U.S. DEPARTMENT OF JUSTICE
Federal Bureau of Prisons

PROGRAM STATEMENT
Quality Program Manual

Approved by	William K. Marshall III Director, Federal Bureau of Prisons
DPI	FPI
Number	8340.12
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Summary of Changes

Program Statement Rescinded:

- 8340.09 Quality Program Manual (6/22/2017)

Changes:

- Removes language falling under other Federal Prison Industries (FPI) branches, program statements, or standard operating procedures.
- Updates course requirements quality representatives must meet, timeframes for completion, and clarifies the source of funding for trainings.
- Adds a requirement for the Chief, Corporate Quality Branch, to establish a system for reporting nonconforming product, corrective actions, and internal quality audits to the Assistant Director (AD), FPI or designee.

1. PURPOSE AND SCOPE

To establish quality standards, guidelines, and corporate procedures for Federal Prison Industries (FPI).

FPI quality systems will be designed to collect quality-related data and use it to:

- Improve operations.
- Reduce costs.
- Increase reliability.
- Provide total customer satisfaction.

a. **Program Objectives.**

- The quality of FPI products and services will meet or exceed customer expectations.
- The cost to FPI of repairing or replacing products will be minimized.
- Quality-related data will aid in continuous improvement of FPI products, services, and operations.

b. **Institution Supplement.** None.

Table of Contents

1.0 MANAGEMENT RESPONSIBILITY

1.1. QUALITY PRINCIPLES

Federal Prison Industries (FPI) takes great pride in teaching inmates good work ethics and marketable job skills to provide our customers with high-quality goods and services priced competitively and delivered on time. We are committed to complete and continual customer satisfaction.

Three core principles form the foundation of FPI's quality program:

- Ultimately, it is the customer who decides whether an item is of acceptable quality. Every effort will be undertaken to ensure total customer satisfaction, even if it may cause extra cost for FPI.
- Quality must be built into FPI's products and services. This is accomplished primarily through clearly defined and well-designed processes and effective training of staff and inmates.
- Quality is everyone's responsibility. Everyone is expected to improve operations continuously to provide the highest quality products and services at the lowest possible cost.

1.2 ORGANIZATION

1.2.1. **Responsibility and Authority.** The Chief, Corporate Quality Branch, or in their absence, the corporate quality representative, is responsible for the corporate quality program and maintenance of corporate quality policies and procedures.

The corporate quality representative, under the direction of the Chief, Corporate Quality Branch, administers the corporate quality program and provides technical advice and assistance to other FPI staff in matters related to quality.

The quality representative is responsible for the overall integrity of the quality system at the respective FPI location. If a quality representative position does not exist to oversee a factory, the factory's Operations Manager may appoint the Factory Manager to this responsibility.

The quality representative and Factory Manager are responsible for ensuring the duties and responsibilities outlined in the local Quality Management System (QMS) are in accordance with the corporate quality program and are well defined and understood by all staff.

The Operations Manager will delegate one position to be responsible for implementing and managing the quality system. Regardless of official duty title, this position will be identified throughout this program statement and in the local QMS manual as the quality representative.

The Operations or Program Manager have the authority to delegate any Factory Manager duties identified in this program statement to other staff, except the quality representative. When applicable, delegation of these duties must be identified in the local QMS manual.

An effective quality system involves all personnel, Central Office and institutional, who manage, perform, or verify work affecting quality. Each individual is responsible for understanding and following the work instructions or procedures for their particular process and can exercise the freedom and authority to initiate action to prevent the occurrence of any nonconforming product, process, and quality system.

Weekly, the Factory Manager and quality representative will walk the manufacturing/ operational floor together to observe and discuss the operations, identifying and addressing any manufacturing/operational issues. These walkthroughs are also referred to as "gemba walks." All issues identified during the walkthroughs will be recorded by the quality representative for improvement analysis.

1.2.2. **Resources.** FPI conducts numerous verification activities to control nonconforming products. The local quality representative will provide training and the necessary equipment to carry out testing and inspection. These activities are normally completed by persons not directly involved in the work performed. If an individual must inspect their own work, objective criteria will be established in the form of inspection instructions and audit checklists.

The Operations Manager is responsible for identifying and providing adequate resources, including the assignment of trained personnel, for management, performance of work, and verification activities, including internal quality audits.

1.2.3. **Quality Representative**. The quality representative at each FPI operation has the authority and responsibility to:

- Ensure the local quality system is established, implemented, and maintained in accordance with this program statement, compliant with the current International Organization for Standardization (ISO) standard, and, when required by the General Manager, certified to the current ISO-9001 Quality Management Systems (QMS) - Requirements standard.
- Routinely report on the performance of the quality system to the Operations Manager for review and as a basis for improving the quality system.
- Identify and record any problems related to the product, process, or quality system.
- Provide assistance to develop solutions to identified problems and verify implementation and the results of these solutions.

- Prevent further processing or shipment of nonconforming products until the deficiency or unsatisfactory condition has been corrected.
- Elevate any dispute concerning product quality between the quality representative and the Operations Manager that cannot be resolved at that level to the Chief, Corporate Quality Branch, for resolution.
- Prepare quality plans.

1.3. REVIEWS AND AUDITS

Reviews and audits are designed to ensure the continuing suitability of the quality system and its effectiveness in satisfying the requirements of the corporate quality policy and objectives.

1.3.1. **Management Review.** The Factory Manager, with support of the management team, conducts annual review of the management system. Additional reviews must be held if a change is made to one or more members of the management team, significant product or contract changes affecting the mission occur, or if it is determined by the management team an additional review would benefit the company. Financial and staff meetings will be considered a part of the management review process. The purpose of the review is to determine the continuing suitability and effectiveness of the system, including quality policy and objectives. Attendance is mandatory for all department managers. In the event a scheduled manager cannot attend, the acting manager must attend. Only one manager per meeting may be absent to hold the meeting. The Factory Manager is responsible for preparing the meeting agenda. Refer to the M-4400 Management System Manual Management Review Input and Output sections 9.3.2 and 9.3.3.

1.3.2. **Internal Audit.** Audits will be conducted as described in Section 17 of this program statement.

