Implementing and Maintaining an ISO 9000 System with the IQS Business System

IQS, INC.
19706 CENTER RIDGE ROAD
CLEVELAND, OHIO 44116-3637
(440) 333-1344
(440) 333-3752 FAX
sales@iqs.com E-MAIL
http://www.iqs.com Web

UNDER REVISION

Table of Contents

Introduction

Introduction By IQS

The purpose of this document is to list all the requirements of ISO 9000 and suggest how to implement them within the IQS Business System. The 15 IQS modules as mentioned throughout this document are abbreviated as follows:

IQS Module	Abbreviation	IQS Module	Abbreviation
IQS CUSTOMER™ Customer Management	CUSTOMER	IQS COLLECT™ Data Collection	COLLECT
IQS SYSDOC™ System Documentation	SYSDOC	IQS SPC™ Statistical Process Control	SPC
IQS PRODUCT™ Product Documentation	PRODUCT	IQS NCM™ Nonconformance Management	NCM
IQS PROCESS™ Process Documentation	PROCESS	IQS CORRECT™ Corrective Action	CORRECT
IQS PREVENT™ Preventive Maintenance	PREVENT	IQS SUPPLIER™ Supplier Management	SUPPLIER
IQS CALIBRATE™ Calibration Management	CALIBRATE	IQS QCOST™ Quality Costs	QCOST
IQS INVOLVE™ Employee Involvement	INVOLVE	IQS PPAP MANAGER™ IQS Production Part and Approval Process Manager	PPAP MANAGER
		IQS AUDIT MANAGER™	AUDIT MANAGER

Special Note: Formatting has been altered to differentiate between comments from IQS and the ISO 9000 standards.

ISO 9000 — Italic print in Times New Roman Font

- IQS — Regular print in Arial Font with bullet markings

4.1 Management Responsibility Element

4.1.1 Quality Policy

The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

- SYSDOC inventories existing policy statements for all departments, not just quality. PROCESS can capture department policy, mission and purpose type statements. Both systems handle scheduling and document audits, and change requests for implementation and maintenance.

- INVOLVE provides the capability to execute employee surveys that can further determine understanding and implementation.

4.1.2 Organization

4.1.2.1 Responsibility and Authority

The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

- PROCESS is best suited to handle this task. Every aspect of PROCESS allows the definition of responsibility, either by Title or by Name. Searches can be made that produce a list of responsibilities, without forcing a name, or title, to a job description. PROCESS documents inputs, outputs, customers, and key product attributes. Discussions regarding the best way to get your customer what they want produces the documentation. Then, responsibilities and job descriptions are a powerful report - from a systems view - not an employee view.

- A PROCESS model for Human Resources usually includes a discussion of how to assign responsibilities and the levels of responsibility. Organization Responsibility - Authority can be delegated, but not responsibility. Conformance to standards on the PROCESS variables that provide input for performance-based compensation systems. INVOLVE has a matrix of skills required and job description by Title. PROCESS allows searches by Title, thereby producing on-line job descriptions.

a) initiate action to prevent the occurrence of any nonconformities relating to product, process and quality system;

- The Quality Assurance PROCESS model defines how corrective actions (reactive and proactive) are determined, and the parameters for determining them. PROCESS defines the formal problem solving method. The CORRECT software manages the entire corrective action process. The nonconformance trend, once identified, is assigned to a specific employee for action (reactive). Proactive, continuous improvement is supported by CUSTOMER input, INVOLVE suggestions, INVOLVE project teams, and SUPPLIER input.

b) identify and record any problems relating to the product, process and quality system;

- The Quality Assurance PROCESS model defines how nonconformances are identified (COLLECT - data collected that is out-of-specification, SYSDOC, PRODUCT, PROCESS -

failed audits or audits with findings, and CALIBRATE - failed calibrations) and recorded (NCM). PROCESS defines standard reactions to out of control processes. The NCM software documents the process - disposition, verification and provides information used to determine when corrective action should be taken.

c) initiate, recommend or provide solutions through designated channels;
- Reactive solutions are managed by CORRECT. Proactive solutions are tracked by CUSTOMER, INVOLVE, and SUPPLIER. The designated channels are usually in a Quality Assurance PROCESS model. Change requests are tracked in SYSDOC, PRODUCT, and PROCESS.

d) verify the implementation of solutions;
- Verification of the solutions is one of the most powerful aspects of a software tickler system. CUSTOMER, INVOLVE, NCM, CORRECT, SUPPLIER all include Follow Up dates, and records of the results. In CORRECT, if the solution is determined to be ineffective, it automatically generates another correct action request (CAR). Simple reminder lists and a little time can provide significant insight as to the effectiveness of your system.

e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.
- The NCM system documents the nonconforming condition, and a PROCESS model in Operations / Manufacturing usually defines controls of nonconforming material. Shipping usually runs an NCM report to make sure all problems have been fixed, verified if needed and closed. An information link to MRP is required as well.

4.1.2.2 Resources

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities, including internal quality audits.
- Verification requirements are defined in COLLECT, with a direct link to PRODUCT and PROCESS requirements. Adequate resources (inventory) and scheduling may be handled in MRP. The skills required are defined in INVOLVE and a report allows for determination of who can perform verification activities. The training is scheduled and documented in INVOLVE. PRODUCT and PROCESS define verification requirements. COLLECT handles a variety of verification tests - from supplier to install by customer. SYSDOC, PRODUCT, PROCESS all generate audit schedules, document audit findings, and manage change requests. Personnel that are independent can be verified with INVOLVE and PROCESS, by checking titles and names.

