requirements found in *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, ANSI/ASQC E4-1994. The sections of this standard that apply to the ETV CCEP are Management Systems and Collection and Evaluation of Environmental Data. The specific requirements are:

- Management Systems
 - Management and Organization
 - Quality System Description
 - Qualifications of Personnel and Training
 - Procurement
 - Documents and Records
 - Computer Hardware and Software
 - Planning
 - Implementation Work Procedures
 - Assessment and Response

- Quality Improvement
- Collection and Evaluation of Environmental Data
 - Planning and Scoping
 - Design of Data Collection Operations
 - Implementation of Planned Operations
 - Assessment and Response
 - Assessment of Data Usability

1.4 Review and Update

This document is reviewed and approved by the Project Manager and the QA Officer for the ETV CCEP and the Environmental Protection Agency. EPA provides input and guidance on key points. This document will be reviewed annually by project personnel. Corrections and additions will be documented and reported to the Project Manager and staff associated with the ETV CCEP.

Major revisions will require the preparation of an updated Quality Management Plan. The updated plan will be reviewed and may be resubmitted to EPA for approval.

2.0 MANAGEMENT SYSTEMS

The goal of the ETV CCEP is to test and verify the performance of innovative technologies that have environmental benefits. The ETV CCEP is to become a self-sustaining, independent entity that serves to provide an unbiased evaluation of these technologies to organic coating users, technical assistance providers, and other industry players. To this end, high standards of quality must be maintained throughout *CTC* and along project lines.

CTC's Quality Policy is:

CTC serves as a national resource to academia, government and industry in the execution of research, development, deployment, training and education activities in the solution of problems for a broad range of clients. As such, we will:

Provide quality products and services that meet or exceed the requirements of our internal and external clients, on-time and every time;

Seek and achieve continuous improvement in the quality and value added of our products and services;

Improve efficiency and reduce waste in all of our business processes.

It is the responsibility of each individual in *CTC* to comply with the provisions of this Policy.

The Quality Policy of the ETV CCEP is to:

Conduct activities to comply with *CTC*'s Quality Policy, the ETV Program Quality and Management Plan, and the requirements of stakeholders.

2.1 Management and Organization

Goals of management are to control and minimize the effects that day to day activities have on the quality of verification data. Figure 1 shows the *CTC* Management Organization and its relationship with the Project Manager of the ETV CCEP and QA Officer. The QA Officer is independent of the Project Manager for the ETV CCEP and reports directly to *CTC* Management. The Project Manager for the ETV CCEP is responsible for ensuring proper communication throughout all project lines and to maintain a cohesive team structure.

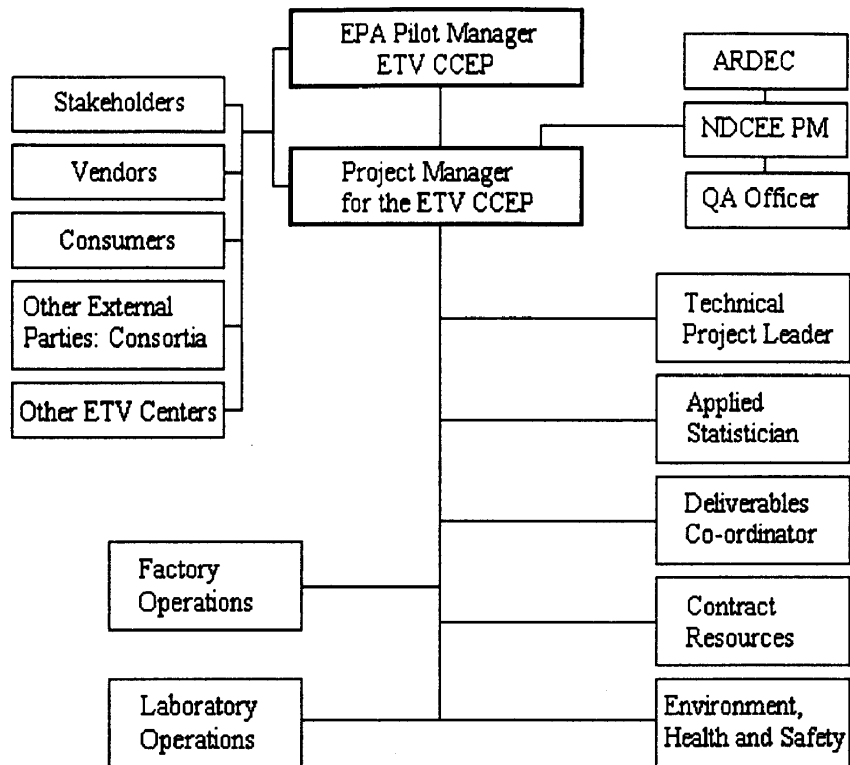


Figure 1. ETV CCEP Project Management and Its Relationship to Other Organizations.

CTC corporate offices are divided into three functional areas; the Materials and Metalworking Facility, the Environmental Technology Facility, and the Systems and Software Facility. The Environmental Technology Verification of Coatings and Coating Equipment Program falls within the environmental technology area and testing performed at *CTC* will be conducted within the Environmental Technology Facility. Mr. Brian Schweitzer is the Project Manager for the ETV CCEP and is responsible for financial and technical performance. The ETV CCEP is a project under the National Defense Center for Environmental Excellence (NDCEE) directed by Mr. David S. Roberts. The NDCEE Program is under the Technology Directorate of *CTC* directed by Mr. Jerry Hudson. Mr. Jacob Molchany is designated as the QA Officer and is responsible for meeting and maintaining the quality requirements of the project. A Technical Project Leader will be assigned to each technology area and will manage verifications performed on technologies within that area.

CTC expects to have sufficient personnel capable of conducting the verification testing required. Additional professional staff such as engineers and statistician may be provided to *CTC* through a subcontractor or consultant. A consultant, Mr. Carl Izzo, will also provide technical guidance for the project.

Testing conducted outside *CTC* facilities may involve the use of additional subcontractors. These will be selected and utilized according to the required work and their capability of meeting the testing and quality assurance requirements. The Project Manager for the ETV CCEP will manage subcontractors with or through the Technical Project Leaders.

A Stakeholder Group will be assembled to assist in the identification of technology areas and development of generic test protocols. The Stakeholder Group will be composed of both state and federal regulators, technology users from both military and industrial sectors, coating technology suppliers, trade and environmental associations, and consortia.

Throughout this document, reference is made to several groups within *CTC*. The following list is provided to identify these groups and their function within the ETV CCEP.

Leadership Team - upper level management group that guides the corporation.

Management Team - group of managers who are heads of sections and directly oversee personnel.

Quality Assurance Officer - person assigned to a project to track quality and ensure proper data collection, execution of tasks, and use of methods. This person is to act independent of project personnel.

Contract Resources - group that acts as go between for contracting purposes. A representative from this group contacts suppliers and vendors for cost and quality information, initiates purchases, handles complaints or return of supplies or material, and handles document delivery and archiving. All activities within this group are carried out according to the instructions provided in the Procurement Manual.

Environment, Health and Safety - group which is responsible for health and safety within CTC facilities. This group deals with worker safety, permitting, inspections, fire safety, waste disposal, Chemical Hygiene Plan, OSHA compliance, and Hazard Communication.

Management Systems Representative - The designated individual, who has been granted the authority to establish, implement, and maintain the Quality Management System (QMS) and Environmental Management System (EMS).

Quality Assurance Representative - personnel reporting to the Management Systems Representative and responsible for documenting compliance to the QMS, identifying root cause, and implementing preventive/corrective action.

Qualified Lead Auditor - Person who has either successfully completed an accreditation body's five-day lead-auditor course for a quality management system or an environmental management system, or has successfully completed an internal auditor course, performed two internal audits of minimum 4-hour duration each, and is approved by the ISO Management.

Project Personnel – all individuals participating in the execution of the project including CTC management, Project Manager for the ETV CCEP, engineers, laboratory and factory personnel, health and safety personnel and QA Officer.