1.3.3. **Monthly Review.** The quality representative prepares a monthly Quality Activity Report and attends the monthly Operations/Financial Review meetings to discuss any significant quality concerns identified in the report. This report will include an analysis of quality data as outlined in Section 20.2, including:

- Defect frequency analysis.
- Analysis of scrap and rework costs by defect category.
- Customer complaint summary.

The report will identify any discernable quality trends and the status of any ongoing corrective actions. Copies will be distributed to all factory staff.

2.0 QUALITY SYSTEM

2.1. GENERAL

FPI's quality system is designed to ensure products, processes, and services conform to specified requirements.

Documents supporting the quality system include:

- This program statement, which defines the infrastructure and establishes corporate procedures and minimum requirements for FPI's quality systems.
- The local QMS manual, which is a local document developed and maintained by the quality representative and approved by the Factory Manager and quality representative. It identifies the specific requirements of the local quality system.
- Work instructions prepared for all processes affecting quality. Preparation of work instructions is the responsibility of the staff member in charge of each process, with the quality representative's approval.
- Inspection records maintained in accordance with this program statement and the local QMS manual to document conformance to the quality system.

2.2. QUALITY SYSTEM PROCEDURES

Detailed quality procedures, consistent with this program statement, are to be documented in the local QMS manual. The range and detail of these procedures depends on:

- The complexity of the work.
- The methods used.
- Skills and training needed by personnel performing the work.

The local QMS manual must include:

- Organization chart.
- Factory layouts with identified inspection points.
- Defined responsibilities for supervision of inspection activities (e.g., in-process inspection may be placed under the supervision of production staff).
- Identification of specific inspection documents (i.e., forms, tags, records, etc.) used to document conformance to quality requirements. These include the minimum documents required by this program statement and any others local management determines will ensure the quality system's integrity and effectiveness.
- Any other requirements identified in the various sections of this program statement.

2.3. QUALITY PLANNING

Methods for verifying quality requirements will be defined and documented with written quality plans for all products and services. When groups of products or services are similar, they may be included under a single quality plan. These may be in the form of a narrative description or process flowchart, including all work processes and inspection points.

The development of quality plans must consider:

- The identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources, and skills that may be needed to achieve the required quality.
- Ensuring the compatibility of the production process, installation, servicing, inspection and test procedures, and applicable documentation.
- The updating, as necessary, of quality control, inspection, and testing techniques, including the development of new instrumentation.
- The identification of suitable verification at appropriate stages in the manufacture of a product.
- The clarification of standards of acceptability for all features and requirements, including those containing a subjective element.
- The identification and preparation of quality records.

3.0 FACTORY CONTRACT REVIEW

3.1. GENERAL

Each factory will establish and maintain procedures for customer contract/order review, and the coordination of those activities. These procedures will be documented in the local QMS manual.

3.2. REVIEW

Upon receiving customer contracts/orders, the Factory Manager, with assistance from the quality representative, will:

- Review the legibility and completeness of all documents, including drawings and technical data packages.
- Ensure all requirements are adequately defined and documented.
- Ensure the factory has the capability to meet all manufacturing and quality requirements.
- Obtain copies of supporting documentation, regulations, and standards that will assist in ensuring product or service performance meets customer expectations.

Quality representatives are tasked primarily with ensuring contract requirements are met at the production level, managing customer complaints, verifying raw material conformity, and supporting contract performance metrics.

Any discrepancies must be resolved with the customer through the Customer Service Center or the General Manager or designee, with technical assistance as needed from the respective business group. Contract/order reviews will be documented and retained as described in the Records and Information Disposition Schedule (RIDS).

3.3. AMENDMENT TO A CONTRACT

All required amendments or changes to contracts or orders must be approved by the procuring activity. This is done by a contract modification, amended order, or documented communications received from the procuring activity's contracting officer or customer's representative.

The local QMS manual must identify how these amendments are communicated to appropriate personnel.

3.4. RECORDS

Records of contract reviews will be maintained by the local quality representative. The format of these records will be defined in the local QMS manual.

4.0 **DESIGN CONTROL**

Design of FPI products will be in accordance with customer-controlled or FPI drawings and specifications. Design control requirements are governed by the Program Statement **Product Design Control, FPI**.

5.0 DOCUMENT AND DATA CONTROL

5.1. GENERAL

This procedure describes the necessary controls required to assure the latest applicable documents and data are used for fabrication, inspection, and testing. Documents and data affecting product, process, or price will be controlled. The following are examples of the types of documents and data requiring control.

- Drawings and specifications.
- Inspection instructions/test procedures.
- Standard operating procedures/work instructions.
- Local QMS manuals and procedures.

Specific procedures for controlling these documents will be established and maintained locally and documented in the local QMS manual.

The Factory Manager is responsible for maintaining control of all approved drawings and specifications, work instructions, and standard operating procedures. The quality representative is responsible for maintaining control of all approved inspection instructions, test procedures, and the local QMS manual and procedures.

5.2. DOCUMENT AND DATA APPROVAL AND ISSUE

5.2.1. Initially upon quotation or upon receipt of a customer's order if there is no quote, the Factory Manager obtains the appropriate drawings and specifications. A master copy of these drawings and specifications is maintained in a designated location to ensure appropriate control.

Upon receiving a solicitation, the Factory Manager and quality representative will inspect each drawing package to ensure it is complete, each drawing is legible, and the proper revisions are on hand. Any inconsistencies within each element must be corrected immediately.

The Factory Manager repeats the drawing package inspection upon receipt of contracts or delivery orders to ensure no revisions or changes have taken place.

5.2.2. The Factory Manager is responsible for maintaining and controlling a master copy of the latest process instructions and will inspect each set of instructions to ensure they are legible and complete. All process instructions will contain approval signatures of the Factory Manager and quality representative.

The quality representative is responsible for maintaining and controlling a master copy of inspection instructions and test procedures to ensure they are legible and complete.

The quality representative signs any inspection instructions and test procedures issued to the production floor.

5.2.3. Both the Factory Manager and quality representative establish and maintain a master list or equivalent document control procedure identifying the current revision status of all documents to ensure only approved documents are released to the production floor.

