

## FOREWORD

The purpose of this Quality Program Manual is to describe E.A. Breeden's Quality Program to be applied to the construction or modification of food facilities (or designated portions thereof) which require a Quality Program meeting Project Specifications and the FDA requirements for compliance with Current Good Manufacturing Practices (cGMP). This Quality Program Manual shall provide an efficient and effective Program meeting Owner/Engineer specifications and requirements.

Validation efforts performed by E.A. Breeden as required in the scope of Work shall be limited to the implementation of Installation Qualification (IQ) and Operational Qualification (OQ) Protocols.

This Quality Program can be amended or modified to meet the needs of Owner/Client requirements that are compatible with the Quality activities and procedures found within.

This Quality Program is to be implemented at the project level where quality related activities are accomplished. Personnel on the project levels using this Manual shall be familiar with and have a working knowledge of this Manual.

## **Project Quality Control Program**

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**SECTION I**  
**ORGANIZATION**

1.0 Purpose

1.1 To describe E.A. Breeden's quality organization at the project site and the responsibility of project personnel.

2.0 Authority and Responsibility

2.1 E.A. Breeden's personnel assigned quality related functions as part of the quality system shall have the responsibility, authority, and organizational freedom to identify, evaluate and recommend or provide solutions to quality problems.

2.2 The following quality related responsibilities shall be performed:

- a. The General Superintendent represents the company in project construction matters. Assures quality construction is completed in compliance with plans and specifications within an approved schedule estimate. Provides interpretation of technical information from owner/engineer or suppliers and translates this information into workable field procedures or plans for the construction forces.
- b. The Purchasing Agent/office Manager represents the company in project procurement matters. Assures services, materials and equipment are purchased only from approved and qualified vendors and suppliers;
- c. The Quality Control Representative represents the project in all Quality assurance matters. Assures compliance with all standards, codes and specifications through review of technical documents, inspection, examination and test procedures.
- d. Subcontractors, suppliers, or service organizations may be contracted to supply items or perform fabrication, construction work, testing: or other services. These organizations shall be evaluated, as necessary, to assure their capabilities comply with requirements of specifications, codes and standards.

## 1.0 Purpose and Scope

1.1 This quality program Manual sets forth the methods and controls to be employed by E.A. Breeden for planning, organizing, implementing, evaluating and maintaining a Quality Program that can be applied to food projects.

It provides the guidelines and methods for performing inspection and tests associated with components, systems, and assuring that these activities are properly documented in compliance with the procedures.

The controls described in this Manual shall be implemented at predetermined points to detect and correct deficiencies, and to document achieved quality throughout the project.

The Quality Program described in this Manual covers the inspection and test activities that E.A. Breeden is contracted to perform on those projects.

### References

- 2.1 ANSI B31 .I; Power Piping
- 2.2 ANSI B31.3; Process Piping
- 2.3 ANSI B31.9; Building Services Piping

## 3.0 General

The E.A. Breeden Project staff shall establish a Quality Program consistent with the requirements as set forth herein and shall assign a competent, knowledgeable individual at the site to be responsible for program compliance utilizing E.A. Breeden's contractors/suppliers, Quality Control Programs and/or qualified nondestructive examination to assure conformance to quality requirements.

E.A. Breeden is responsible for revising and implementing this Quality Program as appropriate to fit a project contractual scope and assure that the quality of items and services provided meet the applicable requirements of the Client designated regulations, codes, standards and technical documents. Requirements and criteria shall not be interpreted in a manner that will result in duplication of work effort.

Although E.A. Breeden may delegate or subcontract quality inspection and test activities, including materials testing and nondestructive examinations to other organizations such as independent testing laboratories, the Company shall retain final responsibility for the adequacy of these activities.

E.A. Breeden shall furnish, or provide access to project related quality documents, records, material samples and other items required by the Client. The Client shall have access to E.A. Breeden, its subcontractor's and supplier's facilities, materials and documents.

Project quality activities shall be applied to the extent and degree consistent with the items' importance.