2.2 Quality Systems and Description

CTC has standardized on ISO 9001 as the quality system model, using ASQC ISO 9001, Quality systems - Model for quality assurance in design, development, production, installation and servicing for guidance. This system is a four-tiered system consisting of a Quality Manual (Tier 1), Procedures (Tier 2), Work Instructions (Tier 3), and Records and Forms (Tier 4). All documentation is available on line through the computer network and can be accessed by each employee from a workstation.

The Quality Manual describes the policies and activities that support and maintain CTC's Quality System. It is designed to meet the 20 target items of the ISO 9001 Standard. Management has reviewed and endorsed the Quality Manual as well as Tier 2 Procedures. Ms. Melissa Rolla has been designated as the Management Systems Representative, reporting to the Senior Vice-President, and participates on the Quality Committee. This committee consists of two Executive Directors, three Directors, the Management Systems Representative, and a senior Vice President and is responsible for implementation of the CTC quality system. Quality Assurance Representatives, reporting to the Management Systems Representative, are responsible for maintaining the documentation, investigating root cause, documenting and implementing corrective action, and maintaining records.

Procedures, Tier 2, provide directions on how to meet the requirements of the quality system. These procedures provide guidance to personnel for project planning through the Quality Planning Checklist, preparation and delivery of documents, purchase of goods and services, scheduling, training, calibration and maintenance of equipment, inspection and testing of products, and assessments.

Work Instructions, Tier 3, provide operating, process, and laboratory personnel with step by step instructions on performing a job function. A work instruction breaks a procedure into its individual parts and describes how the activity is performed. Forms, Tier 4, are used to capture the information required to document the quality system and project execution. Completed forms, computer printouts, test documentation, reports, etc., are records that provide objective evidence that management system activities are being carried out. Records are created as the result of on-going daily activities.

Internal audits are conducted two or three times a year to evaluate the quality system. Qualified staff members who have attained or who are working to attain lead auditor status conduct these audits. Additional staff members have received internal training to assist in the internal audit process. In addition, third party surveillance audits will be conducted every six months upon successful completion of the registration assessment. An ANSI- Registrar Accreditation Board (RAB) certified registrar conducts the surveillance audits.

This Quality Management Plan offers an overall guide to the quality system in place and how it applies to the ETV CCEP. As the quality system for the corporation, the Quality Manual, Procedures, and Work Instructions serve as the basis for project planning, work implementation, and assessment of coatings and coatings equipment technologies. Additionally, a Generic Protocol will be developed for each type of technology verified. A Test and Quality Assurance Project Plan (TQAPP) will be developed to test specific products within the type of technology identified in the Generic Protocol. Objectives of testing, data and

data quality requirements, and specific verification requirements are contained in the TQAPP.

2.3 Personnel Qualifications and Training

CTC utilizes a matrix management system where personnel of various levels of education, experience, and capability are available to act as a manager, consultant, or team member. Certain management personnel possess MBA degrees or are licensed professionals. Numerous personnel maintain a membership in a professional society. This allows for access to experts in key areas. *CTC* also maintains a network of academic, military, and private sector contacts that are available as consultants.

The qualifications of each employee are documented in resumes and position profiles. These are maintained in a database and are updated annually by the employee.

The Project Manager for the ETV CCEP, along with line management, monitors changes in project personnel and ensures that staff is qualified and trained. Identification of specific training requirements for the ETV CCEP is the responsibility of the Project Manager for the ETV CCEP. These will be implemented and documented as required.

Conferences, seminars, and vendor-provided training are available when identified and deemed necessary for project execution. Records are maintained for each employee who receives training from internal and external sources.

Extensive library capabilities provide ready access to information. Internet capabilities allow for on-line searching and connection to external sources of information.

2.4 Procurement

Procurement is implemented through Contract Resources. Contract Resources utilizes the *CTC* Procurement Manual that contains all procedures necessary for the purchase of items and services for the project. Contract Resources not only has responsibility for ensuring that all requirements of a contract are met, but also initiates the purchasing activity subsequent to receiving input from project personnel.

Procurement of equipment and services is initiated using a Procurement Requisition (PR). The PR includes the following information:

- Date PR is prepared
- Date item is required
- Account number that item will be charged to
- Contract number for the project
- PR number for tracking
- Item number
- Description of item
- Vendors identification number
- Quantity desired
- Unit cost and total price
- Vendor name, address, and phone number
- Signature of person preparing the PR
- Signature of Project Manager
- Signature of Director (if required)
- Appropriate approvals

Project personnel are responsible to provide information concerning the specifications of equipment and supplies to procurement personnel. Additional requirements or specifications, such as quality or technical requirements, may be included as an attachment to the PR. By completing the appropriate section on the PR, an inspection of the item or service for conformance to quality and technical requirements will be performed at the time it is received. This inspection is documented on a Material Inspection Receiving Report.

A procurement representative inspects the PR to ensure that all necessary information has been provided. The representative will contact the person who initiated the PR if additional information is required. Major purchases must be made through a competitive bid unless a sole provider can be justified. The bid process is initiated by checking RFQ (Request for Quotation) on the PR. Procurement personnel, along with project personnel, will select vendors and suppliers based on the ability to deliver the appropriate quality and quantity of material or equipment that meets project requirements. Procurement personnel may make these decisions based on past history, performance and reliability history, self-assessment, on-site visit, or product inspection. At a minimum, all material will be inspected at the time of receipt to ensure that the correct item and quantity has been received. Shipping and Receiving will reject unacceptable or damaged material upon receipt. In the event that unacceptable goods or services are received, Contract Resources will act as the agent for negotiating replacement

of parts or services, rework, or refund. Major equipment purchases are assessed through an acceptance test to ensure proper operation.

Subcontractors will be evaluated according to their ability to provide the appropriate quality of service that meets project requirements. An evaluation may be made based upon self-assessment, on-site visit, past performance and reliability history, or by contacting references.

2.5 Documents and Records

CTC has established procedures for document generation, format, and record keeping. Contract Resources will issue document numbers and maintain a chronological log of all memorandums, letters and reports issued. Contract Resources, along with the Project Manager for the ETV CCEP, is responsible for ensuring that required documents are prepared and delivered as scheduled. The following document types may be generated as part of ETV CCEP activities:

- Task Plan
- Quality Management Plan
- Generic Protocols
- TQAPPs
- Engineering Drawings
- Resumes
- Monthly Reports to Management
- Cost Information
- Laboratory Data, Printouts, and Reports
- QA reports, Verification Reports and Verification Statements
- Management and Quality System Audit Reports
- Non-Conformance and Preventive/Corrective Action Reports
- Internal Technical Audit Reports
- Chain of Custody for Evidentiary Records

2.5.1 Task Plan, Generic Protocols and TQAPPs

The Task Plan is a contractual requirement between the contracting agency (Picatinny Arsenal) and *CTC*. It is prepared to document the activities that are planned to accomplish the required work. Generic Protocols and technology specific TQAPPs are prepared by the Technical Project Leader responsible for that verification area (i.e. equipment or coating). The protocols and TQAPPs are prepared according to the requirements of ANSI/ASQC E4 and the ETV QMP and are approved by EPA, *CTC* and

the technology vendor before testing is implemented. These documents are held for 10 years after the verification has been performed.

2.5.2 Document Control and Distribution

The Project Manager for the ETV CCEP assigns the appropriate personnel for document preparation. Documents are issued for review according to an established distribution list. Reviewers return the document with comments, initials, and date for revision by the document author. An approval page is affixed for signatures after revisions are made. The latest versions of documents for the ETV CCEP will be maintained at CTC offices in Johnstown, PA. Documents are identified and controlled according to title, date, and revision level. Copies of electronic and printed documents will be saved. Electronic files are copied to a secure network drive that is backed up daily to guard against loss of information or file corruption. CTC Management, ETV Management and team members, and document control personnel will receive copies of all documents as appropriate. The QA Officer is responsible to ensure that all project personnel are using the most recent and approved document. Project members are requested to use the revised document and remove all previous versions.

Contract Resources issues the final approved document to the customer. Printed copies of reports are maintained in Contract Resource's offices. Copies are filed according to contract number, letter number and document number. Copies are held for a period of 10 years.

2.5.3 Laboratory Data and Reports

Process records, bench sheets and data printouts are maintained with the report files located within CTC's laboratory area. All data, calculations, and records are identified by verification trail and the specific technology evaluated. Data and records are held up to 10 years.