These control procedures will ensure:

- Appropriate documents are available where needed.
- Invalid or obsolete documents are removed from all points of issue or use.
- Any obsolete documents retained for legal or historical purposes are clearly marked "Obsolete," removed from the production floor, and secured appropriately to prevent their unintended use. Documents no longer in use due to completion of a contract are to be secured appropriately, but do not need to be marked "Obsolete."

5.3. DOCUMENT CHANGES AND MODIFICATIONS

Upon receiving drawing or specification revisions from the issuing activity or contract modifications from the customer, the Factory Manager and quality representative will review the document to determine the effect on existing instructions and procedures and approve any required changes. The documented control procedures identified in Section 5.2.3 will include steps to recall, revise, and reissue any documents affected by these revisions/modifications.

6.0 PURCHASING

6.1. GENERAL

The following procedures are established to ensure materials and services received from FPI's vendors conform to specified requirements.

6.2. EVALUATION OF VENDORS

The Contracting Officer is responsible for evaluation and selection of vendors based on quality, delivery, price, and other relevant capabilities. The process for selecting vendors and the types of controls placed upon them is governed by the Program Statement **UNICOR Acquisition Policy** and the Federal Acquisition Regulation (FAR). Quality representatives must take the Federal Acquisition Representative Contracting Officer Representative (FAC-COR) Level 1 course within twelve months of assignment and assist Contracting Officers in the evaluation of vendors through the Contractor Performance Assessment and Reporting System (CPARS).

6.3. PURCHASING DATA

Individuals authorized to generate Requests for Purchase (RFP) and Requests for Contract Action (RCA) will ensure they include a complete item description (i.e., type, class, style, grade, etc.) of the required products or services; specification or drawing number, if applicable; reasonable delivery dates; and any applicable clauses to establish the extent of control exercised over the vendor.

Quality representatives assist in evaluating vendor quality and verifying purchased products but do not manage purchasing activities. Quality representatives' primary role is limited to ensuring quality standards are met and providing quality evaluations for vendor performance. Quality representatives provide vendor evaluations and product verification to support overall quality objectives. They also provide input on quality-related amendments and ensure implementation at the factory level.

6.4. VERIFICATION OF PURCHASED PRODUCT

Verification by the customer will not absolve the vendor of the responsibility to provide an acceptable product, nor will it preclude subsequent rejection by the customer.

7.0 CUSTOMER-SUPPLIED PRODUCT

7.1. GENERAL

The following procedures are established to control the verification, storage, and maintenance of customer-supplied products provided to FPI for use on a contract or order. The customer-supplied products provided by a private sector customer will be identified as Customer-Supplied Products (CSP), and customer-supplied products provided by the government will be identified as Government Furnished Materials (GFM) and will be referred to as such throughout these procedures.

7.2. VERIFICATION

All items received and verified to be CSP or GFM will be promptly processed by the receiving inspector and identified with a tag or label indicating CSP or GFM in bold lettering and the contract number for which it is to be used.

All item discrepancies will be reported immediately in writing to the supplier and the responsible government Quality Assurance Representative (QAR) for verification and disposition instructions when applicable.

The warehouse staff will prepare and issue a receiving report or miscellaneous receipt adequately describing the CSP or GFM received and showing the manufacturers:

- Part number.
- National Stock Number (NSN) (if applicable).
- Receiving document number.
- Quantity.
- Condition.
- Damage description (if applicable).
- Location of storage.
- Date received.
- Who received the item(s).
- Contract or purchase order number.

In addition to the above data, the equipment's serial or identification number and model number are required for Government Furnished Test Equipment (GFTE). The applicable receiving report will be annotated as CSP or GFM.

7.3. STORAGE AND MOVEMENT

Warehouse staff will store the CSP and GFM indoors in a clean, dry area adequately protected and designated by a prominent CSP or GFM marking. All movement of CSP or GFM property to the factory will be authorized by the Factory Manager or designee and supported by proper documentation such as a CSP or GFM receiving report or requisition. For additional guidance, see the Program Statements **FPI Warehouse Procedures** and **Physical Inventories - FPI**.

7.4. MAINTENANCE

A physical inventory of CSP and GFM is performed annually, as required by the customer, or at the termination of the contract, whichever occurs first.

Personnel who perform the physical inventory must not be the same individuals who maintain property records or have control of the property as their assigned position.

Upon completion of the inventory, the quality representative will submit the following results to the QAR or designated representative as appropriate:

- A listing with identified discrepancies, including overages, shortages, and damages disclosed by the physical inventory.
- A written certificate stating the physical inventory of CSP and GFM was completed on the given date and the official contract records are in agreement with the physical inventory.

8.0 PRODUCT IDENTIFICATION AND TRACEABILITY

8.1. GENERAL

Materials and products will be identified by suitable means from receipt and during all stages of production, delivery, and installation. Methods of identification will be established locally and made a part of the local QMS. Local procedures will include traceability to job/work order and product level, as applicable. Traceability provides a system to identify subcomponents from vendors to lot number or purchase order (PO) used in the finished product that may be used in a recall situation.

8.2. PROCEDURES

8.2.1. The initial phase of product traceability begins with the receipt of raw materials. The receiving department inspection will verify material conformance to applicable contract or purchase order requirements. All serviceable material will be clearly identified to indicate its suitability for release. Traceability must be provided to the contract or purchase order and maintained until delivery of the product to the production floor.

8.2.2. Materials on the production floor (i.e., components, subassemblies, assembled products, etc.) will be uniquely identified and traceable, as outlined in the local QMS manual, to the job/work order.

8.2.3. The finished products will be packaged and marked in accordance with the contractual requirements. Unless excluded by contractual requirements, all FPI packaged products will be clearly marked prior to shipment to the customer to provide traceability to the location of manufacture with the job/work order or customer order number.

9.0 PROCESS CONTROL

9.1. GENERAL

Production, installation, and servicing processes directly affecting quality will be planned and documented to ensure all work is performed in a controlled and uniform manner consistent with contractual requirements.