4.1.2.3 Management Representative

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for
- A Human Resource PROCESS model usually defines various responsibilities levels. A jobcode of MGTREP (management rep) can be defined and report generated to list responsibilities. One of the responsibilities of the Management Representative is to identify how your company's business system meets the ISO 9000 standards.

a)   ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and

- Remember, your quality system does not have to be modeled after ISO 9000 - after all, ISO 9000 is not an information systems model.

b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

- All IQS modules hold and report all vital data to determine if your company is meeting goals driven by quality costs and continuous improvement efforts.

NOTE 5: The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

- PROCESS maps out how external liaison is handled.

- PROCESS models and documents the who, what, where, when and how of each phase of production. PROCESS audits against all mentioned activities ensure that all documented processes for success are being adhered to.

4.1.3   Management Review

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives. (see 4.1.1). Records of such reviews shall be maintained. (see 4.16).

- Management reviews are scheduled and documented in SYSDOC, PRODUCT, and PROCESS - all the documentation modules. IQS recommends further review of information from all modules - see 4.17 Internal Audits. The objective is the definition of a management Quality Report, reviewed like the balance sheet and income statement. All modules keep records and allow a variety of reporting capability.

4.2 Quality System

4.2.1 General

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

- SYSDOC, PRODUCT, and PROCESS document the business system, including quality. Product conformance is documented in COLLECT and resolved in NCM. The Quality Manual is a controlled document in SYSDOC

NOTE 6: Guidance on quality manuals is given in ISO 10013.

4.2.2 Quality System Procedures

The supplier shall

a) prepare documented procedures consistent with the requirements of this International Standard and the supplier's stated quality policy, and

- All procedures and work are managed within SYSDOC and PROCESS. Remember, you must also define how you use the IQS software in SYSDOC and/or PROCESS.

b) effectively implement the quality system and its documented procedures.

- The implementation effectiveness is documented by the audit results in AUDIT MANAGER, SYSDOC, PRODUCT, PROCESS, and NCM. INVOLVE can define and manage an Employee survey to further investigate - ability to describe, actions taken that support, etc. CUSTOMER and SUPPLIER surveys provide additional information along with reviewing trends within NCM.

For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system depend on the complexity of the work, the methods used, the skills and training needed by personnel involved in carrying out the activity.

- It is up to you to define how you must manage and improve your company.

NOTE 7: Documented procedures may make reference to work instructions that define how an activity is performed.

- PROCESS and SYSDOC manage all levels of documentation. Organized training plans supplement communication of all processes.

4.2.3 Quality Planning

The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

a) the preparation of quality plans;
- SYSDOC, PRODUCT, PROCESS and COLLECT define inspection plans.

b)   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;
- The identification of needs can come from a variety of sources, including CUSTOMER, INVOLVE, COLLECT, NCM, CORRECT, SUPPLIER, and QCOST. Equipment and fixtures are managed in PREVENT. Inspection device capability is available in CALIBRATE. Total production resources - people - in INVOLVE - scheduling/capacity in MRP. Skills are defined in INVOLVE, including past job experience with resumes.

c)   ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation;
- The updating of documentation in all 3 systems are tracked by a Change Request system. The assigned to get an answer, tracking of approvals (with approval due reports), and incorporation is documented through change history. CALIBRATE R&R, Linearity, and Stability studies can identify the need for new instrumentation - the means of determining is defined in PROCESS.

d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;
- CALIBRATE R&R studies can identify requirements beyond capability - the means of determining is defined in PROCESS. The requirements defined in PROCESS and PRODUCT include tolerances, that can search against the CALIBRATE device inventory.

e) the identification of any measurement requirement involving capability that exceeds the known state of the art in sufficient time for the needed capability to be developed;
- The identification of subjective standards usually occurs when loading PRODUCT AND PROCESS. PRODUCT allows the documentation of a Requirement type - SUB (subjective) - allowing reporting across product/service for comparison of the application and interpretation of subjective standards. SYSDOC documents the subjective element definition, and an image. SYSDOC could also track video tape inventory explaining the interpretation of subjective standards.

f) the identification of suitable verification at appropriate stages in the realization of product;
- An Engineering PROCESS model defines how this is accomplished. PRODUCT defines the verification requirements and COLLECT records the execution of the process. Capability between PRODUCT and PROCESS with COLLECT is automatic.

g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;
- All standards of acceptability are documented in PRODUCT and PROCESS and can be inspected for in COLLECT. Monitoring these standards is done by analyzing and collecting data in CUSTOMER, COLLECT, NCM and CORRECT.

h) the identification and preparation of quality records (see 4.16).
- All 13 modules provide quality records.