This manual will be implemented at the project level by the use of pertinent project procedures that identifies the use of an appropriate forms based on the requirements of Owner/Client specifications.

### 3.1 Definition

3.1 a. Quality Control - Comprises those actions related to the physical characteristics of a material, structure, components or system that provides the means to verify the quality of the materials, structure, components or system to predetermined requirements.

### 4.0 Description of the Program

When E.A. Breeden is contracted to custom manufacture and installs a system used in the production of food and drugs for human use, it engages in an activity that falls under the Good Manufacturing Practice (GMP). This program documents the installation procedures require to meet those principles.

The Quality Representative is responsible for administering and maintaining the Project Quality Program including:

- ~ Develop and maintain the necessary staff to competently and efficiently perform Quality activities;
- ~ Review project technical documents for quality criteria and requirements for performing inspections and examinations;
- ~ Monitor of project activities to assure compliance with established procedures, practices and standards;
- ~ Develop and/or review special process procedures and instructions for inspection, examination and testing;
- ~ Maintain and control the in-process and completed quality-related records required on the project;
- ~ Audit subcontractor quality programs to verify the integrity of work being performed;
- ~ Report significant quality problems to project management and Corporate Quality Assurance Manager as appropriate;
- ~ Determine requirements for qualification, certification and performance evaluation of Project Inspection and Test personnel;
- ~ Coordinate day to day quality activities, progress and problems with the Project Manager and cognizant project department heads.
- ~ Maintain good communications and coordination with the client, state, and federal regulatory authorities, subcontractors, suppliers, and when necessary, the authorized inspection agency.
- ~ Monitor, review and evaluate the development, implementation and effectiveness of subcontractors and suppliers programs, methods, procedures and personnel;

### 3.0 Quality Program

3.1 The Project Manager is responsible for and delegated the requisite authority to:

- ~ Develop, coordinate, implement and monitor Project Quality Programs in accordance with this Manual;
- ~ Identify and establish personnel prerequisites, responsibilities, and tasks;
- ~ Evaluate effectiveness and performance of Project Quality Programs and personnel;
- ~ Report quality achievements and problems to Process Division Management;

3.2 A Quality Representative shall be designated for the Project. This Quality Representative may be in a full time quality role or may perform other tasks depending on the size and complexity of the Project. The Quality Representative functionally reports directly to the Project Manager but is free to communicate with and ultimately reports to the Corporate Quality Assurance Manager in matters that affect quality. The Quality Representative is delegated the requisite authority and responsibility for implementing the Project Quality Program. The Quality Representative has the freedom to identify quality related problems and initiate, provide and/or recommend solutions. The Quality Representative has the authority to stop work at the project when adverse quality conditions exist and proper corrective action is not being taken in a timely manner.

### 3.3 Supervisor for Quality Inspection

- ~ Coordinate, verify and document site acceptance inspections and examinations performed at established hold points, or witness and verify inspections and tests performed by others in accordance with established contract requirements and criteria;
- ~ Periodically verify the qualifications and certifications of personnel performing special process, nondestructive examinations, inspections or tests;
- ~ Verify that certifications, records, data and reports are accurate, complete, identified, legible and reproducible;
- ~ Assure that discrepancies are documented and reported;

### 4.0 Inspection. Test. and Operating Status

- 4.1 Provisions shall be made and implemented for identifying and maintaining the inspection and test status of designated items from the receipt of those items and materials through installation, testing and final acceptance.
- 4.2 Item identification and inspection status will be shown by means of attaching name plates, labels, tags and/or marking and stamping on the item or material.
- 4.3 Items and materials found to be discrepant will be reported.

## SECTION II

### Procurement

#### 1.0 Purpose

1.1 To describe the methods utilized in the procurement of materials, equipment, items, or services.

#### 1.0 Responsibilities

2.1 Any E.A. Breeden supervisory person may initiate a Purchase Requisition for material, equipment, items, or services .