9.2. WORK INSTRUCTIONS

Written work instructions must be prepared for all processes affecting quality. These work instructions will be directly accessible to the personnel performing the work. The work instructions must include:

- Step-by-step process instructions.
- Identification of materials, tools, and equipment required for each operation.
- Methods of monitoring and controlling process parameters, tolerances, and product characteristics.
- Identification of any applicable drawings, specifications, standards/codes, quality plans, and documented procedures.
- Criteria for workmanship that will be stipulated in the clearest practical manner (e.g., written standards, representative samples, or illustrations).
- Instructions for set-up and suitable maintenance of equipment to ensure continuing process capability.
- Approval signatures of the Factory Manager and quality representative.

9.3. SPECIAL PROCESSES

Special processes are those processes for which results cannot be verified fully by the product's subsequent inspection and testing. Deficiencies in such processes may become apparent only after the product is in use. It is imperative such processes are carried out under tightly controlled conditions and only by qualified operators.

All special processes must be identified in the local QMS manual. The work instruction for any special processes must detail operator qualifications and any procedures for continuous monitoring and control of process parameters.

10.0 INSPECTION AND TESTING

10.1. GENERAL

The quality representative must establish and maintain documented procedures for all inspection and testing activities to verify specified requirements for products and services are met. Required inspection and testing activities, and records to document the results, will be detailed in the local QMS manual or in individual quality plans.

10.2. RECEIVING INSPECTION AND TESTING

10.2.1. **Local procedures include:**

- Step-by-step inspection and testing instructions.
- Description of inspection characteristics and acceptance/rejection criteria.
- Identification of tools and equipment required.
- Reference to any relevant standards or specifications.
- Methods of controlling incoming materials to ensure they are not processed or paid for until inspection and acceptance has occurred.
- Sampling plan requirements based on ANSI/ASQC Z1.4-2003 (R2018), American National Standard, Sampling Procedures and Tables for Inspection by Attributes.

10.2.2. **Exceptions.** When incoming materials are needed for urgent production purposes, only the quality representative may approve their release prior to receiving inspection verification. Methods for recording these occurrences and identifying the materials involved will be defined in local procedures.

If rejection of a lot based on results of a sampling plan would cause curtailment of production, the quality representative may approve 100 percent sorting of the lot until a sufficient quantity of supplies has been segregated to assure continued production.

10.3. IN-PROCESS INSPECTION AND TESTING

Local procedures will include:

- Step-by-step inspection and testing instructions.
- Description of inspection characteristics and acceptance/rejection criteria.
- Identification of tools and equipment required.
- Reference to any relevant standards or specifications.
- Methods of controlling in-process material until required inspections and tests have been completed and materials are found to be in conformance with requirements.
- Sampling plan requirements based on ANSI/ASQC Z1.4-2003 (R2018), American National

Standard, Sampling Procedures and Tables for Inspection by Attributes.

10.4. FINAL INSPECTION AND TESTING

10.4.1. Final inspection and testing are the quality representative's responsibility. Local procedures will include:

- Step-by-step inspection and testing instructions.
- Description of inspection characteristics and acceptance/rejection criteria.
- Identification of tools and equipment required.
- Reference to any relevant standards or specifications.
- Methods for controlling finished products to ensure all specified inspections and tests have been performed and the results meet specified requirements.
- Sampling plan requirements based on the ANSI/ASQC Z1.4-2003 (R2018), American National Standard, Sampling Procedures and Tables for Inspection by Attributes series.

No product will be released for packaging or shipment until the final inspection and testing has been performed and documented.

10.4.2. **Finished Goods Re-inspection.** The quality representative and Factory Manager will personally inspect two items of finished goods from the finished goods storage area monthly. Typical inspection characteristics include:

- Conformance to specified requirements (i.e., dimensional, operational, etc.).
- Proper cleaning and packaging of product.
- Signs of deterioration or damage during storage due to improper handling.

The quality representative is responsible for documenting the re-inspection findings and initiating any corrective actions.

10.5. INSPECTIONS AND TEST RECORDS

Local procedures for all inspection and testing activities will detail the format of required forms and records providing evidence the product has been inspected and/or tested and found to be acceptable. The individual responsible for releasing the product for final shipment will be recorded on the inspection/test record.

11.0 INSPECTION, MEASURING, AND TEST EQUIPMENT

11.1. GENERAL

The quality representative is responsible for preparing and maintaining a master list of all inspection, measuring, and test equipment that can affect product quality. All equipment on this master list will be controlled, calibrated, and maintained according to procedures outlined in this section. All calibrated equipment must be traceable to the National Institute of Standards and Technology (NIST) standards. These procedures do not override local institution security procedures relating to the control of test equipment but should be used in conjunction with them.

11.2. CONTROL PROCEDURES

11.2.1. Procedures will be established and maintained for each piece of inspection, measuring, and test equipment on the master list prepared by the quality representative. At a minimum, these procedures will specify:

- Step-by-step procedures for performing calibrations.
- Measurement standards and equipment to be used.
- Required accuracy of the measurement standard.
- Acceptance criteria.
- Action to be taken when results are unsatisfactory.

11.2.2. Measurement standards used for calibrations will be supported by certificates attesting to the:

- Description of the item.
- Calibration source.
- Date of calibration.
- Calibration assigned value.
- Statement of uncertainty.
- Environmental conditions under which the calibration results were achieved.

Measurement standards will be traceable to the NIST standards, and have the accuracy, stability, range, and resolution required for the intended use.

Unless otherwise specified in the order, the accuracy of the measurement standard must be at least four times more accurate (4:1) than the allowable tolerance of the equipment characteristic being checked; (e.g., for an allowable tolerance of two percent, the accuracy of the measurement standard will be 0.5 percent).

11.2.3. Inspection, measuring, and test equipment will be calibrated and used in an environment

controlled to the extent necessary to assure continued accuracy, giving due consideration to temperature, humidity, vibration, cleanliness, and other controllable factors.

11.2.4. Calibration records will be maintained on each piece of inspection, measuring, and test equipment. These records will include:

- Complete equipment descriptions (i.e., model number, serial number, etc.).
- Equipment location.
- Calibration intervals.
- Dates and results of calibrations.
- Next calibration due date.

11.2.5. Prior to issuance for use, and when practical, all applicable measuring and test equipment will have a valid calibration status label. The label must clearly indicate acceptability for use and next calibration due date. Equipment may be recalled at any time during the calibration interval if the unit is suspected of being damaged, defective, or for any other special reason.