2.5.4 Verification Reports and Verification Statements

Results of verification testing will be documented in a verification test report. Data collected from both process and laboratory testing will be included. This report will include a QA section that documents data quality indicators, deviations from the approved TQAPP, and confidence intervals associated with the data. In addition, a Verification Statement will be issued that includes the testing performed and results, statistical analysis of the data, process information, and QA/QC narrative. The EPA and CTC approve the Verification Reports and Verification Statements prior to publishing the information. Once the Verification Statement is approved, it will be published on the ETV web site where it will be available to the public.

2.5.5 Evidentiary Records

All handwritten data, instrument printouts, computer printouts, reports, forms and records for verification tests are maintained in files within the laboratory area. In the event that this information is required for legal actions, a copy of the information contents of the packet will be made to replace the original. A Chain of Custody for Evidentiary Records (CoC/ER) will be signed by the Project Manager for the ETV CCEP, Laboratory Manager, and QA Officer to indicate transfer of the information. The person receiving the information will also sign the CoC/ER to indicate receipt of the information. The final destination and contact person responsible for the information will be indicated as well. A copy of the CoC/ER will be held with the laboratory packet until all original information is returned.

2.6 Computer Hardware and Software

CTC maintains adequate computer resources to provide computing capability to the project. Computer hardware, software and networking capabilities are geared toward three major areas. These are corporate computing, process control, and data collection.

2.6.1 Corporate Computing

Corporate computing is based upon advanced computing, software, and networking technology which allow personnel to solve a broad range of industrial problems. Readily available and proven standard technologies which are reasonably priced yet geared toward current trends and technological advances are utilized. CTC has established guidelines to assure a uniform yet flexible system which is able to meet the daily demands of the contracts it supports.

Computing is based on a workgroup approach with each workgroup or contract having its own server. The system requires password login from desktop PC for security. Desktop computers are connected to the server to provide applications such as word processing, spreadsheet, presentation graphics, forms, printing, filing, network access, and electronic mail. Backup procedures are performed at the end of each workday in order to preserve information stored in network files. Database service, multimedia, and video-conferencing are also possibilities. Engineering applications require a UNIX-based system.

Hardware types utilized are IBM compatible PCs, UNIX, or Macintosh workstations. PCs are Pentium II processors operating at 300MHz or higher. Printers are HP 4 si MX or HP 5 si MX units connected to area networks. Color printers and plotters are also accessible. Peripherals include CD-ROM, ZIP, and tape drives, scanners, speakers, microphones and video equipment.

2.6.2 Process Control

Process Control is achieved through programmable line controllers which allow for automatic adjustment of temperatures of ovens or solutions, flow of water, gas or air, and process time and conditions. These connections are initially verified through an Acceptance Test. The programmable controllers are connected to the network to allow process monitoring at desktop via PC connection. Proper operation of all monitoring devices is confirmed according to a regular maintenance and calibration schedule. Whenever possible, NIST-traceable standards are used for the calibration of monitoring devices.

2.6.3 Data Collection

Computers and electronic readouts are used to collect data where computers are interfaced directly to instruments. Vendor-supplied software is employed for this type of data collection. Software allows for multiple point calibrations and automatic readout of sample values. Laboratory management will assess calibration data, raw data, and final results to ensure proper equipment operation and data accuracy.

A Computer Software Inventory is maintained to document the software/hardware combinations used for laboratory equipment. This list includes the name and identification number, version, and copyright date of software used with each piece of equipment. Backup copies of disks are maintained to minimize down time in the event of computer malfunction or failure. Only vendor supplied software/hardware configurations are used for testing equipment. These systems are calibrated and used for a specific test (i.e. thickness). Laboratory personnel are responsible for assessing proper operation of equipment using standard material, secondary standards, spike samples, etc. prior to analysis (see section 3.2.8). Results are documented with the raw data collected for sample analysis and are assessed by Laboratory Management during data review. Upgrades to software and maintenance of equipment are documented and assessed in the same manner.

2.7 Planning

At the beginning of a project, the Project Manager completes a Quality Planning Checklist shown in Appendix A. This checklist is used to ensure that all aspects of a project have been considered and that the required resources are available. These include equipment, facilities, personnel, test methods, processes, materials, criteria for inspection/assessment/validation, worker health and safety, waste disposal, training, cost, and a schedule of deliverables. The Project Manager is also responsible for identifying any legal or regulatory requirements that apply to the execution of project activities (i.e. air permits or monitoring).

The Project Manager will regularly schedule a meeting which includes all project personnel. The meetings typically address the following:

- project schedule
- project performance
- product delivery
- personnel requirements

- the specific coating technologies to be evaluated and the performance criteria which will be examined
- technical and quality goals which are necessary to appropriately evaluate the technology
- the technical and quality goals translated into a test plan which will adequately validate the technology
- test plans which fit within the cost and schedule constraints
- experimental designs, with acceptance criteria included, which will adequately verify the coating technology

CTC will establish a Stakeholder Group composed of representatives from military, industrial, government and academic institutions that have experience in the organic coatings industry. This group, assembled with the guidance and approval of EPA, will assist in identifying and selecting technologies for verification.

After a technology area has been selected, a Generic Protocol will be developed. This protocol will contain a wide range of test parameters that apply to the technology area being verified. Included in the protocol will be all testing required to gather sufficient data for environmental verification of the technology. *CTC* project personnel, EPA, and the Stakeholder Group design the Generic Protocol with input from the vendor community. The Generic Protocol includes the following sections:

- Purpose and objectives of the planned testing
- Verification description including approach, experimental design, performance criteria, measurements to be taken, critical and non-critical parameters
- Personnel and responsibilities
- Data quality objectives such as accuracy, precision, comparability, representativeness, and completeness including calculations
- Sample collection including site selection, sampling procedures, and sample frequency
- Analytical procedures, calculations, and calibration
- Data collection, reduction, validation, and reporting
- Internal quality control checks
- Audits and corrective action

After agreement by all parties, the Generic Protocol is approved and signed by the Project Manager for the ETV CCEP and QA Officer at *CTC* and the ETV Pilot Manager and Quality Assurance Officer at EPA. An example of an Approval Form is shown in Attachment 1.

The requirements for verification testing are included in the TQAPP prepared for each coating technology evaluated. The TQAPP is reviewed and approved by the organization requesting verification testing, the Project Manager for the ETV CCEP and QA Officer at CTC and the ETV Pilot Manager and Quality Assurance Officer at EPA prior to implementation of testing.

2.8 Implement Work Procedures

The Project Manager for the ETV CCEP is responsible for implementing the requirements of the CTC QMS as well as the planning documents applicable to the ETV CCEP. He also provides input and guidance as offered by the EPA ETV Pilot Manager for project planning. The QA Officer is responsible for assuring that the proper planning documents (TQAPP) are used during testing and that the quality requirements are met. The Technical Project Leader designated for a technology area is responsible for the verification testing conducted for that technology. Testing is conducted according to the approved and accepted TQAPP.

The specified operations and methods are followed according to written procedures and work instructions. The procedures and work instruction are prepared using the following outline:

- Purpose
- Applicability
- Definitions
- Supporting Documents
- Equipment & Materials
- Training
- Instruction/Process
- Records

When required as part of the TQAPP, standards are analyzed to verify that analytical methods are performed satisfactorily. Instruments are calibrated and verified prior to analysis of samples. NIST-traceable standards are used wherever possible when this type of material is available. Duplicate and spike analysis is performed and data quality indicators are calculated with each batch of samples analyzed. The Calibration Technician, factory personnel, and laboratory personnel are responsible for this activity when required by the TQAPP.

2.9 Assessment and Response

Regular assessments of both the management and technical aspects of the project are planned and scheduled. Assessments are conducted both internally through self-assessment and externally by independent entities. These assessments may be in any of the following forms:

- audits
- data quality assessments
- quality and management system reviews
- peer review
- performance evaluations
- readiness reviews
- surveillance
- technical review

The Project Manager tracks project status through any of *CTC*'s assessment tools such as:

- Cost Tracking System
- Matrix Management System
- Software tools (En, Ei, MS Project)

2.9.1 Management Assessments

The Project Manager will regularly conduct quality assessments to ensure that the quality objectives of the project are being met. These internal reviews will be documented and reported to management in a monthly report prepared to document the cost, schedule and technical performance of the project.