2.2 Project Superintendent is responsible for reviewing and approving Purchase requisitions and associated technical documents, including material specifications and special processes, used in the procurement process.

2.3 Project Purchasing is responsible for processing the approved Purchase Requisitions, identifying qualified suppliers or subcontractors, and selecting suppliers or subcontractors with whom the Purchase Order is to be placed.

#### 3.0 Procedure

3.1 When the need for an item, material, equipment, or service is identified, a Purchase Requisition shall be prepared. Necessary information, drawings, or applicable technical requirements are to be included with the Requisition.

3.2 Purchasing shall receive the approved Requisition. Purchasing shall identify and evaluate potential suppliers and select a list of qualified bidders. This list shall take into consideration the Owner/Client supplier/subcontractor preferences.

3.3 Purchasing shall coordinate with Quality Representative to ensure supplier quality documentation and shop surveillance requirements are incorporated in the purchase requisition prior to award of purchase order or subcontract. It is very important that the documentation requirements are very clearly defined and understood upfront.

3.4 The Quality Representative shall periodically monitor Purchase Orders to verify conformance to the conditions of the Purchase Requisition and Project Specifications. Particular attention shall be given to assuring that all appropriate documentation, i.e. certificates of conformance (C of C's) Certified mill test reports (CMTR'S).



3.5 Purchasing and Accounting shall not make final payments or release of retention until it has been verified by management or the Quality Representative that all required documentation has been received and is acceptable. The importance of this documentation cannot be ignored! Trying to obtain this documentation after final payment is very difficult. A copy of the signed final acceptance of the Receiving Report is required by accounts payable prior to release of final Payments or retention.

### 3.6 Procurement Control

3.6.1 Subcontracts and purchase orders for designated items and changes thereto, for which E.A. Breeden is responsible shall be reviewed by the Quality Representative. Procurement documents shall identify the quality documents to be prepared and submitted, such as:

- ~ Quality Control Manuals;
- ~ Drawings and specifications;
- ~ Work Process, inspection and test plans and schedules;
- ~ Fabrication/Construction Process Controls;
- ~ Special Process and nondestructive examination methods and procedures;

3.6.2 The Quality Representative's review and approval of procurement documents for permanent plant items and changes are, as necessary, to assure that appropriate quality requirements are extended to subcontractors and suppliers.

4.0 At time of receiving inspection, the Quality Representative shall verify that material or item identification has been maintained and document this inspection on a receiving report. At other inspection points, the Quality Representative shall monitor that material or item identification has been maintained throughout fabrication and installation.

4.1 Critical material shall have the manufacture's unique heat/lot number on each piece of material. This heat/lot number or a material control number shall be transferred to the portion of the material to be cut prior to cutting. Any Piece of Critical Material found with out a unique heat/lot or material control number shall be scrapped. If the piece or pieces of Critical Material found with out a unique heat/lot or material control number can not be scrapped immediately, it shall have a Hold Tag applied to prevent use prior to being scrapped.

4.2 For Non Critical material, specifically piping a color coding system may be used. Piping or tubing shall have a color coded stripe painted along it's entire length so that any pieces cut from the material will clearly identify the type of material of the cut portion. A copy of the color coding system shall be posted in cutting any fabrication areas utilizing these materials. If the material requires traceability of the manufacture's unique heat/lot number on each piece of material. This heat/lot number or a material control number shall be transferred to the portion of the material to be cut prior to cutting.

## 5.0 Control of Purchased Material. Equipment and Services

5.1 E.A. Breeden shall select subcontractors and suppliers for construction items, work and services on their demonstrated capability to provide a quality product or service on time, at a reasonable cost. Purchasing shall maintain an up-to-date list of trade subcontractors, suppliers and support service companies used on the Project for information purposes.

5.2 As required inspections will be performed to assure that items received have not been damaged in shipment, are properly identified and documented.

5.3 Review and verify documents required by the Purchase Order such as certifications, test reports and inspection and test data are complete and legible before accepting items for use or storage.