11.2.6. The quality representative will establish calibration intervals taking into consideration such factors as:

- Type, purpose, and degree of usage.
- Manufacturers' recommendations.
- Calibration history.

All intervals will be established in terms of calendar time, usage, or both.

11.2.7. All outside sources providing calibration services will meet the requirements of the ANSI/NCSL Z540.3 series. The vendor will supply a certificate of calibration or report with each instrument calibrated containing the following information:

- Manufacturer name.
- Name of instrument.
- Model number.
- Serial number.
- Date calibrated.
- Description of any "out of tolerance conditions" discovered during the calibration of the instrument, and action taken to correct it.
- Statement that the standards used for calibration are traceable to the NIST.

The requirements for calibration performed by NIST or Department of Defense (DoD) calibration facilities do not require a statement of traceability.

11.2.8. Tamper-resistant seals will be affixed to operator-accessible controls affecting the equipment's calibration if moved. This does not apply to equipment enclosure panels, which must be opened and inspected for contraband. If the quality representative chooses to use tamper-resistant seals on such panels, they will be applied after receipt by the warehouse staff and prior to release to the floor. Tamper-resistant seals will be unique in design and will be controlled and applied by the quality representative.

Equipment users will not use inspection, measuring, and testing equipment if the tamper-resistant seal is broken or damaged in any way. Such equipment will be considered void of calibration and returned to the quality representative, who will determine if the equipment is acceptable for use.

11.2.9. Any inspection, measuring, and test equipment found to be out of tolerance will be segregated and/or clearly marked to prevent improper use until the out-of-tolerance condition is corrected.

11.2.10. The quality representative will conduct a thorough investigation when equipment is found to be out of tolerance. This investigation will address any effect on material accepted during the calibration interval on the basis of out-of-tolerance equipment, including notification to the customer when the out-of-tolerance condition is considered significant and the material in question was not subsequently checked with a serviceable piece of equipment.

12.0 **INSPECTION AND TEST STATUS**

12.1. **GENERAL**

The local QMS manual must define the means of identifying the inspection and test status (conformance/nonconformance) of materials and products throughout production and installation to ensure only products that have passed the required inspections and tests are dispatched, used, or installed. Examples of suitable means of identification include, but are not limited to:

- Markings.
- Authorized stamps.
- Tags (i.e., Job History, Reject, Rework, etc.).
- Labels.
- Route sheets.
- Process tickets.

12.2. **INSPECTION STAMPS**

Inspection stamps are used to provide visible evidence of results of inspection activities (acceptance/rejection) on tags, forms, records, etc. These stamps will be issued only to inspectors who the quality representative has trained and certified. Each stamp will uniquely identify the inspector to whom it is assigned.

A record of the assignment of all numbered stamps will be maintained, and an inventory of all issued stamps conducted every six months, including a physical impression of each stamp to ensure its legibility and suitability for continued use. Style and format of inspection stamps and records will be identified in the local QMS manual.

13.0 CONTROL OF NONCONFORMING PRODUCT

13.1. GENERAL

Procedures for control of nonconforming material will be established and maintained locally and documented in the local QMS manual. These procedures will ensure products and materials not conforming to specified requirements will be clearly identified. See Section 12 for additional guidance.

Nonconforming material may not be further processed or shipped until the deficiency or unsatisfactory condition has been corrected. If practical, this material will be segregated from conforming material pending review and disposition.

13.2. REVIEW AND DISPOSITION OF NONCONFORMING PRODUCT

13.2.1. **Receiving Rejection**. The quality representative will examine material received from vendors found to be nonconforming during receiving inspection to confirm the nonconformance. The quality representative will notify the Contracting Officer in writing of the details concerning the nonconforming materials. The Contracting Officer is responsible for contacting the supplier to determine the disposition of these materials. Notification of disposition will be provided to the:

- Quality Representative.
- Factory Manager.
- Business Manager.
- Warehouse Manager.
- Operations Manager.

13.2.2. **Preliminary Review and Disposition**. Materials and products in process found to be nonconforming will be examined initially by the responsible foreman to determine if the nonconformance can be routinely eliminated by rework or requires scrapping. Local procedures and standards will define the criteria for these on-the-spot disposition decisions to the extent practical.

Both the quality representative and the responsible foreman will review all other non- conforming materials and products to determine if it:

- Requires scrapping because it is obviously unfit for use and cannot be economically reworked or repaired.
- Can be resolved by rework to eliminate the nonconforming characteristic.
- Can be used for alternative applications.
- Requires return of the material to the supplier.

- Is repairable (with QAR concurrence, if applicable). A repair procedure is distinguished from rework in that it reduces the effect of the nonconformance but does not eliminate it.
- Can be used as is (with QAR concurrence, if applicable).

Upon completion of rework or repair, nonconforming material will be submitted for re-inspection. If the nonconforming product is repaired or used as is, this decision will be documented on the appropriate inspection record.

13.2.3. **Customer Returns**. Both the Factory Manager and the quality representative will examine items returned by customers to determine disposition. All rework will be performed, inspected, and tested in accordance with written instructions.

All controls described in this program statement and required by local procedures apply equally to customer returned materials (i.e., corrective action, in-process inspection, final inspection, etc.).

13.2.4. **Material Review Board Disposition**. In the event of a dispute between the quality representative and the Factory Manager regarding the disposition of a nonconforming product, the decision will be elevated to a Material Review Board (MRB). The MRB members include, at a minimum, the:

- Quality Representative.
- Factory Manager.
- Operations Manager.
- Representative from the Corporate Quality Branch.

Disposition by the MRB could include all items listed in Section 13.2.2, or the request of a waiver/deviation from the customer.

13.3. REPORTING REQUIREMENTS

The Chief, Corporate Quality Branch, is responsible for establishing a monitoring and reporting system based on appropriate industry benchmarks to provide regular reports about nonconforming product to the Assistant Director, FPI, or their designee. This monitoring and reporting system, detailed in the local QMS manual, should be designed to provide timely information enabling effective management of quality concerns and the prompt identification and correction of nonconforming product trends.