- CUSTOMER - inventory, feedback transactions, surveys
- SYSDOC - inventory, change requests, audit findings
- PRODUCT - inventory, change requests, audit findings
- PROCESS - inventory, change requests, audit findings
- PREVENT - inventory, preventive and reactive maintenance
- CALIBRATE - inventory, calibrations, R&R studies
- INVOLVE - inventory, skills, resume, training, input, teams and meetings, surveys
- COLLECT - plans & results, by lot #, PO #, serial #, etc.
- SPC - analysis reports
- NCM - inventory, dispositions, verification, trends analysis
- CORRECT - inventory, action taken, effectiveness
- SUPPLIER - inventory, feedback transactions, surveys
- QCOST - as much as you care to record
- AUDIT MANAGER - audits, findings, observations

NOTE 8: The quality plans referred to [see 4.2.3a] may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.

4.3   Contract Review

4.3.1   General
The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.
- In PROCESS, the Sales Model defines all activities for proper contract review. INVOLVE is used to manage the contract review team and all contract review notes are tracked in CUSTOMER.

4.3.2   Review
Before the submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the supplier to ensure that;

a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance;
- A Sales PROCESS defines contract review. IQS recommends when to say "NO" - every order is not a good order. If you get every bid, you are too low. If you are out of capacity with big back orders - raise your price. A checklist can be made in COLLECT to ensure that all requirements are clearly understood.

b) any differences between the contract or accepted order requirements and those in the tender are resolved:
- How differences are resolved are defined in the Sales PROCESS model. CUSTOMER tracks the due dates and answer to contract review items, (CRI) - for feedback type.

c) The supplier has the capability to meet the contract or accepted order requirements;
- A Sales PROCESS model defines how the decision is made. Input for the decision comes from CUSTOMER - past experience, COLLECT, SPC, and NCM - looking at results on previous or similar jobs. MRP must verify delivery date and quantity.

d) all customer requirements, including those in Section III of this document, can be met.
- Activities for ensuring that all customer requirements can be met are defined in PROCESS. All specific requirements are defined and reviewed in PRODUCT.

4.3.3   Amendment to Contract
The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.
- Changes to contracts can be documented within CUSTOMER. Specific changes to product characteristics must be documented in PRODUCT by issuing a Change Request. This may also affect Inspection Plans which are updated in COLLECT. The routing and activities involved are defined in PROCESS.

4.3.4   Records
Records of contract reviews shall be maintained (see 4.16).
- Records of contract reviews are kept in CUSTOMER feedback transactions. The software link feature can link from the contract review transaction to any other Windows application.

NOTE 9: *Channels for communication and interface with the customer's organization in these contract matters should be established.*

- CUSTOMER holds all contact and assignment information. Notes can be kept for each customer and each customer contact. PROCESS defines responsibilities in the supplier's organization for maintaining interface with the customer.

4.4 *Design Control*

4.4.1 General

The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

- The Engineering PROCESS model defines the design process. COLLECT verifies against requirements defined in PRODUCT and PROCESS.

4.4.2 Design and Development Planning

The supplier shall prepare plans for each design and development activity. The plans shall describe or reference these activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated, as the design evolves.

- The Engineering PROCESS model defines activities and responsibilities. Updates in the PROCESS and/or PRODUCT can come from CUSTOMER, INVOLVE, SPC, CORRECT, and SUPPLIER. PROCESS and PRODUCT document change request processing. INVOLVE maintains skills required by title, for example, Product Designer, Product Development Manager, etc.

4.4.3 Organizational and Technical Interfaces

Organizational and technical interfaces between different groups which input into the design process shall be defined and the necessary information documented, transmitted and regularly reviewed.

- The Engineering PROCESS model specifically defines Key Input Variables (KIVs). Part number specific requirements are defined in PRODUCT as requirement type DIR - design input requirement. Resolution of issues is handled with CUSTOMER, SUPPLIER, and INVOLVE.

4.4.4 Design Input

Design input requirements relating to the product including applicable statutory and regulatory requirements shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements.

Design input shall take into consideration the results of any contract review activities.

- The Engineering PROCESS model specifically defines Key Output Variables (KOVs). Part number-specific requirements are defined in PRODUCT, including text storage of equations and/or calculation results.

4.4.5 Design Output

Design output shall be documented and expressed in terms of requirements that can be verified and validated against design input requirements.

Design output shall:

a) meet the design input requirements;

- Conformance to standards for PRODUCT requirement type = DIV and for PROCESS element search on DIV.

b) contain or make reference to acceptance criteria;
- PRODUCT and PROCESS require a lower, nominal, and upper, or MAX, MIN, or attribute (Y/N), or text notes.

c) identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g. operating, storage, handling¸ maintenance and disposal requirements).
- PRODUCT can define and track - requirement type REG - regulatory, etc.

Design output documents shall be reviewed before release.
- Review of such documents are noted COLLECT which serves as the release checklist.

4.4.6　　　Design Review

At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel as required. Records of such reviews shall be maintained (see 4.16)
- The Engineering PROCESS model documents all activities necessary for proper deign review. INVOLVE can assign and manage all associated teamwork including agenda and minutes.

4.4.7　　　Design Verification

At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see 4.16).
- The Engineering PROCESS model defines design verification. INVOLVE allows checking against skill type DESVER - design verification or search through resumes by title. If the design inputs are defined in PROCESS, COLLECT will check them - same for design output requirements.

NOTE 10: *In addition to conducting design reviews (see 4.4.6), design verification may include activities such as the following:*

- *performing alternative calculations;*
- *comparing the new design with a similar proven design, if available;*
- *undertaking tests and demonstrations; and*
- *reviewing the design stage documents before release.*

- In PROCESS, all of the above mentioned activities should be defined within your Engineering Model.