5.4 Acceptable materials and items may be identified as to the inspection status by an inspection "Accepted" tag attached to the item and processed to a storage or construction area for use. The Quality Representative shall ensure that the identification and status of materials or items is properly documented on a Receiving Report.

5.5 Materials or items that are found to be damaged upon receipt or supplier-generated documents that are incomplete or in noncompliance with purchase order requirements, shall be identified with a "Hold" tag or withheld and segregated from further use.

## 6.0 Handling. Storage and Shipping

6.1 Instructions for site storage, preservation, handling, cleanliness and control of items and equipment shall be developed by Project superintendent

6.2 When required by the Client's equipment specifications, special preservation and storage instructions will be prepared, and implemented by client. These instructions shall define the special storage requirements such as protective covers, materials, equipment and gages necessary for maintaining, servicing, preserving and checking such as inert gas or desiccants and other specified environmental conditions.

6.3 Fabrication and shipping of long lead time items and equipment from the manufacturer is the responsibility of the client's designated representative and the manufacturer.

6.4 Field Quality Inspection shall periodically monitor storage areas and provide surveillance of storage, maintenance, preservation, and handling activities to assure compliance with requirements.

## **SECTION III**

### **MATERIAL CONTROL**

#### **1.0 Purpose**

1.1 To describe the methods for identification and control of materials and items from receiving inspection through fabrication and construction to final installation. This control applies to materials and items whose identity must be maintained throughout construction activities.

#### **2.0 Definitions**

2.1 Materials are classified as either Critical Material are those material that will or potentially may come into contact with sterile products (wetted parts). All other materials are classified as Critical Material shall be stored and secured separately from all other 'materials and access to these materials shall be restricted.

#### **3.0 Responsibilities**

3.1 The General Superintendent are responsible for the proper identification and marking of materials and items within their areas of responsibility.

3.2 The Quality Representative is responsible to verify the identification and documentation of materials and items at receiving inspection and to monitor for proper identification at inspection points.

3.3 Subcontractors of E.A. Breeden shall have a similar system of material control and this system/procedure shall be submitted to E.A. Breeden for approval prior to receiving of materials. The Quality Representative shall verify the subcontractor's compliance with the approved system/procedure.

#### **4.0 Procedure**

4.1 The requirements for the identification and documentation of materials and items shall be included in the Purchase Order and specifications.

4.2 Correct material identification and documentation shall be verified at receiving inspection. Material that does not match the Purchase Order, does not have Certified Mill Test Reports/Certificates of Conformance, if required, or is damaged shall have a Hold Tag applied. This material shall be isolated from acceptable material and documented in accordance with Sections VI & X.

4.3 The General Superintendent and Field Engineers shall periodically monitor to ensure that only accepted and properly identified materials and items are used for fabrication, construction and installation.

## SECTION IV

### **RECEIVING INSPECTION**

#### 1.0 Responsibilities

1.1 The Quality Representative or his designee shall perform receiving inspection and any other necessary associated actions (material overchecks, review of documentation) to assure compliance with the procurement documents and specification requirements.

1.2 Warehousing or applicable subcontractors are responsible for the handling and storage of incoming material, equipment, and items to prevent damage, deterioration, and unauthorized release or issue.

#### 2.0 Procedure

2.1 Client supplied materials and items shall be received, inspected and handled in the same manner as E.A. Breeden's Procured items.

2.2 Subcontractors materials shall be handled in a similar method as outlined above and shall be monitored for compliance by the E.A. Breeden Representative.

## SECTION V

### **INSPECTION AND TESTING**

#### 1.0 Purpose

1.1 To describe the methods used for performing inspections and tests to verify and document the fabrication, construction and installation of items, equipment, and materials.

#### 2.0 Responsibilities

2.1 The Superintendent is responsible to develop construction control procedures or methods as required to perform the activities required by the contract and specifications.

2.2 The Quality Representative is responsible for establishing the specific methods, procedures and instructions for inspecting, testing, monitoring and documenting construction activities. The Project Quality Representative shall also perform, document or monitor inspections and/or tests as required.