14.0 CORRECTIVE ACTION

14.1. GENERAL

The quality representative is responsible for monitoring, coordinating, and recording all formal corrective actions. Actions will be consistent with the magnitude of problems identified and commensurate with the risks associated with failure to take the actions proposed.

To be effective, corrective actions must address the root causes of nonconformity and potential nonconformity.

Corrective actions must include results indicating if other processes or products were affected by the root cause and what actions were taken to eliminate distribution of identified products.

Any required changes to documented procedures, work instructions, or inspection instructions will be implemented and recorded by the responsible department head upon approval of corrective and preventive actions.

14.2 CORRECTIVE ACTION

14.2.1. **On-the-Spot Corrective Action**. On-the-spot corrective action may be initiated when nonconformity is minor in nature and the root cause is easily identified and corrected, eliminating the need for more formal corrective action and follow-up. All on-the-spot corrective actions will be recorded on the appropriate inspection record. The local QMS manual must contain terms distinguishing qualification for on-the-spot corrective actions from formal corrective action.

14.2.2. **Corrective Action Request**. When more formal corrective action is needed to identify and eliminate the root cause of nonconformities related to a product, process, or quality system, the quality representative must initiate a Corrective Action Request (CAR). Situations typically resulting in the initiation of a CAR include:

- Repetitive on-the-spot corrective actions for the same characteristic.
- Recurring trends of customer complaints for the same problem.
- Significant or increasing scrap and rework costs for a specific defect category.

The decision to initiate a CAR is at the quality representative's discretion. The appropriate staff will:

- Investigate the cause of the identified nonconformities.
- Identify and implement appropriate corrective action.
- Forward a written response to the CAR within three working days of its issuance.

The quality representative will then evaluate the corrective action and follow up to verify the action has been taken and is effective.

14.2.3. **Customer Complaints.** Procedures for handling customer complaints are identified in the Program Statement **Customer Service Center Manual - UNICOR**. Local procedures will establish responsibility for monitoring and following up on customer complaints.

14.2.4. **FPI Form 31: Defective Work/Scrap Report.** The quality representative will generate a Form 31 whenever the cost of a specific instance of scrap or rework exceeds the threshold for abnormal costs. The minimum threshold will be when the cost of a scrap/rework action exceeds 10% of the total planned cost of a job.

Lower thresholds may be approved locally by the Operations Manager. Requests to use criteria exceeding this threshold must be approved by the Corporate Quality Branch. Form 31 thresholds will be identified in the local QMS manual.

A Form 31 is not to be used to report cumulative scrap and rework costs over a period of time or over the life of a job. Scrap and rework costs accumulating over time must be tracked and reported in the monthly quality report.

Upon receiving a Form 31, the appropriate department head will:

- Investigate the cause of the identified nonconformance.
- Identify and implement appropriate corrective action.
- Complete the corrective action portion of the form.

The Form 31 will be returned to the quality representative within three working days of receipt for follow up to verify the corrective action has been taken and is effective.

The quality representative will submit the Form 31 to their respective FPI Business Office to ensure proper accounting for scrap and rework costs incurred.

14.2.5. **Rejected Vendor Materials**. When nonconforming materials are received from a vendor and the quality representative determines the vendor's corrective action is required, they will notify the responsible Contracting Officer to issue a "show cause" notice to the vendor. This notice will request the vendor take corrective action to prevent the nonconformity's recurrence. A written response is required from the vendor. Upon receiving the vendor's response, the quality representative will determine if the action identified is adequate.

14.2.6. **Government Representative Request for In-Plant Corrective Action**. When a government QAR issues a request for corrective action, the quality representative will investigate the deficient condition with the appropriate FPI department head and help develop a corrective action plan to prevent recurrence. Corrective action responses must be submitted on the requesting government agency's form.

The quality representative will follow up to verify the appropriate corrective action has been taken and respond to the QAR's request for corrective action. Copies of the request and response will be sent to the appropriate Operations Manager and the Corporate Quality Branch.

14.3. FAILURE MODE AND EFFECT ANALYSIS

The ultimate goal of an effective quality system must be defect prevention rather than detection. It must provide a mechanism to continuously improve the process of manufacturing and service provision, improve quality and productivity, reduce liability, and thus reduce costs.

Failure Mode and Effect Analysis (FMEA) will be initiated by the Factory Manager and used to determine risk in all processes to minimize variations.

Quality must be built into the product or service through well-designed processes and effective training to minimize variation in the end results of processes. An effective quality system lessens the need for multiple inspection points that increase costs and inhibit product flow. A well-engineered quality program focuses on process control.

14.3.1. **Suggestion Program**. The quality representative will establish and maintain a suggestion program to provide an opportunity for all FPI staff and inmates to identify opportunities to improve operations in accordance with the Program Statements **Awards Program, Incentive Awards** and **Work Programs for Inmates -FPI**.

Copies of FPI suggestion forms will be readily available and suggestion procedures clearly posted in an area accessible to inmates. Individuals whose suggestions are adopted will be appropriately recognized and rewarded.

14.3.2. **Quality Action Team**. Each factory will have a Quality Action Team (QAT) to implement and maintain a quality enhancement program. Members of the QAT will include:

- Factory Manager.
- Quality Representative.
- Applicable FPI staff.
- Inmates.

The objective of the QAT is to continuously improve operations by identifying and resolving

problems and potential problems. The Factory Manager and quality representative are permanent members of the QAT. Other staff and inmates selected by the Factory Manager and quality representative should be rotated occasionally to provide increased familiarity with the continuous improvement process. The QAT will meet at least once every two months.

Ideas for process improvement will be developed by reviewing quality cost reports, defect analyses, and customer complaints to identify areas of high potential payoff, adverse trends, and recurring nonconformities. When a problem has been identified as a candidate for formal problem solving, the QAT will:

(1) **Define the problem.** Each problem will be defined as specifically as possible.

(2) **Prepare process flowchart.** Observe the process and prepare a process flowchart to better understand where the problem is most likely occurring.

(3) **Define, collect, and analyze data.** Develop check sheets to understand graphically when and where problems are occurring and Pareto analyses to further understand the magnitude of the problem.