- COLLECT creates, analyzes, and stores all test results.

4.4.8　　　Design Validation

Design validation shall be performed to ensure that product conforms to defined user needs and/or requirements.
- The Engineering PROCESS model defines design validation activities and responsibilities.

NOTES

11   Design validation follows successful design verification (see 4.4.7).

12   Validation is normally performed under defined operating conditions.

13   Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.

14   Multiple validations may be performed if there are different intended uses.

- The Engineering PROCESS model documents all validation activities with KIVs defined for each. Validation activities do not start until design verification activities are successful per the Engineering model.

4.4.9   Design Changes

All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel before their implementation.

- The Engineering PROCESS model defines product changes. The IS PROCESS model defines process changes. PRODUCT and PROCESS have change request processing that provide records of identification, documentation, review, and approval (or not approval), including a "Pending" status. An unlimited change history can be recorded. Identification or generation of a change request can come from CUSTOMER, INVOLVE, SUPPLIER, and CORRECT.

4.5   *Document and Data Control*

4.5.1   General

The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings.

- Documentation is found in SYSDOC, PRODUCT, and PROCESS - all three share similar capabilities for scheduling reviews. All three document change review and approval - by employee name or title. The approval lists may include customer contacts as well. In INVOLVE, skill types define authorized personnel.

NOTE 15: Documents and data can be in the form of any type of media, such as hard copy or electronic media.

- IQS software supports both electronic and manual systems. The Software Link feature out of every module allows direct linking to and launching of electronic documents. The IQS software may be used as the index to manual documents and data, yet there is more effort to ensure proper control of a manual system versus an electronic system.

4.5.2   Document and Data Approval and Issue

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

- Everything is available - ON-LINE - with security restrictions. IQS recommends a complete analysis of computer terminals versus binders, file cabinets, and manual document control

b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

- SYSDOC, PRODUCT, and PROCESS document the distribution, making recall faster. Same capability allows verification of what employees possess. SYSDOC, PRODUCT, and PROCESS also have status identification - current, revision, obsolete. A change request automatically changes the status to revision. A change history record (date and/or revision level) is posted when changes are approved. Effectiveness can be defined in terms of either time or production. Again, in an electronic system, only the electronic master document is changed - no manual copies exist.

c) any obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified.

- The IS PROCESS model defines all procedures for identifying and storing preserved and obsolete documents. These documents may either be stored and secured electronically or physically.

4.5.3   Document and Data Changes

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/

organizations shall have access to pertinent background information upon which to base their review and approval.

- Change Request records allow reporting on who performed the previous (perhaps several) review (s). All IQS modules provide information - including the origin of the change request (CUSTOMER, INVOLVE, SUPPLIER, NCM, CORRECT). The Change request description defines the nature of the change, along with Cause Type and Cause codes for further analysis, perhaps part number / process independent. Three inventory lists are maintained - SYSDOC, PRODUCT, PROCESS. Revision Level, Dates and Status codes are defined. An Information Systems Process Model defines when PROCESS documents are "re-issued" or made available. An Engineering PROCESS model defines re-issue, and allows tracking revisions at the requirement level - with bulk updating to a single revision level (or date) when the document is re-issued. Re-Issuing control is required in both software and manual systems - effectiveness based on time and/or production.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

- SYSDOC, PRODUCT and PROCESS hold all change information on-line. Anyone with access to the system can quickly inspect all changes to the document through the software. In a manual system, the list of changes can be printed out of the IQS software and attached to the document.

4.6 *Purchasing*

4.6.1 General

The supplier shall establish and maintain documented procedures to ensure that purchased product (see 3.1) conforms to specified requirements.

- COLLECT defines and documents product conformance requirements - requirements must be specified in PRODUCT. Inspection plans in COLLECT allow for verification by collecting data on the products. PRODUCT can be used to identify characteristics which must be verified at the supplier - in a good supplier-customer relationship, "redundant" receiving inspection is minimized by requiring data on the key characteristics thus eliminating re-verification.
  - CUSTOMER   Customer
  - You   Supplier
  - SUPPLIER   Subcontractor

4.6.2 Evaluation of Subcontractors

The supplier shall:

a) *evaluate and select subcontractors on the basis of their ability to meet sub-contract requirements including quality system and any specific quality assurance requirements;*

b) *define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of sub-contracted product on the quality of final product and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors.*

c) *establish and maintain quality records of acceptable subcontractors (see 4.16).*

- A Purchasing PROCESS model defines supplier selection and assessment. SUPPLIER maintains a list of acceptable suppliers - STATUS = Active. Supplier ability can be defined at the part number, commodity, or process levels - meaning that a supplier may be great at one thing, but don't use them for this.

- The extent of control is defined in COLLECT, and developed with information from SPC, NCM, CORRECT, SUPPLIER. PRODUCT defines product type (complexity) and requirement class - critical, major, minor. COLLECT can define - supplier supplied data, source inspection data, and receiving data - all in the same system.

- COLLECT, NCM, CORRECT, and SUPPLIER can store information on past performance/communication.

- SUPPLIER schedules and documents supplier surveys. Survey results are reported and analyzed. NCM tracks any deficiencies and their resolution. CORRECT tracks efforts to improve and the results of their improvement process.