2.3 The General Superintendent are responsible for assuring that all inspections required by local, state or federal agencies are performed in a timely manner and the required inspection report documentation from these agencies are provided to document control for turn over to the client.

#### 3.0 Procedure

3.1 The Quality Representative shall monitor on-going activities to assure required inspections and tests are performed and documented.

3.1.1 If it is necessary to use the services of a Material or NDE subcontractor to perform specialized material and NDE tests, these subcontractor activities shall be monitored to assure compliance to technical specifications and contractual requirements.

3.2 When construction activities reach an inspection or test point, the Quality Representative shall be notified so that the designated inspection or test can be performed or coordinate the inspection/test with the Client. The results of these inspections shall be documented on an Inspection Report, Protocol, or Check List. The performance of inspections or tests may be documented on a form developed specifically for that inspection or test. These inspections and/or tests are to be performed in a manner to provide for a minimum of work stoppage.

3.3 Inspection of work activities of subcontractors will be performed either by E.A. Breeden's Quality Representative or Independent Inspection personnel provided by the subcontractor's organization subject to approval by E.A. Breeden and reporting to E.A. Breeden. Subcontractors with technical expertise and inspection capability may be responsible for performance of inspections as identified in the scope of their subcontract if specifically approved to do so in advance by E.A. Breeden and the Owner/Client. The E.A. Breeden Quality Representative will monitor performance and documentation of these inspections. For other subcontractors, the E.A. Breeden Quality Representative or authorized representative may perform required inspections. The E.A. Breeden Quality Representative shall monitor all quality related activities in order to assure that inspections required are performed properly and documented.

## SECTION VI

### SPECIAL PROCESS CONTROL

#### 1.0 Purpose

1.1 To describe the methods and Procedures to be used for the control of Special Processes such as Welding, Nondestructive Testing, Heat Treatment, and Pressure Testing.

#### 2.0 Responsibilities

2.1 Procedures describing Special Processes shall be prepared and reviewed under the direction of Project Engineering and when contractually required, approved by the Owner / Engineer.

2.2 Quality Representative and the General Superintendent shall assure the proper implementation of the special process procedures, workmanship, controls, inspection, and documentation within their respective areas of responsibility.

#### 3.0 Procedure

3.1 Procedures and instructions necessary to define and control special processes such as welding, stress relieving, heat treating, cleaning, nondestructive examination and testing will be reviewed by Project Engineering and when contractually required and approved by Client. These special process procedures shall be reviewed to assure that the quality requirements and inspections are incorporated and acceptance criteria for inspecting, testing, and documenting the activity are defined as required.

3.2 Qualification requirements of the personnel performing the tasks, methods and documentation requirements.

##### 3.3.1 Welding

3.3.1.1 All welding shall conform to requirements of contractually specific codes and standards.

3.3.1.2 Quality Representative shall select from those welding procedures that are approved by Corporate Quality Assurance and are to be used in the project work. Welding Procedure Specifications (WPS) have been qualified by Quality Assurance by the preparation of test coupons and the testing of these specimens. Tests have been recorded and certified by the Corporate Welding Engineer on the Procedure Qualification Record (PQR). The Welding Procedure Specifications may be amended to be project specific. These Welding Procedure Specifications shall be maintained at the project and readily available to the Client, supervision, and craft personnel as necessary.

3.3.1.3 Welding Procedure Specifications and Procedure Qualification Records used at the Project shall be available for review and approval if required by the Owner/Engineer.

3.3.1.4 Welders and welding operators producing welds shall be tested and qualified in accordance with the requirements of applicable Codes and Standards. Records of qualifying tests for welders and welding operators shall be documented and kept on file by the Quality Representative or Project Engineer for all welders including subcontractors. Welders shall be issued stamps to uniquely identify their welds.

3.3.1.5 The General Superintendent or subcontractor's General Superintendent shall maintain an up-to-date log of qualified welders and provide a copy of these lists to the Quality Representative for monitoring of welding. This log shall include the welder's stamp number, weld procedure or procedures for which he is qualified for and other welding data including process, materials, thickness or position limitations.