Internal audits of the ISO 9001 and ISO 14001 systems are conducted periodically to assess compliance with the written and approved Quality Manual and Procedures. *CTC* has a highly qualified staff to guide and direct this effort. The staff includes assessors certified by the ANSI-RAB, quality engineers certified by the American Society for Quality (ASQ), as well as quality professionals with expertise in Quality Improvement Programs, ISO 9000 Systems Development and Auditing, and Industrial Problem Solving.

Audits of the QMS and EMS are conducted according to established written procedures. The following guidance documents are used as references for these auditing procedures:

- ISO 8402 : 1994, Quality Management and Quality Assurance Vocabulary
- ISO 9001 : 1994, Model for Quality Assurance in Design, Development, Production, Installation, and Servicing
- ISO 9004-2: 1991, Quality Management and Quality Systems Elements
- ISO 10011-1 : 1990, Guidelines for Auditing Quality Systems (Part 1 : Auditing)
- ISO 10011-2 : 1991, Guidelines for Auditing Quality Systems (Part 2 : Qualification)
- ISO 10011-2 : 1991, Guidelines for Auditing Quality Systems (Part 3 : Management)
- ISO 14001 : 1996, Environmental Management Systems – Specification with Guidance for Use
- ISO 14004 : 1996, Environmental Management Systems – General Guidelines on Principles, Systems and Support Techniques
- ISO 14010 : 1996, Guidelines for Environmental Auditing -- General Principles of Environmental Auditing
- ISO 14011/1 : 1996, Guidelines for Environmental Auditing -- Audit Procedures -- Auditing of Environmental Management Systems
- ISO 14012 : 1996, Guidelines for Environmental Auditing -- Qualification Criteria for Environmental Auditors

CTC has also established a formal Quality Committee, chaired by the Management Systems Representative, which reports to a senior Vice President within the organization. The Quality Committee is responsible for guidance, direction and oversight of the QMS, as well as providing the necessary resources for successful realignment of the quality and environmental systems to meet the ISO requirements.

An audit of the quality system will also be conducted by an independent organization every six months as part of the surveillance requirement for ISO 9001 certification. These audits are to ensure that the policies, practices, and procedures are sufficient to provide results of the type and quality required. Results of these audit activities are reported to upper management.

2.9.2 Technical Assessments

A Testing and Quality Assurance Project Plan (TQAPP) is prepared for each coating technology verification. The TQAPP contains the specific requirements for each coating technology evaluated. Project and operating personnel are responsible for assessing the quality of the data collected during testing. The QA Officer and laboratory personnel are also present during testing and data collection to assess the technical quality of the verification. These personnel document the adherence to specified procedures and have the authority to suspend work when unsafe or unacceptable quality conditions arise. Multilevel reviews by the appropriate and qualified personnel will be conducted on test data and reports to ensure that testing, data collection, and reporting are performed according to the TQAPP requirements. Verification Reports will be reviewed by members of the Management Team, Leadership Team, and EPA to ensure that conclusions are technically sound.

2.9.3 Data Quality Assessments

Reviews will include specific data quality indicators and procedures specified in individual TQAPP prepared for each technology assessed. The QA Officer also conduct audits of the testing performed to determine whether the quality objectives specified in the TQAPP are met. Assessment also includes an evaluation to determine whether the data collected fulfill the test objectives and design of experiment established for the technology. A statistical evaluation is performed to summarize the data and arrive at conclusions. Data assessment will be conducted according to the procedures specified in the generic protocol and TQAPP prepared for the specific technology using EPA QA/G-9 Guidance for Data Quality Assessment as a guideline. These assessments are the responsibility of the Project Manager, QA Officer, laboratory personnel, and statistician. Results of the data assessment will be documented in the Quality Assurance section of the verification report.

2.10 Quality Improvement

As test protocols and plans are developed, input is provided through the stakeholder groups, project personnel and vendors. As testing is performed and reports are generated, CTC will provide feedback on the Quality Management Plan based on input received and lessons learned.

Leadership Team meetings and Management Team meeting are held regularly to evaluate and gauge compliance to quality management objectives. Important

project requirements are covered and the appropriate briefings are held to communicate findings. A Preventive/Corrective Action Request is used to document any deficiencies. A Quality Assurance Representative, independent from the ETV CCEP, is responsible for conducting an investigation into the root cause of the deficiency and documenting the findings. The Project Manager, Quality Assurance Representative, and other project personnel devise and implement the appropriate corrective action. Effectiveness of the corrective action is verified and documented by the Quality Assurance Representative. Procedures and instructions are revised as necessary to reflect the implemented changes.

3.0 COLLECTION AND EVALUATION OF ENVIRONMENTAL DATA

Evaluation and verification of environmental technologies for organic coatings will be carried out at *CTC* facilities in Johnstown, Pennsylvania, or off site at appropriate facilities. *CTC* and ETV CCEP personnel will be responsible for the performance of this testing. When verification testing occurs at facilities other than *CTC* operations, testing will be conducted by either *CTC* personnel or under the close supervision of ETV CCEP Management. All activities will be carried out according to the TQAPP approved for the coating technology.

Important aspects of the collection and evaluation of environmental data are:

- Planning and Scoping – the data collected must be sufficient to ensure that the objectives of the testing are adequately addressed
- Design of the Data Collection - identification of the important experimental parameters to be collected and development of a Design of Experiment
- Implementation - how the designed experiment is executed and how operations are carried out
- Assessment and Response - how data are reviewed, validated and what tools are used to determine whether the data are useful and meet the objectives of the testing
- Assessment of Data Usability - methods and tools used to determine whether data are sufficient, accurate, and useful in fulfilling the objectives of the testing.

3.1 Planning and Scope

Task Plans are submitted for each project conducted. The Task Plan, a requirement for projects conducted under TACOM-ARDEC oversight, lists the goals of the project as defined by the statement of work and describes how the required work will be performed. Included is a list of personnel involved with the project and their role. A schedule of important milestones and deliverables is usually included. Generic Protocols will be prepared for each technology area (powder coating, liquid coating, coating equipment) to be evaluated. Test and Quality Assurance Project Plans are developed for each verification conducted.

Technical Audits will be planned for each verification test based on past testing experience, the personnel involved and the complexity of the test. Technical Audits may be conducted prior to, during, and/or after verification testing to ensure that equipment, procedures, and personnel are capable of providing the data quality required. Technical Audits include the following:

- Readiness audits
- Performance evaluations
- Data quality audits

Readiness audits are used to verify that personnel are trained, practiced, and capable of performing the required procedures and tests. Readiness audits are initiated by the Technical Project Leader to evaluate preparations for verification testing. Readiness audits are also used to ensure that equipment is functioning properly, is calibrated, and is available for verification testing. Readiness audits may take the form of dry runs or actual practice testing.

Performance evaluations will be performed to verify proper calibration and operation of equipment. Performance evaluations may also utilize "blind" samples provided by an auditing party during internal or external audits.

Data quality audits consist of reviewing methods used, verifying calibration, evaluating precision and accuracy data, and comparing results to data quality objectives. Data quality audits are performed on the data collected during verification testing. Data quality audits are performed for each verification test.

3.1.1 Generic Protocol and TQAPPs

Generic Protocol and TQAPPs are used to convey the objectives and requirements of the verification testing to be conducted for each technology. Both Generic Protocol and TQAPPs will address:

- objectives
- ID of people involved with task
- data required
- QA/QC requirements (data quality indicators, acceptance levels of confidence, level of validation and verification required)
- documentation needed to describe the quality of the results
- personnel and their roles
- regulatory requirements and other constraints (i.e. time and budget)

The Generic Protocol and TQAPP comply with the quality assurance requirements of ANSI/ASQC E4 and the ETV QMP.

3.1.2 Waste Disposal and Regulatory Requirements

Rinse solutions are collected during processing. The volume of these solutions is reduced, under permit by the Pennsylvania Department of Environmental Resources, in an atmospheric evaporator. Solids from the evaporator and other process wastes are placed into containers.