4.6.3 Purchasing Data

Purchasing documents shall contain data clearly describing the product ordered, including where applicable:

- The Purchasing PROCESS model defines the purchasing document requirements / contents. SUPPLIER can track RFP - MRP ordering systems can provide the same capability.

SALE 5182 (11/22/96)   18 of 39

a) the type, class, grade or other precise identification;
- PRODUCT can define part specific information - PROCESS defines generic requirements.

b) the title or other positive identification and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;
- Theoretically, the suppliers should dial into you computer system and access the same information - with security. Eliminate the change control problem. Reduce lead times - information transfer is eliminated. PRODUCT contains all part number specific information. COLLECT defines inspection instructions.

c) the title, number and issue of the quality system standard to be applied.
- Part specific in PRODUCT - general in PROCESS. Records of verification are in COLLECT.

The supplier shall review and approve purchasing documents for adequacy of the specified requirements prior to release.
- The Purchasing PROCESS model clearly defines review of all contract requirements.

4.6.4 Verification of Purchased Product

4.6.4.1 Supplier Verification at Subcontractor's Premises
Where the supplier proposes to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents.
- The Purchasing PROCESS model defines all necessary arrangements, responsibilities and checklists. Inspection Plans in COLLECT designate where the product must be accepted/rejected which become contract requirements.

4.6.4.2 Customer Verification of Subcontracted Product
Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.
- COLLECT defines inspection plans - at supplier, by source, in receiving, etc. Rejections are handled in NCM. SUPPLIER schedules and documents surveys - in additional to verification results. PREVENT and CALIBRATE can document equipment supplied by the CUSTOMER.

Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

4.7   *Control of Customer Supplied Product*

The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.16).

- The Operations PROCESS Model defines product processing through receiving and storage/retrieval. NCM resolves and records lost, damaged, etc. issues.

Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

4.8 *Product Identification and Traceability*

Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation.

- The Operations PROCESS model defines product identification and traceability. COLLECT and NCM document Purchase Order #, Lot Number, and can process data at the serial number level - individual part. PRODUCT bill of material allows COLLECT to record as built configuration. MRP usually contains additional information - by order, operation, serial number, etc.

Where and to the extent that, traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16).

- The Operations PROCESS model must clearly define all aspects of product identification including all the special requirements identified in PRODUCT.

4.9   *Process Control*

The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

- This is PROCESS, COLLECT, and SPC.

a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality;

- Work Instructions can be documented in SYSDOC, PRODUCT, and PROCESS.
  Equipment information is available from PREVENT, CALIBRATE, COLLECT, and NCM.

b) use of suitable production, installation and servicing equipment, and a suitable working environment;

- PREVENT and CALIBRATE manage all equipment and the Operations PROCESS model identifies the necessary environment with all housekeeping standards.

c) compliance with reference standards/codes, quality plans and/or documented procedures;

- SYSDOC and PROCESS can manage all regulations. Audits scheduled within these two modules ensures and documents compliance. COLLECT may be used to track necessary checklists and measurements - Characteristic Type ENV - Environmental.

d) monitoring and control of suitable process parameters and product characteristics;

- Centralized in COLLECT and SPC.

e) the approval of processes and equipment, as appropriate;

- The Operations PROCESS model defines who - COLLECT documents it. PREVENT can generate equipment approval work requests for tracking equipment approval.

f) criteria for workmanship which shall be stipulated, in the clearest practical manner (e.g., written standards, representative samples or illustrations);

- Criteria for workmanship, or acceptance definition, can be defined in PRODUCT and PROCESS. Samples can be tracked by SYSDOC, and may take the form of parts, pictures, videos, etc. INVOLVE ensures that proper training and certifications have been achieved

g) suitable maintenance of equipment to ensure continuing process capability.

- PREVENT ensures that all equipment is maintained in a preventive mode. Reactive maintenance is also tracked and analyzed continually as a part of process improvement. COLLECT and SPC constantly monitor process capability.

- PREVENT manages all preventive and reactive maintenance. Analysis reporting helps determine effectiveness of preventive maintenance. All maintenance instructions and checklists are controlled on-line for easy access. Preventive maintenance records can be linked out tool/machine studies.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations including associated equipment and personnel (see 4.18) shall be specified.

NOTE 16: *Such processes requiring pre-qualification of their process capability are frequently referred to as special processes.*

Records shall be maintained for qualified processes, equipment and personnel, as appropriate. (see 4.16.).
- Records are recorded as follows:
    - process records - PROCESS
    - equipment records - PREVENT / CALIBRATE
    - personnel records - INVOLVE

4.10   *Inspection and Testing*

4.10.1   General

The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan (Control Plan) *or documented procedures.*

- The Operations PROCESS model defines the receiving inspection process. COLLECT records both PROCESS - part independent and PRODUCT - part dependent information. MRP needs to know inspection status.

4.10.2   Receiving Inspection and Testing

4.10.2.1

The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as confirming to specified requirements. Verification of the conformance to the specified requirements shall be in accordance with the quality plan (Control Plan) *and/or documented procedures.*

- The Quality Assurance PROCESS model defines release decision, identification, and documentation. NCM defines transaction closed when verified - verification not complete reporting available. COLLECT defines as built - at serial number level. Remember, a good percentage of receiving inspection takes place because the sub-contractor has poor process control.