(4) **Identify potential causes of the problem.** Brainstorm to define as many potential causes as possible. Cause and effect diagrams are a very useful tool to assist in this process.

Potential causes may include:

- Training.
- Environmental factors.
- Equipment.
- Methods.
- Materials.

(5) **Determine recommendations.** Recommended solutions will be based on the identification of the most likely causes of the problem.

(6) **Implement corrective action.** Corrective actions will be delegated to the appropriate department heads for implementation. The quality representative will follow up to verify recommended actions have been taken.

(7) **Review results and revise as needed.** Return to step (3) and determine if the actions implemented have resolved the problem. If not, develop alternative recommendations and implement additional corrective actions until the desired improvement is achieved.

Corrective action recommendations will be recorded in the QAT meeting minutes, with copies distributed to all local FPI staff. Results of preventive action activities will be discussed at the

monthly operations/financial review meetings (see Section 1.3.3).

14.4 **REPORTING REQUIREMENTS**

The Chief, Corporate Quality Branch, is responsible for establishing a monitoring and reporting system based on appropriate industry benchmarks to provide regular reports about corrective actions to the FPI Assistant Director or their designee. This monitoring and reporting system, detailed in the local QMS manual, should be designed to provide timely information that will enable effective management of quality concerns and the prompt identification of corrective action trends.

15.0 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

15.1. GENERAL

Procedures for handling, storage, packaging, preservation, and delivery of materials will be established and maintained locally and documented in the local QMS manual.

The handling, storage, packaging, preservation, and delivery of materials and products will be in accordance with the contractual requirements or drawings/specifications. Absent these requirements, the local standard operating procedures and process instructions apply.

15.1.1. **Handling**. Materials and products will be handled appropriately to prevent damage or deterioration. Appropriate product protection may require the use of:

- Pallets.
- Specialized containers.
- Work platforms.
- Conveyors and other automated transfer systems.
- Pallet jacks, forklifts, and other vehicles.

Handling procedures will be documented in work/process instructions.

15.1.2. **Storage**. Designated areas (i.e., warehouse, shop stock, etc.) will be used for storage of raw materials, subassemblies, and finished goods to prevent damage or deterioration pending use or delivery. These areas will be detailed on the local plant layout.

Receipt to and dispatch from such areas will be authorized through:

- Automated pick-lists.
- Manual requisitions.
- Shipping documents.
- Other automated means as stipulated in financial management policies.

The condition of materials and product in stock will be assessed during internal quality audits (see Section 17).

15.1.3. **Packaging**. Packing, packaging, and marking will be in accordance with contractual requirements, drawings/specifications, or local instructions as applicable. All finished goods must be cleaned thoroughly in a manner appropriate for the type of product. At a minimum, items will be free of dust, dirt, and other contaminants. Packaging and marking will be inspected as either a characteristic of final inspection or as a separate inspection process.

15.1.4. **Preservation**. Staff responsible for designated storage areas will ensure the maintenance of the storage environment to prevent damage or deterioration of materials and products.

Warehouse staff will conduct monthly inspections of all materials with a limited shelf life and document the results. Materials with an expired shelf life will be identified and segregated as nonconforming (see Section 13).

15.1.5. **Delivery**. Warehouse staff will ensure outbound trailers are properly loaded to guarantee the protection of finished products. Shipping procedures will identify responsibility for ensuring customer delivery requirements (i.e., inside delivery, prior notification, installation, removal of debris, etc.) are communicated clearly to the transportation provider.

The quality representative will monitor the performance of transportation providers and recommend corrective measures to appropriate staff when warranted.

16.0 CONTROL OF QUALITY RECORDS

16.1. GENERAL

Quality records provide evidence of conformity with specified requirements and effective operation of the quality system. Pertinent records include documents such as:

- Inspection records.
- Test reports.
- Corrective Action Requests.
- Customer complaint reports.
- Internal audit reports.
- Calibration records.
- Vendor quality records.

Quality records will be legible, readily retrievable, and stored in a manner to prevent loss, deterioration, or damage.

16.2. PROCEDURES

The quality representative will establish and maintain documented procedures for controlling quality records, to include:

- Identification.
- Collection.
- Indexing.
- Access.
- Filing.
- Storage.
- Maintenance.
- Disposition.

These procedures will define retention times of quality records. Records documenting the results of inspection or test activities will be maintained not less than three years, or as required by the customer contract. Retention and disposition of records are governed by the National Archives and Records Administration (NARA) General Record Schedule, and by the Bureau of Prisons (Bureau) Records and Information Disposition Schedules (RIDS).

17.0 INTERNAL QUALITY AUDITS

17.1. GENERAL

Internal quality audits are conducted to determine compliance with this program statement and local procedures, and to ensure the quality system's effectiveness.

17.2. PROCEDURES

The quality representative will develop an internal quality audit matrix to verify compliance with the local QMS manual.

Internal quality audits are coordinated by the quality representative. Audits may be conducted in monthly or quarterly segments, provided all audit elements are checked annually.

Internal audit steps include:

- Review of a random sample of quality records for proper application, preparation, storage, and retention.
- Review of a random sample of work/process instructions for clarity and assessment of whether they include all required elements. (See Section 9.)
- Observation of operations to determine compliance with work/process/inspection instructions.
- Interview of staff and inmates to determine accessibility to and familiarity with work/process/inspection instructions.
- Review of customer complaints and quality costs to highlight potential weaknesses in the quality system.
- Review of materials in production for proper indication of inspection and test status.
- Review of storage areas for proper handling and storage of products.
- Review of training records of production workers and inspectors for timely completion of required training.
- Review of Corrective Action Requests for timely completion and follow-up.
- Review of customer complaints for appropriate action and timely follow-up.
- Review of controls and calibration of measuring and test equipment.
- Review of a random sample of contract review records for compliance with defined procedures.
- Review of documents (e.g., drawings, specifications, work/inspection instructions, quality procedures) for compliance with document control procedures.
- Review of a random sample of purchase requests for evidence of approval by the quality representative.

Selection of audit elements and frequency of audits will be based upon the status and importance of the activity being audited and the inherent risks associated with failure to comply with

documented procedures.