Environment, Health and Safety (EHS) staff use MSDS information and prior knowledge of the process to identify waste characteristics.

Containerized waste is turned over to a licensed, bonded waste handler for disposal. The waste handler tests each waste and will dispose of these according to the applicable regulations. Wastes that are generated during testing are also containerized. These are lab-packed, tested, and disposed of by the same waste handler.

CTC has implemented elements of ISO 14000 into the EHS operations. As such, EHS is responsible for compliance to federal, state, and local regulations, which includes SARA, OSHA, RCRA, and emission permitting. EHS staff conduct employee training in Hazardous Communication, Safe Work Practices, and Right to Know. EHS personnel work with the Project Manager to ensure compliance with permits and regulations, which includes review of MSDS information, emission monitoring and reporting, disposal of process waste, and exposure monitoring and identification. The Quality System requires the Project Manager to identify any legal requirements and environmental aspects and impacts of project operations during the project-planning phase. Environmental issues are also addressed on the Quality Planning Checklist described in section 2.7.

3.2 Design of Data Collection

Experimental Design and data collection requirements are included in the TQAPP. The TQAPP is prepared with input from the Project Manager, QA Officer, statistician, laboratory management and personnel, and EHS staff as well as operating personnel. The TQAPP defines the following requirements:

- Objectives of the planned testing.
- Design of Experiment (DOE) to meet the objectives.
- Parameters, sample points, and number of measurements required as part of the DOE.
- Sampling methods, analytical methods, equipment, and chemicals to be used and the level of quality required, including critical and non-critical parameters.
- Calculations and data quality indicators.

- Methods of data assessment and evaluation.

The TQAPP is reviewed by Management Team and Leadership Team members to ensure it is technically sound and that the DOE, analytical parameters, and collection of data are sufficient to meet the objectives of the testing.

A draft copy of the TQAPP is reviewed by all project participants to ensure a clear understanding of the work to be performed. Comments and technical points are incorporated into the TQAPP prior to the initiation of any work.

3.2.1 Intended Use of the Data

The data collected may be used not only to verify the performance of an environmentally friendly technology, but also verify the reduction of pollution potential gained by using the technology. The data may also be used to compare utility costs and compliance to regulatory standards. Therefore, the data collected must be of sufficient quality to allow these types of comparisons with reasonable certainty. The objectives of the testing to be performed in the Generic Protocol describe the intended use of verification data.

3.2.2 Data Quality Indicators

The data quality indicators (precision, accuracy, completeness, and comparability) will be listed in the TQAPP for all critical and non-critical parameters. Factory personnel, Calibration Technician, and laboratory personnel are responsible for assessing data quality indicators during analysis and performing re-calibration/reanalysis if required.

3.2.3 Performance Characteristics

All critical and non-critical parameters will be listed in the TQAPP along with the required method, performance characteristics (i.e. accuracy, precision, bias, etc.) and calibration requirements. Parameters will be analyzed using approved methods such as ASTM, EPA, MIL-SPEC, or SAE whenever possible. Factory personnel and the Calibration Technician are responsible for assessing the equipment prior to operation or measurement during verification testing. Laboratory personnel are responsible for assessing the proper operation of the method prior to testing. This validation will be done using known standards and NIST-

traceable material whenever possible. In some instances, no commonly accepted method may exist due to the lack of a suitable calibration material or the proprietary or innovative nature of the technology. The performance of these non-standard methods will be evaluated based on the manufacturer's specifications or on in-house developed protocols. Requirements and results of replicates, spikes, and reference standards will be fully documented.

3.2.4 Specifications

Trained and qualified personnel carry out all sampling and data collection activities. Sampling methods and requirements will be listed in the TQAPP. These methods will be taken from the appropriate source such as air regulations, RCRA methods for solid and liquid waste, EPA water and wastewater, Standard Methods, or MIL-SPEC.

Testing occurs according to the methods and procedures specified in the TQAPP. Any modification of or deviation from an approved method such as alternate wavelength or dilution used is documented on bench data sheets.

3.2.5 Factory Equipment

The Calibration Technician is responsible for calibrating equipment used to record factory process conditions. Calibration procedures for the factory equipment are derived from ISO 10012-1 and MIL SPEC 45662A guidelines. A software package is used for recording, storing, and retrieving calibration information. This software provides a schedule for maintenance and calibration of the factory equipment.

Gauges and monitoring devices used for process monitoring and data collection are maintained and calibrated at the appropriate and specified interval. Each piece of equipment is given a unique identification number. A sticker is placed on each piece of equipment after calibration to indicate proper performance. Date of calibration, initials of the person performing the calibration, standard used for calibration and identification number, and next calibration date are indicated on the sticker. NIST-traceable material is used whenever possible. Records of the calibration data generated during calibration are stored both electronically and as printouts.

Equipment not passing calibration requirements is labeled "NOT IN CALIBRATION SYSTEM" to indicate that the equipment is not to be used for testing. If necessary, equipment is sent to a qualified vendor for

repair or re-calibration. The Calibration Technician is responsible for preparing an Out-of-Calibration Assessment form when a piece of equipment is found to be out of calibration. This form is forwarded to the Quality Representative who is responsible for reporting findings to management. An Impact on Quality form is completed to assess the effects on the quality of measurements obtained using the equipment. Samples will be re-tested when the quality of collected data is unacceptable or unknown.

During verifications, the equipment will be checked against standards.

3.2.6 Laboratory Equipment

Each piece of laboratory equipment is given a unique identification number. Logs are kept for maintenance, calibration, and use. Each standard is given a unique identification number as well (including standards prepared by dilution of another standard). To maintain complete traceability, calibration logs include the identification number of the equipment, calibration date, person performing the calibration, identification number of the standards used, and the identification number of the samples that were analyzed using that calibration.

Proper operation of all laboratory equipment will be verified according to the manufacturer's recommended procedure or published reference standard prior to testing any samples. This will be done using samples of known value or, when available, purchased standard reference material. A standard is analyzed with each batch of samples to verify proper equipment function. Duplicates and spikes are also analyzed and precision and accuracy data are generated. Re-calibration, maintenance, or repair is indicated when unacceptable recovery of data quality indicators occurs. For example, balances will be verified using traceable weights and ovens will be checked using thermometers calibrated against an NIST-traceable thermometer.

Proper operation of equipment that uses a computer software program to calibrate, collect data, and calculate results is verified prior to analysis of samples. A typical scenario utilizes a minimum of three standards plus a blank to establish a calibration curve. This calibration is verified using a "check" standard from a different supply source. If the check standard is acceptable, the curve is verified by checking the highest standard that must meet the method requirements (typically a 5% to 10% error). To completely verify the performance of the method and sample preparation steps, a method blank, blank spike, and, when available, a known sample/standard from a third source are analyzed. These checks and

spikes must meet method requirements for recovery before analysis of samples can begin. The data quality indicators (precision, accuracy, and recovery) must meet method requirements for the data to be acceptable. Finally, the calibration blank, highest standard, and check standard are again analyzed to verify that the calibration is still accurate and no drift has occurred. Other instrument checks include spectral interference samples, internal standards, or surrogates. Only after the above requirements are met are data reported, otherwise, the instrument is re-calibrated and re-analysis is performed.

The Calibration Technician maintains a list of all calibration standards. A list of all standards that need to be re-certified by an outside vendor (weights, thermometers, micro-hardness blocks), expire, or are replaced on a regular basis (thickness standards) is issued monthly. This list also indicates laboratory equipment such as thermocouple controllers for ovens, freezers, etc. that are due for calibration. This list is issued monthly to laboratory personnel for completion of the service activity. Laboratory Management is responsible for ensuring that the service is performed within the scheduled period.

3.2.7 Sample Handling Procedures

Samples are collected at the location and frequency specified by the design of experiment detailed in the TQAPP. Samples are preserved at the time of or as soon as possible after collection. Sample panels or parts are stamped with a unique identification number prior to coating. Other samples such as liquids or solids are clearly labeled with the date, time, sampler ID, location and process at the time of collection.