- Amount of control defined in COLLECT, with information from SPC, NCM, CORRECT, and SUPPLIER. Records are stored in COLLECT.

4.10.2.2

In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.

- The Purchasing PROCESS model determines the structure and amount of control excersized at the subcontractor's facility. PRODUCT and COLLECT are used to document characteristics and inspection plans. Receiving inspection should be minimal, data should be required with each shipment from the subcontractor. Routine audits of the subcontractor's system managed through SUPPLIER should cover all areas of data collection.

4.10.2.3

Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

- The Operations and Quality Assurance PROCESS models ensure that expedited material is properly identified and acceptable for use. MRP and COLLECT document as such.

4.10.3   In-process Inspection and Testing

The supplier shall:

a) inspect the test product as required by the quality plan (Control Plan) *and/or documented procedures;*
- Defined in and inspected per PRODUCT / COLLECT.

b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified except when product is released under positive recall procedures (see 4.10.2.3). Release under positive recall procedures shall not preclude the activities outlined in 4.10.3a.
- Control of product processing is defined in Operations PROCESS model. MRP usually controls further processing - based on information from NCM. COLLECT inspection status can be checked, prior to further processing.

c) All process activities should be directed towards defect prevention methods, such as statistical process control, error proofing, visual controls, rather than defect detection.
- This is the underlying methodology of the IQS Model!

4.10.4   Final Inspection and Testing
The supplier shall carry out all final inspection and testing in accordance with the quality plan (Control Plan) *and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.*

The quality plan (Control Plan) *and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.*
- COLLECT is used to verify that all PROCESS and PRODUCT requirements have been met

No product shall be dispatched until all the activities specified in the quality plan (Control Plan) *and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.*
- PRODUCT and PROCESS define the acceptance criteria. COLLECT records the results. COLLECT allows reporting of product inspection status with a STATUS = Complete. Criteria recorded and verified in both PRODUCT and PROCESS.

4.10.5   Inspection and Test Records
The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass and inspection and/or test, the procedure for the control of nonconforming product shall apply (see 4.13).
- COLLECT holds evidence that the product has met the requirements. In cases where requirements weren't met, NCM contains the record of nonconformance(s), disposition(s), and verification(s) which were automatically posted from CORRECT.

Records shall identify the inspection authority responsible for the release of the product. (see 4.16).
- PRODUCT and PROCESS define the acceptance criteria. COLLECT records the results. COLLECT allows reporting of product inspection status with a STATUS = Complete. Criteria recorded and verified in both PRODUCT and PROCESS.

4.11   *Control of Inspection, Measuring, and Test Equipment*

4.11.1   General

The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability.

- CALIBRATE handles most of this. A device inventory is maintained, with information that allows reporting by - customer supplied, part number, etc. Device usage and selection is defined in Operations PROCESS model. Specific work instructions may be included in SYSDOC. Repeatability and Reproducibility (R&R) studies analyze measurement variation.

Where test software or comparative references such as test hardware is used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation, or servicing and shall be re-checked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).

- CALIBRATE controls all gages and software used to accept/reject product. No gage or software is used until accepted in CALIBRATE. Calibration intervals are set-up by device type and may be adjusted specifically to each gage.

Where the availability of technical data pertaining to the inspection, measuring, and test is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection , measuring. and test equipment is functionally adequate.

- CALIBRATE's records are on-line, reporting of history and special studies is quite simple.

NOTE 17*: For the purposes of this International Standard, the term "measuring equipment" includes measurement devices.*

4.11.2   Control Procedure

The supplier shall:

a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision;

- The measurements to be made are defined in COLLECT, with information on past performance and requirement class - (critical, major, minor). The accuracy required is usually 1/10, or a decimal point past the acceptance criteria. PRODUCT can calculate this from the requirement acceptance criteria, then search CALIBRATE for devices that are capable - R&R studies can also impact the selection.

b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such Standards exist, the basis used for calibration shall be documented;

- The Operations PROCESS model defines how the intervals are determined and adjusted, and then CALIBRATE schedules calibrations based on these intervals. Records of certified

equipment or standard usage are maintained - with reporting of where it was used. Treat the standards just like devices - put them in inventory and schedule, record, react.

c) *define the process employed for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;*
- The Operations PROCESS model defines the procedures above. Unsatisfactory results are documented in NCM. Actual characteristics and standards used are kept in CALIBRATE, thus allowing procedures to be more "generic."

d) *identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;*
- Calibration status is known at all times in CALIBRATE - when past due the status is automatically changed. COLLECT checks calibration status of devices, and will not allow use if it is out. If you have to, stickers are still available.

e) *maintain calibration records for inspection, measuring and test equipment (see 4.16);*
- CALIBRATE has extensive record keeping of calibrations results

f) *assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration;*
- COLLECT records what device is used - a report will allow a link to LOT #, PO #, and/or serial #.
- CALIBRATE records what standard is used during calibration - so traceability is maintained if the standard is found to be out.

g) *ensure that the environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out;*
- CALIBRATE records temperature and humidity. The Operations PROCESS Model defines required conditions - COLLECT verifies compliance.

h) ***ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained;***
- Handled through the Operations PROCESS model. COLLECT verifies compliance.

i) *safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.*
- The Operations PROCESS model defines:
- the safeguard for measuring device adjustments
- extent and frequency
- COLLECT verifies compliance.

