From: Frank Festa <Frank.Festa@IMSSystemsInc.com>
To: William Ward <WRW1@nrc.gov>
Date: 8/1/01 12:01PM
Subject: Correction

Hello Bill,

I am very sorry that I did not pick-up on the error in the QA program sooner. After review of my notes I realized the mistake. I believe that it is now corrected.
My draft of the QA program had a 2b paragraph that I eliminated and did not follow through on the correction.
Thanks,
Frank

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by nrcgwia.nrc.gov; Wed, 01 Aug 2001 11:59:59 -0400
Received: from nrc.gov
by smtp-gateway ESMTPœ id LAA00779
for <WRW1@nrc.gov>; Wed, 1 Aug 2001 11:57:48 -0400 (EDT)
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by pgh.nauticom.net (8.10.1/8.8.7) with ESMTP id f71G15532733
for <WRW1@nrc.gov>; Wed, 1 Aug 2001 12:01:05 -0400 (EDT)
Message-ID: <3B6825C2.5AA88AB8@IMSSystemsInc.com>
Date: Wed, 01 Aug 2001 11:52:34 -0400
From: Frank Festa <Frank.Festa@IMSSystemsInc.com>
X-Mailer: Mozilla 4.76 [en] (Windows NT 5.0; U)
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To: William Ward <WRW1@nrc.gov>
Subject: Correction
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Subject: Correction
Creation Date: 8/1/01 11:52AM
From: Frank Festa <Frank.Festa@IMSSystemsInc.com>

Created By: Frank.Festa@IMSSystemsInc.com

Recipients
nrc.gov
owf1_po.OWFN_DO
WRW1 (William Ward)

Post Office	Route
owf1_po.OWFN_DO	nrc.gov

Files	Size	Date & Time	
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QUALITY ASSURANCE AND CONTROL PROGRAM.doc			198144
Header	796		

Options
Expiration Date: None
Priority: Standard
Reply Requested: No
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QUALITY ASSURANCE AND CONTROL PROGRAM

Manufacturer's Program Outline

1. Introduction

   a. Purpose

   The Quality Assurance and Control Program is drawn up in accordance with the requirements of the AECB INFO-0338-1 "Guidelines for Approval of Nuclear Gauging Devices", Section 3, paragraph a , "quality assurance standard for design and construction", and ANSI N538 Classification of Industrial Ionizing Radiation Gauging Devices, Appendix B, (Quality Assurance and Control).

   b. Scope

   The Quality Assurance and Control Program applies to all activities concerned with the design, purchase, fabrication, handling, assembly, inspection, testing, operation, maintenance, repair and modification of gauge components which are significant to safety.

2. Organization

   The overall responsibility for the Quality Assurance Program is retained and exercised by IMS. The responsibility for the Quality Assurance Program is shared by a number of departments within the company. The responsible departments, by function, include:

3. Engineering

   The responsibility for design control, instructions, procedures and drawings in support of the design, assuring that all parts and components are manufactured to specifications, evaluation of the capability of a supplier to provide an acceptable service, all testing requirements, receiving inspections, and the control of measuring and test equipment, rests with the Engineering Department.

4. Purchasing

   The responsibility for communicating to the manufacturers, via procurement documents, all applicable regulator requirements rests with the Purchasing Department.

5. Health Physics & Safety

The responsibility for overall coordination and monitoring of the handling, assembly, construction and shipping of the gauge related to the containment of activity and operator safety rests with the Quality Assurance/Health Physics Department. The Quality Assurance/Health Physics Department also has responsibility for advising other departments on regulatory requirements and reviewing the program to see that the requirements are being met.

6. Manufacturing

The responsibility for proper construction, testing and dispatch of gauges rests with the Manufacturing Department.

7. Quality Assurance

The responsibility for auditing the gauge quality assurance program to ensure that it has been properly established and implemented rests with the Quality Assurance Department.

An organizational chart is attached (see page 12).

8. The key positions involved in the administration of the Quality Assurance Program, and included in the departments outlined above, are listed below with a brief description of the responsibilities of each.