Samples are delivered to the laboratory for entry into the laboratory system. A Chain of Custody is completed to track samples through the laboratory. The Chain of Custody is signed by the delivery person and the receiving person to indicate transfer of samples. Each sample is given a unique laboratory identification number and logged into a bound book. The receiving person compares the samples with the Chain of Custody to ensure that all samples are correctly logged. Samples are stored in the appropriate storage areas (refrigerators, rooms, freezers, etc.) as recommended in the analytical method and laboratory work instructions. A Work Order is completed to indicate what samples were processed and collected and the analysis to be performed. The Work Order is reviewed and signed by the Project Manager to initiate analysis of samples. Job Assignments are prepared to indicate the analysis to be performed on each sample. Job Assignments are provided to the laboratory personnel assigned to analyze the samples. Laboratory management reviews the

Chain of Custody, LogBook, Work Order, and Job Assignment to ensure that all information has been correctly entered. Laboratory management is responsible for reviewing the TQAPP and adhering to the methods, calibrations, and QA/QC requirements during the testing of samples.

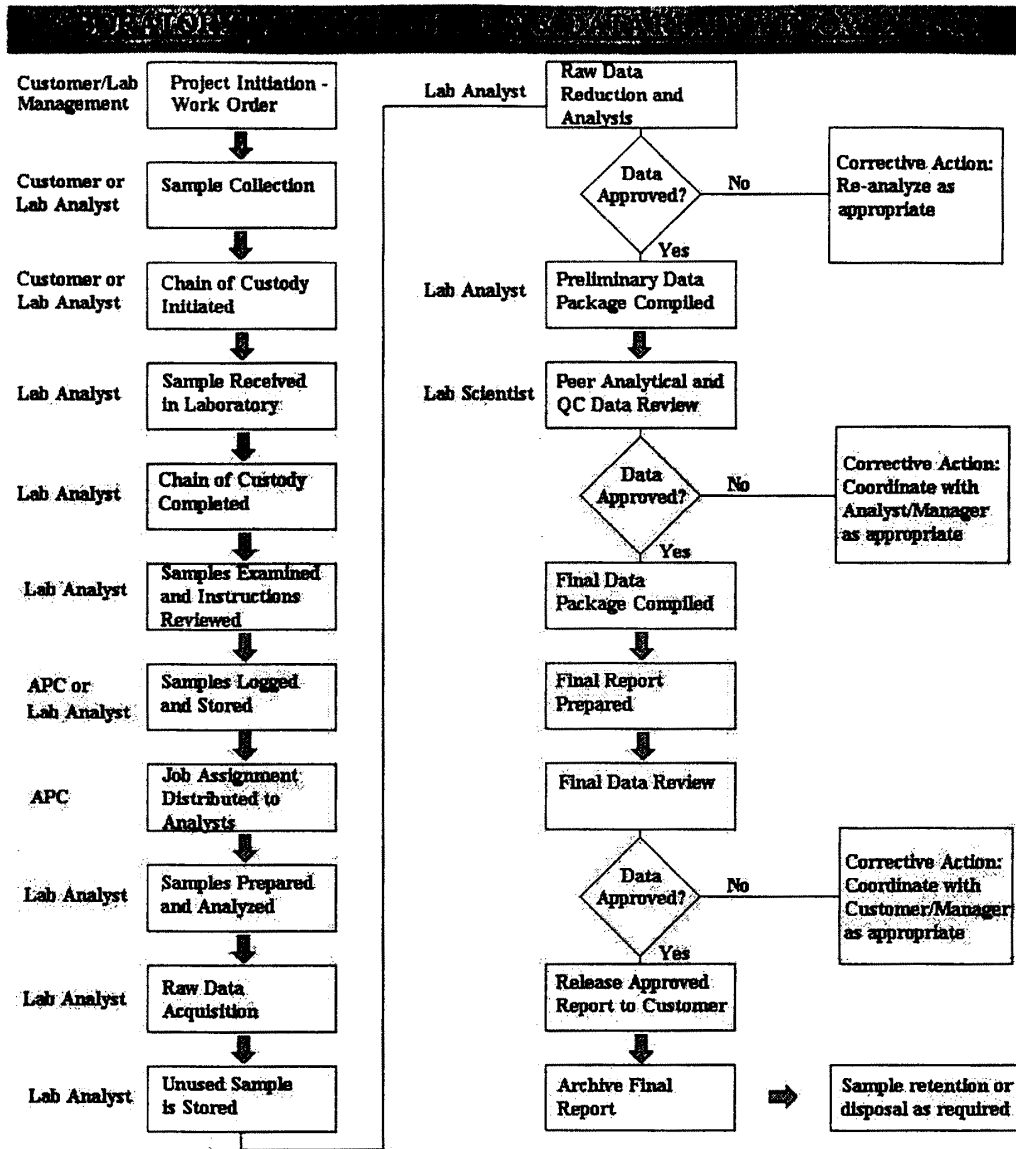
Equipment usage and calibration logs are used to indicate the standards, samples, and reagents used during analysis of samples. A log is used to document any repair or maintenance performed on the equipment.

3.2.8 Laboratory Data Handling, Validation, and Reporting

Data collected in the factory is placed on QA/QC Data Forms. This information is reviewed by the QA Officer and forwarded to the Project Manager and Technical Project Leader for inclusion in final reports and verification statements.

Data collected during laboratory testing are placed on an analytical bench sheet. This sheet includes the parameter and method used for testing, date, analyst initials, identification number of samples and standards, equipment ID number, calibration number, dilution, instrument reading, and final result. This information is transferred to a Data Results form that includes the parameter, method, date, analyst initials, equipment number, test description, sample identification, final result, and method detection limit. Results for the analysis of duplicate, standard, and spike samples are transferred onto a QA/QC Summary. Figure 2 shows a flow diagram for data handling.

A member of laboratory management reviews all of the data on these sheets to ensure that the proper samples, method, standards, reagents, and equipment have been used and that all verification requirements are met. Calculations, dilution, and data quality indicators are verified as well as percent recovery of standard and spike samples. The results from the analysis of duplicate, standard, and spike samples are plotted and compared to the method requirements and values stated in the TQAPP.



Administrative Point of Contact (APC) - Secretary

Figure 2. Data Review Flow Chart

The reviewer will initial and date all of the sheets after review to show that all information has been verified. The data are forwarded for entry onto the laboratory report form.

Data are entered from the result sheets onto the laboratory report form using word processing software. The laboratory report contains the sample ID number, description, parameter, result (including units), detection limit, date, and analyst. The report filename is assigned based on the first sample number listed on the Chain of Custody. In this way, the results are traceable from the Chain of Custody, Sample Log Book, and report. The lab report is returned to the review analyst who will recheck the initial results and ensure correct entry of data onto the report. If all information is correct, the report is signed and approved for release.

Electronic files of the report are e-mailed to the person requesting the results. Copies of laboratory reports are sent to project personnel for assessment and incorporation into project reports.

The Project Manager may request interim results for preliminary evaluation of the data. In these instances, the data are clearly marked "Results are unofficial until all data are reviewed and a final report is issued".

Restrictions on the use of data are indicated in the comment section of the report. This may occur when matrix interference results in poor recovery of spike standards and the sample is diluted to remove the interference. The detection limit may be greater than the value recorded in the TQAPP. In this instance, the detection limit will be flagged in the report section and indicated in the comment section.

3.2.9 Data Reporting and Archival

Printed laboratory reports are filed in a locking cabinet in the laboratory area. Laboratory reports are filed in numerical order along with Work Order, Chain of Custody, Job Assignment, raw data, and associated Demonstration Plan (See Section 3.3) for easy retrieval. Copies of lab reports are maintained for a period of ten years. Electronic files are copied to a network-drive that is backed up daily to prevent loss of information. Laboratory report files are also copied on floppy disks to provide an additional guard against data loss.

3.3 Implementation

Upon acceptance of the TQAPP by CTC, EPA and the technology vendor, a Demonstration Plan is generated. The Demonstration Plan provides the operating personnel with all necessary set up parameters such as pressure, temperature, flows, etc. of process baths, ovens, equipment, etc. All testing and data collection activities to be performed both during and after processing are listed on a Work Order. The QA/QC Data Forms shown in Attachment 3 are used to document the settings, parts, and equipment actually used. These QA/QC Data Forms also document factory conditions during processing. These are prepared in response to the critical and non-critical parameters listed in the TQAPP for the specific verification conducted. Any deviations from the methods and parameters specified in the TQAPP and Demonstration Plan are recorded and reported to the Technical Project Leader, Project Manager, and QA Officer. Deviations will be evaluated to determine their effect on the data quality and objectives of the testing. The Technical Project Leader, Project Manager, and QA Officer will determine what corrective action will be taken.