### 3.3.2 Weld Rod Control

3.3.2.1 The storage, handling and issue of welding material shall be controlled by the General Superintendent and monitored by the Quality Representative. Welding materials if not Owner/Client supplied shall be purchased by Purchasing, receipt inspected by Project Quality Representative or designee, and handled and stored by Warehousing personnel.

3.3.2.2 Low Hydrogen electrodes shall be stored in temperature controlled weld rod ovens at a temperature of 250 degrees F +/- 25 degrees F. Other electrodes, weld filler metals and fluxes shall be stored in clean, dry, locked storage.

3.3.2.3 Only that amount of weld rod that can be conveniently stored in the portable rod ovens will be issued at any time. Low hydrogen electrodes shall not be issued for a period of more than four (4) hours if portable rod ovens are not used. Weld rod that has been contaminated or that has lost its identity shall be destroyed. At the end of each working shift, unused weld rod shall be returned to rod storage for reconditioning, overnight storage or destruction.

3.3.2.4 Subcontractors shall have a similar approved procedure in place that shall be monitored for compliance by the E.A. Breeden's Quality Representative.

### 3.3.3 Nondestructive Examination

3.3.3.1 Nondestructive Examination may be supplied by the Owner/Client, performed by E.A. Breeden Personnel or subcontracted to an independent testing laboratory. The Project Quality Representative shall monitor the performance of such work.

3.3.3.2 All personnel performing Nondestructive Examination, shall be trained, tested, qualified and certified in accordance with AS NT - TC-IA, the Companies Written Practice, and to the requirements of applicable Codes and Standards.



### 3.3.5 Pressure Testing

3.3.5.1 Pressure Testing procedures have been developed and are available to Project Engineering. These procedures shall be implemented by construction supervisory personnel. Acceptance inspection and testing shall be monitored and verified by the Quality Representative. The Owner/Engineer shall be notified for witness of final pressure testing.

## 4.0 Test Control

4.1 E.A. Breeden Quality Representative is responsible for assuring implementation of approved test procedures and instructions for proof tests, equipment checkouts and final acceptance test of components, equipment and systems.

4.2 Acceptance tests shall be witnessed and verified by the Field Engineer Quality Inspection and when required by the Client's Representative to assure tests are performed in accordance with approved procedures and instructions, meet requirements and are properly documented.

**E.A. Breeden**

**TYPICAL PROJECT RECORDS LISTING**

<u>Title</u>	<u>Responsible Department</u>
Purchase Orders/Subcontracts	Purchasing
Receiving Reports	Purchasing
Material Certifications	Quality
Certificates of Compliance	Quality
Inspection/and Test Records	Quality
Personnel Qualification Records Superintendent/Quality	General
Vendor Supplied Information (As requested)	Purchasing

Any other records required by the job specifications will be added to this list. Latest revision of drawings, specifications and field changes received at time of completion of project or work activity. Operating Manuals, Parts Lists, Assembly Drawings, etc.

## SECTION VII

### **PROJECT QUALITY RECORDS**

#### 1.0 Purpose

1.1 To describe the methods and procedures for the accumulation, maintenance, and retention of project quality records.

#### 2.0 Responsibilities

2.1 Each individual department (Engineering, Purchasing, and Quality) is responsible for the accumulation and retention of its working and completed Project records.

#### 3.0 Procedure

3.1 At the beginning of the Project, a list of required Project Records shall be compiled. This list represents those records that are to be accumulated, maintained, and retained until the Project's completion.

3.2 As the records are initiated, they are to be retained by the using department. Upon completion, the records shall be reviewed by the using department for completeness and accuracy.

3.3 Project records are to be protected against damage/deterioration and loss. Project records whether in process or completed shall be available for review by the Client's Representative.

3.4 At Project completion, the records shall be processed per contractual agreement, maintained by E.A. Breeden or turned over to the Client's Representative.