NOTE 18: *The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance.*
- All defined in the Quality Assurance PROCESS Model.

4.11.3   Inspection, Measuring, and Test Equipment Records

Records of the calibration/verification activity on all gages, measuring, and test equipment, including employee owned gages, shall include:

∗   revisions following engineering changes (if appropriate);
∗   gage conditions and actual readings as received for calibration/verification;
∗   notification to customer if suspect material has been shipped.

- All are contained in CALIBRATE - out-of-calibration conditions are posted to and managed through NCM.

4.12 *Inspection and Test Status*

The inspection and test status of product shall be identified by suitable means, which indicates the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan (Control Plan) *and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is dispatched, used or installed.*

- The Operations PROCESS model defines how - PRODUCT records anything that is part number specific. Inspection status in MRP - fed from COLLECT/NCM. COLLECT records who reported the data. PROCESS defines who has authority, and INVOLVE assigns the skill type. NCM has verification due reporting.

4.13   Control of Nonconforming Product

4.13.1   General

The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product and for notification to the functions concerned.

- The Operations PROCESS model defines the handling of nonconforming product. NCM handles the record keeping for assignment, due date, disposition and approval, and verification.

4.13.2   Suspect Product Review and Disposition of Nonconforming Product

The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures. It may be

a) *reworked to meet the specified requirements,*
b) *accepted with or without repair by concession,*
c) *re-graded for alternative applications, or*
d) *rejected or scrapped.*

- A PROCESS model defines responsibility and authority. NCM records disposition code, assignments and text. Trend analysis on disposition codes available - rework, scrap, use, re-grade, scrap. "Use as Is" dispositions can generate a PRODUCT change request or CORRECTive action.

Where required by the contract, the proposed use or repair of product (see 4.13.2b) which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition. (see 4.16).

- Complete NCM reporting available for proper disposition and verification. (Review and Authority - defined by SECURITY - By Customer, Program, etc.)

Repaired and/or reworked product shall be reinspected in accordance with the quality plan (Control Plan) *and/or documented procedure.*

4.14   *Corrective and Preventive Action*

4.14.1   General
The supplier shall establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

4.14.2   Corrective Action

The procedures for corrective action shall include:

a) the effective handling of customer complaints and reports of product nonconformities;

- The Customer Service and Quality Assurance PROCESS models document how all nonconformities are managed. Customer complaints are handled in NCM, but may be initially documented in CUSTOMER.

b) investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation. (see 4.16);

- A Quality Assurance PROCESS model defines what trend analysis is performed and how the decision to generate a CAR is made, or at least the parameters for deciding.

- The investigation of cause is available from : CUSTOMER, SYSDOC, PRODUCT, PROCESS, PREVENT, CALIBRATE, INVOLVE, SPC, and SUPPLIER. Reports of transactions and changes on these files are available:
  - Was the acceptance criteria changed ? Why?
  - is the equipment past due on maintenance
  - is the device capable ?
  - is the employee qualified?
  - etc.

c) determination of the corrective action needed to eliminate the cause of nonconformities;

- CORRECT manages all root-cause corrective actions as identified from NCM analysis.

d) applying controls to ensure that corrective action is taken and that it is effective.

- CORRECT handles the generation and assignment of CARs, with due date reporting. CORRECT follow up reports provide tickler list and Effective (Yes/No) is documented. If ineffective, then a new CAR is automatically generated, with cross referencing to the initial CAR.

4.14.3 Preventive Action

The procedures for preventive action shall include:

a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities;

- All information is available in CUSTOMER, SYSDOC, PRODUCT, PROCESS, CALIBRATE, PREVENT, INVOLVE, COLLECT, NCM, CORRECT, and SUPPLIER.

b) determination of the steps needed to deal with any problems requiring preventive action;

- Per your Quality Assurance PROCESS model.

c) initiation of preventive action and application of controls to ensure that it is effective;

- Per your Quality Assurance PROCESS model and documented in CORRECT, SYSDOC, PRODUCT, PROCESS, INVOLVE and COLLECT.

d) confirmation that relevant information on actions taken is submitted for management review. (see 4.1.3).

- The management review team should review and record all corrective actions assignments and ratings of effectiveness of those actions taken.

4.15   Handling, Storage, Packaging, Preservation, and Delivery

4.15.1   General
The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.
- Engineering and Operations PROCESS models define how these are determined and controlled. PRODUCT defines product specific information. COLLECT verifies compliance.

4.15.2   Handling
The supplier shall provide methods of handling product that prevent damage or deterioration.
- Engineering and Operations PROCESS models define how these are determined and controlled. PRODUCT defines product specific information. COLLECT verifies compliance.

4.15.3   Storage
The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.
- Engineering and Operations PROCESS models define how these are determined and controlled. PRODUCT defines product specific information. COLLECT verifies compliance.

4.15.4   Packaging
The supplier shall control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.
- Engineering and Operations PROCESS models define how these are determined and controlled. PRODUCT defines product specific information. COLLECT verifies compliance.

4.15.5   Preservation
The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

4.15.6   Delivery
The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.
- Engineering and Operations PROCESS models define how these are determined and controlled. COLLECT verifies compliance. MRP defines and controls delivery performance.