3.3.1 Control of Test Plans, TQAPPs, and Methods

Test Plans and TQAPPs are clearly marked "DRAFT" to indicate that they are preliminary, in the review process, and are not to be used to conduct testing. After the Test Plan or TQAPP is approved, the document is given a revision number. Revision 0 is used to indicate the first level of revision. Any change to an approved document will require another review and approval step. The changed document will become Revision 1, etc. Also, the date is imprinted on each page of the document to indicate the date approved. Project personnel will be required to use the current revision with the approval date. The QA Officer is responsible for ensuring that the most recent document is used. Laboratory management is responsible for ensuring that the most recent document is available to laboratory personnel.

The Laboratory Manager is responsible for ensuring that the most recent methods are available to laboratory staff. Laboratory management is responsible for maintaining a list of current procedures and methods used and ensuring that testing is performed according to the method specified in the TQAPP.

3.3.2 Work Procedures and Work Instructions

Procedures for operation of factory equipment are documented in work instructions. Engineering staff responsible for the equipment writes the work instruction. The engineer prepares the instruction based on information provided from equipment manuals, vendor training, EHS staff, and experience of the factory personnel responsible for the operation of the equipment.

The CTC laboratory primarily uses EPA and Standard Methods as sources for environmental measurements. ASTM, MIL-SPEC, SAE, or industry specific protocols are followed for finish quality testing. The laboratory documents all test methods into CTC's ISO 9000 format Work Instructions. A Laboratory Analyst that is trained and experienced in performing the specific method is assigned to write the Work Instruction. The steps of the Work Instruction are arranged in logical sequence as indicated in the reference standard. The Work Instructions are reviewed and approved by laboratory management prior to implementation.

3.3.3 Verification of Equipment Operation Prior to Testing

Prior to verification testing, equipment and instruments will be checked to ensure proper operation and function. This determination will be conducted according to the procedures listed in section 3.2.5 and 3.2.6.

3.3.4 Procedures for Data Validation

Data reduction will be performed according to the requirements and calculations listed in Generic Protocols and technology specific TQAPPs. An assessment and statistical analysis of the data will be conducted to determine whether the data meet the design of experiment and the objectives of the testing as provided in the TQAPP. Data assessment will be conducted according to Guidance for Data Quality Assessment (EPA QA/G-9).

A Quality Assurance Summary will be provided to document all qualitative and quantitative quality measurements such as precision, accuracy, and problems encountered during processing and testing. The QA Summary will be included in the Verification Report.

3.4 Assessment and Response

Data will be collected according to the quality requirements specified in the TQAPP. This may involve the analysis of blanks, duplicates, spiked samples, or standards of known value. The collected data are assessed through peer review channels after the testing is completed. Peer reviewers check data collected from both at line monitoring and laboratory testing to confirm adequate calibration, correct method usage, data transcription, and that all data quality indicators are met. Transcription errors are confirmed with the analyst prior to any correction of data. A request for re-analysis is completed and issued to the analyst when data quality indicators are not met. Reanalysis is performed when an inadequate calibration or an inappropriate method is used. Laboratory management reviews final data packages to make sure all results conform to chemical principles, mass balances, or charge balances.

Statistical methods will be used to evaluate the collected data. This may involve generating control charts or identifying outliers in the data quality indicators.

The QA Officer is responsible for monitoring the performance of testing and the collection of data during verification testing. The evaluation is based upon the requirements of the TQAPP and the defined data quality objectives.

3.4.1 Maintenance and Calibration Frequency

Preventive maintenance and calibration of equipment and instruments is performed on a regular basis. Maintenance and calibration schedules for factory equipment are maintained using the calibration software package (See Section 3.2.5). Each piece of equipment is labeled with a unique identification number and logged into the software. The software provides a complete history and traceability of calibrations performed.

A monthly schedule is issued for maintenance and calibration activities to be performed on laboratory equipment, standards, and instruments (See Section 3.2.6). Each instrument, standard, and piece of equipment is given a unique identification number. Use, calibration, and maintenance activities are traced using binders for each instrument.

A Preventive/Corrective Action Request is completed and forwarded to the Quality Assurance Representative (See Section 2.1) when a piece of equipment is found to be out of calibration, improper methods or procedures are used, or equipment, supplies, and instruments do not meet quality requirements. The QA Representative is responsible for determining the root cause and implementing corrective action. In the event that equipment or instruments have been out of calibration during

testing and results have been reported, the Calibration Technician issues an Out-of-Calibration Assessment. Supervisory personnel are responsible for determining the impact on the quality of the reported data using the equipment. The Out-of-Calibration Assessment is forwarded to the QA Representative who is responsible for follow-up and corrective action. The findings are reported to management.

3.4.2 Analysis of Known Samples/Standards

Proper operation and calibration of equipment is verified prior to testing. NIST-traceable material is used, when available, for this type of testing. These standards are analyzed after each batch of samples and after all samples are analyzed to ensure that instrument drift has not occurred.

CTC is certified by the state of Pennsylvania for the analysis of drinking water. Under this program, the laboratories are evaluated through performance evaluation samples that must be analyzed twice per year. The laboratory must meet the required analytical results to maintain certification.

3.4.3 Internal and External Audits

As part of *CTC*'s Quality System, the facilities undergo quarterly internal audits. *CTC* has a highly qualified staff to guide and direct the audit efforts. The staff includes assessors certified by the Registrar Accreditation Board (RAB), quality engineers certified by the American Society for Quality (ASQ), as well as quality professionals with expertise in Quality Improvement Programs, ISO 9000 Systems Development and Auditing, and Industrial Problem Solving. As part of our internal audit Program, *CTC* will use the skills and expertise of a RAB accredited registrar.

CTC's Quality Committee, chaired by a Management Systems Representative, reports to a senior Vice President within the organization. This committee is responsible for guidance, direction, and oversight of the management system, and for providing the necessary resources for successful realignment of the QMS and EMS activities to meet the ISO requirements. A report of the audit results are posted electronically and provided to management. A Preventive/Corrective Action Request is used to document findings of these audits and to initiate the corrective action process. The Quality Assurance Representative (See Section 2.1) is responsible for determining the root cause, documenting the action to be taken and ensuring implementation of the corrective action.

During an on-site inspection the Pennsylvania Department of Environmental Protection evaluated the environmental laboratories for compliance with the certification requirements. An evaluation report was issued and CTC had 90 days to correct deficiencies and provide documented proof of compliance. The laboratories were subsequently granted certification status after successfully analyzing performance samples. The laboratory receives and analyzes performance audit samples every six months and undergoes an on site inspection every two or three years to maintain this certification.

Representatives from the EPA may conduct assessments of the program and perform inspections prior to and during verification testing.

3.4.4 Assessment of Data Usability

An evaluation is conducted after the execution of a demonstration plan to identify any problems encountered during processing or collection of data. The project team assesses the usability of the data collected from a demonstration plan after laboratory analysis is completed. This evaluation involves the statistician, Project Manager, laboratory management, quality assurance, and process operations personnel. Evaluation is based upon the requirements specified in the TQAPP and will include any limitations (such as ranges or confidence intervals) on data parameters.

A statistical analysis of the data will be performed using a software package (such as MiniTab 12 or Excel). Measurements such as mean, median, standard deviation, t-test, and f-test will be generated to describe the results and the confidence level. The EPA will also conduct an assessment of the data.

After the evaluation is conducted, the QA Officer prepares a report to document the findings. This report will identify any problems encountered during testing, calibration, analysis, or data reduction and provide the corrective action steps required for resolving the issues. The impact on the test objective and verification results will be provided. This information is included in the QA section of the verification report.