The quality representative selects internal audit team members. Audit team members only audit activities for which they are not directly responsible. Upon completion of audits, the quality representative will prepare a report of findings and submit it to the Operations Manager, with copies accessible to all FPI managers.

Within three working days of submission of the internal audit report, the audit team will meet with the quality representative to identify if corrective actions are required to resolve any deficiencies found.

Within 30 days of submission of the audit report, the review team will reconvene to determine the effectiveness of the corrective actions taken. The quality representative will submit a final report of closure to the Operations Manager when all findings have been corrected.

17.3 **REPORTING REQUIREMENTS**

The Chief, Corporate Quality Branch, is responsible for establishing a reporting system based on appropriate industry benchmarks to provide regular reports about internal quality audits to the FPI Assistant Director or their designee. This reporting system, detailed in the local QMS manual, should be designed to provide timely information that will enable effective management of quality concerns and the prompt identification and correction of deviations from the requirements in this program statement and the local QMS manual.

18.0 **TRAINING**

18.1 **GENERAL**

Personnel performing activities affecting overall quality will be determined qualified based on appropriate education, training, or experience, as identified by local and agency standards.

Supervisors of staff and inmates are responsible for identifying and providing the training needs of all personnel under their supervision. Appropriate records of training will be maintained utilizing document control procedures.

18.2 **QUALITY TRAINING**

18.2.1. **Staff**. Personnel who are hired for quality positions will complete the New Quality Manager Self Study Course within four months of assignment. Interested parties may request to be assigned the course as a routine developmental activity for other employees through the Corporate Quality Manager.

The Corporate Quality Branch ensures the course is updated and available to FPI manufacturing sites.

Newly selected quality representatives will have the opportunity to observe and be taught all aspects of the quality program at another FPI manufacturing facility within six months of reporting for duty. It is recommended the duration of this training be at least one week. This training will be funded by the FPI Training Department.

Requests for this training will be made by the quality representative to the Operations Manager, who coordinates the training through the Corporate Quality Branch.

18.2.2. **Inmate Training**. The quality representative will develop, implement, and maintain a written training program for all inmate inspectors to include, but not be limited to, the following:

- Familiarization with this program statement.
- Local QMS manual.
- Written standard operating procedures for each inspection station.
- Classroom training.
- Training aids for measuring and testing equipment.
- Documentation of inmates' training progress.
- Testing on course content.
- On-the-job training.
- Post-training monitoring as appropriate.

18.3 **OTHER TRAINING**

18.3.1. **Staff**. Procedures for identifying and providing training are contained in the Program Statement **Employee Development Manual**. All staff are responsible for their own career development and are encouraged to seek out continuing education courses or other job-related training to enhance their job skills.

FPI will conduct an annual assessment of its technical training needs and publish a schedule of training classes offered. Staff submit requests through the Factory Manager to attend these classes.

18.3.2. **Inmates**. FPI factory staff will establish and document the minimum education, training, and experience required for each inmate position under their supervision. They must maintain records of completed training as appropriate. The extent and formality of the training required is dependent on the complexity and critical nature of the process as it relates to quality.

19.0 **SERVICING**

19.1. **GENERAL**

Servicing is the after-sale attention provided on FPI products. When servicing is a specified requirement, local procedures will be established and maintained for performing, verifying, and reporting any servicing provided meets the specified requirements.

20.0 STATISTICAL TECHNIQUES

20.1 GENERAL

Statistical techniques are sometimes used to establish control and verify process capability and product characteristics.

Statistical techniques are also used to:

- Establish sample sizes.
- Detect quality trends.
- Establish priorities for corrective action (see Section 14).

20.2 PROCEDURES

20.2.1. **Statistical Process**. The quality representative will identify the need for statistical techniques, such as statistical process control (SPC), as established by contractual requirements or local needs. Where SPC is used, detailed procedures will be documented in the process/work instructions (see Section 9).

20.2.2. **Statistical Analysis**. The quality representative will establish a system to gather information concerning process or product defects and associated costs. This information will be analyzed to perform trend analysis and identify statistically significant opportunities for process improvement. Appropriate statistical techniques include, but are not limited to:

- Control charts.
- Pareto charts.
- Histograms.
- Scatter diagrams.
- Line graphs.
- Cause/effect diagrams.

Appropriate data for analysis includes, but is not limited to:

- Frequency of nonconformity by defect category.
- Cost of nonconformity by defect category.
- Customer complaints.

20.2.3. **Statistical Sampling**. Statistical sampling of inspection lots or batches will be in accordance with contractual requirements. Absent contractual requirements, an appropriate sampling plan, as outlined in the ANSI/ASQC Z1.4-2003 (R2018) series, will be used.

Inspection levels and acceptable quality levels (AQL) appropriate for the production and inspection activity will be:

- Established locally.
- Identified in inspection instructions.
- Documented in inspection records.

REFERENCES

Program Statements
Awards Program, Incentive Awards
Employee Development Manual
Work Programs for Inmates, FPI
Product Design Control, FPI
Customer Service Center Manual – UNICOR
Physical Inventories – FPI
FPI Warehouse Procedures
UNICOR Acquisition Policy

Other References
ANSI/ASQC Z1.4-2003 (R2018), American National Standards Institute/American Society of Quality Control, Sampling Procedures and Tables for Inspection By Attributes
American National Standards Institute/National Conference of Standards Laboratory, and ISO/IEC 17025 (Calibration) (ANSI/NCSL Z540.3)
National Institute of Standards and Technology (NIST)

FPI Forms
Form 31 Defective Work/Scrap Report

ACA Standards
Performance-Based Standards and Expected Practices for Adult Correctional Facilities, 5th Edition: 5-ACI-7A-08, 5-ACI-7A-09, 5-ACI-7A-10, 5-ACI-7A-11, 5-ACI-7A-12

Performance-Based Standards and Expected Practices for Adult Local Detention Facilities, 5th Edition: 5-ALDF-5C-13, 5-ALDF-5C-14, 5-ALDF-5C-15, 5-ALDF-5C-16

Records Retention Requirements
Requirements and retention guidance for records and information applicable to this program are available in the Records and Information Disposition Schedule (RIDS) on the Bureau's intranet site.