4.16   *Control of Quality Records*

The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition (DISPOSAL) *of quality records.*

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

- The entire IQS system stores a significant amount of quality records. As mentioned previously, MRP has some additional information on As Built Configuration, times, dates, names of people involved.

- The computer provides legible and identifiable records as well as vast storage with significantly better retrieval and analysis capabilities. The Information Systems PROCESS model defines storage environment and retention requirements. SYSDOC records retention requirements.

- Partial List of Records
  - CUSTOMER - complaints, etc.
  - SYSDOC - all procedures - with Retention Requirements
  - PRODUCT - part number stuff
  - PROCESS - all process (part number independent stuff)
  - PREVENT - all equipment information
  - CALIBRATE - all measuring device information
  - INVOLVE - all employee information
  - COLLECT - all data
  - SPC - data analysis - charts - Cp - % conformance
  - NCM - conformance and trends
  - CORRECT - CARs
  - SUPPLIER - supplier performance
  - QCOST - appraisal, failure versus prevention
  - ALL - made available - from the computer - archiving - history

- COLLECT - inspection plans are documents - require change request and status

NOTE 19: *Records can be in the form of any type of media, such as hard copy or electronic media.*

4.17 *Internal Quality Audits*

The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on the deficiencies found during the audit.

***Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken** (see 4.16).*

- The key to this section is effectiveness - how do we know that the system is effective. One indicator is conformance to documented procedures, as identified through the document audits - SYSDOC, PRODUCT, PROCESS, and AUDIT MANAGER schedule and record audits results. NCM handles nonconformance identified during audits. NOTE: In the IQS model, a nonconformance is Issued on deficiencies - not a corrective action request (CAR). CARs are Issued based on trend analysis.

- PROCESS model defines audit system, intervals, qualified people, etc.

- IQS also considers PREVENT preventive maintenance and CALIBRATE as "audits". CUSTOMER and SUPPLIER have surveys. INVOLVE has "employee maintenance" scheduling and reporting.

NOTES:

20   *The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3.)*

- SYSDOC, PROCESS, and AUDIT MANAGER manage audits, evidence gathered from all IQS Modules.

21   *Guidance on quality system audits is given in ISO 10011.*

4.18 Training

The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 4.16).

- The HUMAN RESOURCES PROCESS model defines the procedures for identifying training needs- then INVOLVE manages the training scheduling and execution. Qualified personnel are defined with skill types. Training needs can be identified by asking what skills do I need for this job? Or what course should I go to that I haven't? INVOLVE has a course inventory, with registration records, and attendance/competence records. INVOLVE also maintains a resume of past assignment inside and outside the current organization. Internal promotions can search for people with required skills/experience from resume.

4.19   *Servicing*

Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.

- The Engineering and Operations PROCESS model define the process. PRODUCT records part number specific servicing issues, or commodity specific issues.

- COLLECT records service results. CUSTOMER documents service complaints and compliments. PRODUCT can define requirement type = SERVICE for reviewing the application across part numbers.

4.20   *Statistical Techniques*

4.20.1   Identification of Need

The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

4.20.2   Procedures

The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.

- PRODUCT and PROCESS identify the need for SPC. COLLECT and SPC give the tools for collecting, analyzing, and reporting data.

- The IQS software environment provides the opportunity to review a significant amount of information in a variety of views. Of course, traditional SPC on product and process requirements, but further - to a Quality Report - reviewed with the balance sheet and income statement.

- In general, every file can be analyzed for quantity of time and different groupings within the file.

- The IQS view of statistical techniques is a monthly posting of trends from all the modules. Graphical analysis will include X-MR charts of quantities over time, and Pareto charts of various groupings.

- Changing critical few and changes (up/down) can relate to corrective actions/changes effectiveness.

- Examples Include
  - CUSTOMER / SUPPLIER
    - customer analysis
      - type, assigned to, territory, etc.
    - feedback analysis
      - type, subject, assigned to, etc.
    - survey summary status
      - % done, past due, remaining
      - distribution of survey scores - by supplier type
    - quantity - by customer, total,

  - SYSDOC, PRODUCT, PROCESS
    - document inventory
      - types, functions, developed, approve, distribute
    - change requests - change reason, type, % approval, approval time
    - audit status - due, past, remaining - % Pass

  - PREVENT / CALIBRATE
    - inventory analysis - equipment and spare parts - by type, etc.
    - work requests - who, how much, what spare parts, what machines
    - $ maintain versus $ to buy new

  - CALIBRATE
    - results analysis, % adjusted, fail - X-MR chart of results

- R&R studies - distribution of results total, by device type, by part number, etc.
- R&R - scheduling people for these - if they have this skill type - INSPR - Inspection - Receiving

- INVOLVE
    - input analysis
    - team analysis
    - course analysis
    - course attendance - completed - and/or - schedule, % done, past due, and remaining
    - survey status

- COLLECT
    - number of plans
    - number of requirements under control- active

- SPC - process and product and general - Data analysis - Reports
    - Control charts
    - histograms
    - conformance to standards
    - Cp/Cpk Reports

- NCM - NCM trend analysis
    - by part number, operation, requirement,

- CORRECT - CAR analysis
    - part number, cause code, % effective