3.5 Reporting

Upon completion of verification testing, a report will be prepared for the EPA that details the results of the verification testing. Raw and summary data will be made available to EPA and other qualified reviewers for technical peer review and QA review. The report will document the results of the verification testing of the product against the specific criteria detailed in the test protocol. A verification report will include the following information:

- Verification Statement
- ETV Overview
- Discussion of the Technology Area Tested
- Test Protocol
- Summary Data and Results
- Quality Assurance Narrative
- Summary and Conclusions

All data and analysis for each verification test will be organized into its own Data Notebook. These data and analyses will be technically peer-reviewed by EPA and other qualified reviewers but will not be published as an EPA report. Technology providers will have the opportunity to review the Data Notebook. The report will be submitted to the EPA for publication as an EPA report. The EPA will issue a verification statement based on the summary data in the report. The verification report and verification statement will be provided in EPA format using WordPerfect software.

The release of the verification statement is the technology provider's option. Also, the verification statement will be made available over the Internet on the ETV CCEP web-site (<http://www.epa.gov/etv>) as well as through other sources, for example, publications and meetings. Should the technology provider not agree with the verification results, the test report will still be submitted to the EPA; however, no verification statement will be issued. The EPA and the ETV CCEP will keep a copy of all reports on file. Technology providers are allowed one chance, with EPA support, at verification per product per focus area. A retest will be available, provided that the technology provider pays 100% of the cost.

Appendix A:
Quality Planning Checklist

QUALITY PLANNING CHECKLIST

The purpose of this Quality Planning Checklist is to aid in project planning by providing a structured and guided approach to the various aspects of the Quality and EHS Management System. The Checklist, therefore, serves as a guideline and is an integral part of the overall quality management process. The checklist has been designed to walk PMTs through the necessary procedures and supporting documentation necessary to comply with the QMS/EMS system requirements.

The completed Checklist shall be retained by the Project Manager and appropriately filed with project documents.

The following acronyms are used within this document:

PMt	Project Manager, Technical
NCEMT	National Center for Excellence in Metalworking Technology
PR	Purchase Requisition
PO	Purchase Order
MIRR	Material Inspection Receiving Report
FSRS	Facility Support Request System
WBS	Work Breakdown Structure
EHS	Environmental Health and Safety
MMS	Matrix Management System
MSDS	Material Safety Data Sheet
JSA	Job Safety Analysis
PCAR	Preventive/Corrective Action Request

Attachment 1:

Example Approval Form

Attachment 2:

Crosswalk for ISO 9001 v ANSI/E4

Quality Management Plan

Comparison Matrix for ISO 9001 and ANSI/E4

ANSI/E4

	Part A-Management and Organization										Part B-Environ. Data				
	2.1 Management & Org	2.2 Quality System & Description	2.3 Personnel Qualifications & Training	2.4 Procurement	2.5 Documents & Records	2.6 Computer Hardware & Software	2.7 Planning	2.8 Implement Work Procedures	2.9 Assessment & Response	2.10 Quality Improvement	3.1 Planning & Scoping	3.2 Design of Data Collection	3.3 Implementation	3.4 Assessment and Response	3.5 Assessment of Data Usability
ANSI/ASQ ISO 9001	1 Management Responsibility	X	X												
	2 Quality System		X												
	3 Contract Review						X	X			X				
	4 Design Control						X			X					
	4.5 Design Output						X			X					
	4.6 Design Review						X			X					
	4.7 Design Verification						X			X					
	4.8 Design Validation						X			X					
	4.9 Design Changes						X			X					
	5 Document and Data Control					X									
	6 Purchasing			X											
	7 Ctrl of Cust-Supp Product							X	X						
	8 Product ID and Trace							X	X						
	9 Process Control							X	X						
	10 Inspection and Testing							X	X		X				X
	11 Ctrl of Insp. Meas. Test Eq							X	X						X
	12 Inspection & Test Status								X						X
	13 Control of Non-cnfr Prod.								X						X
	14 Corrective/Prev Action								X						
	15 Handling, Storage, Packaging, Pres, Deliv.								X					X	X
16 Contr of Qual Rcrds					X	X									
17 Int. Qual. Audits								X					X		
18 Training			X												
19 Servicing								X					X		
20 Statistical Procedures										X				X	

Attachment 3:

Environmental Technology Verification (ETV) QA/QC Data Forms

Environmental Technology Verification (ETV) Testing QA/QC Data

ETV CCEP QMP
Revision No. 0
December 21, 1998
Page Attachment 3-2

Demo Plan #: _____ Run #: _____ Date: _____

General Equipment Information

Type of Spray Gun Used	
Manufacturer	
Model Number	
Type of Feed	
Date(s) Used	

Special Manufacturer Recommendations/Instructions for Use:

Other Observations (start-up, clean-up, ergonomics, etc.):

Environmental Technology Verification (ETV) Testing QA/QC Data

ETV CCEP QMP
Revision No. 0
December 21, 1998
Page Attachment 3-3

Demo Plan #: _____ Run #: _____ Date: _____

*****INCLUDE UNITS FOR ALL DATA RECORDED*****

Ambient Factory Conditions

Date	
Trial Number	
Factory Temperature (°F)	
Factory Relative Humidity (%)	
Booth Temperature (°F)	
Booth Relative Humidity (%)	
Factory Air Pressure (psi)	

Panel Pretreatment Conditions

Date Pretreated	
Run Number	
Zinc Phosphate Settings	
Dry Off Oven Temperature (°F)	
Dwell Time in Dry Off Oven (min.)	

Observations:

Environmental Technology Verification (ETV) Testing QA/QC Data

ETV CCEP QMP
Revision No. 0
December 21, 1998
Page Attachment 3-4

Demo Plan #: _____ Run #: _____ Date: _____

Paint Preparation

Prepared by: _____

Date: _____

Time: _____

Name of Paint as it appears on the Can: _____

Type of Coating: _____

Are Product Data Sheets Available? _____

Material Safety Data Sheets (MSDS)
Available? _____

Was Paint Premixed? _____

If not, Paint Ratio: _____

As per? _____

Volume of Paint: _____

Volume of Catalyst: _____

Volume of Reducer: _____

Reported VOC Content: _____

Lab Analyzed VOC Content: _____

Lab Analyzed Percent Solids: _____

Paint Temperature (°F): _____

Viscosity: _____

Density: _____

Time between preparation and application: _____

Environmental Technology Verification (ETV) Testing QA/QC Data

ETV CCEP QMP
Revision No. 0
December 21, 1998
Page Attachment 3-5

Demo Plan #: _____ Run #: _____ Date: _____

Other Paint Observations (additional thinning required, special instructions, texture, etc.):

Process Conditions

Trial Number	
Date	
Time	
Substrate Coated	
Substrate Temperature (°F)	
Dimensions of Product	
Number of Products per Rack	
Number of Racks per Run	
ID of panels on racks	
Booth Air Velocity	
Gun to Target Distance	
Gun Traverse Speed	
Number of Passes	
Percent Overlap	
Vertical Drop Between Passes	
Dwell Time Between Passes	
Target Dry Film Thickness	
Paint Flow Rate	
Paint Pressure Entering Gun	

Environmental Technology Verification (ETV) Testing QA/QC Data

ETV CCEP OMP
 Revision No. 0
 December 21, 1998
 Page Attachment 3-6

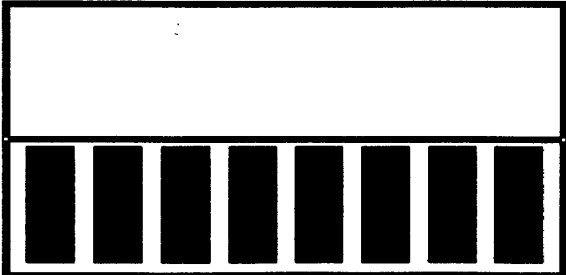
Demo Plan #: _____ Run #: _____ Date: _____

Atomizing Air Pressure (psi)	
Pot Pressure (psi)	
Output Air Pressure (Cap/Air Horns)	
Flash Time (Booth to Oven)	
Oven Temperature (°F)	
Dwell Time in Oven (min.)	
Visual Appearance: Panels	
Visual Appearance: Overall Run	

Process Observations

(Such as preparation, utilities, spray pattern, etc.).

Booth Air Velocities

	Reading Location	Velocity
	Location #1	
	Location #2	
	Location #3	
	Location #4	