- Director of Quality Assurance (and Radiation Safety Officer)

Overall responsibility and authority of the Quality Assurance Program, engineering and technical management, and research and development of new projects.

- Project Manager – Technical

Responsible for the successful coordination and implementation of all engineering aspects of the Quality Assurance Program for each project for which gauges are manufactured, assuring that specifications are met and regulatory requirements are satisfied.

- Purchasing Manager

Responsible for directing purchasing activities and communicating to participating organizations that Quality Assurance Program requirements which must be met as advised by the Projects Manager

Technical, and the Director, Quality Assurance (Health Physics and Safety Officer)

- Health Physics and Safety Officer (Director, Quality Assurance)

Responsible for reviewing the activities of the other departments with regard to operation safety and the containment of radioactive material and for ensuring that all departments are advised of regulatory requirements which must be met in the design, manufacture and use of the gauge.

- Manufacturing Manager

Responsible for construction, testing and dispatch of the gauge; responsible to the Director of Operations.

- Operations Manger – Services

Responsible for the shipping and routine inspection of gauges.

- Director, Operations

Responsible for the overall operation of technical project management, operations (services) management and manufacturing. This position also liaises with the Research and Development Department with regard to new products.

- Director, Commercial

Responsible for all duties performed by the Purchasing and Commercial project managers. This position also carries out periodic examinations of the Quality Audit plan drawn up by the Director of Quality Assurance

9. The duties of the Director of Quality Assurance, who maintains overall responsibility and authority of the gauge Quality Assurance Program, include reviewing and approving procurement documents, and ensuring that any deficiencies found in the program are noted and corrected.

The Directors of Quality Assurance and Operations are both technically-degreed, with sufficient professional experience to judge that the safety-related issues involved in the manufacture and use of the gauge are addressed in the Quality Assurance Program.

It is the responsibility of all individuals listed in 8 to ensure that quality products are produced. Therefore, each person listed has been delegated the necessary authority to stop unsatisfactory work and control further processing, delivery or disposition of non-conforming material until proper disposition of the material is made.

Quality Assurance Program

1. The Director, Quality Assurance, regularly assesses the scope, status, implementation, and effectiveness of the overall corporate Quality Assurance Program to assure that the

program is adequate and complies with the requirements of the AECB INFO-0338-1 "Guidelines for Approval of Nuclear Gauging Devices", and Appendix B, ANSI 538.

2. Provisions are established to control the distribution of gauge quality assurance manuals and revisions thereto. This is the responsibility of the Health Physics and Safety Officer.

3. The Director of Quality Assurance communicates to all responsible organizations and individuals that quality policies and procedures are mandatory requirements which must be implemented and enforced.

4. IMS will ensure that all safety related systems, structures, and components are identified and reviewed. These systems will be subject to the Quality Assurance fabrication and inspection programs.

5. The Director of Quality Assurance has the responsibility and the authority to resolve disputes involving quality arising from a difference of opinion between personnel having Quality Assurance responsibilities and personal having Quality Assurance responsibilities and personal from other departments.

6. Indoctrination and training programs are established, such that personnel responsible for performing quality-related activities are instructed as to the purpose, scope and implementation of the Quality assurance instructions and procedures. They are trained and qualified in the principles and techniques of the activity being preformed, and their proficiency is maintained by re-training, re-examining and re-certifying.

7. All quality-related activities are to be preformed with proper equipment under suitable environmental conditions, and all prerequisites will have been satisfied prior to inspection and testing.

Design Control

1. Measures are established to carry out design activities in a planned, controlled and orderly manner.

2. Measures are established to correctly translate the applicable regulatory requirements and design bases into the specifications drawings, written procedures and instruction.

3. Quality Standards are specified in the design documents, and deviations or changes from the quality standards are controlled.

   Designs are reviewed to ensure that:

   a. The design characteristics can be controlled, inspected and tested;

      and

   b. Inspection and testing criteria have been identified and requirements for handling, storage, cleaning and maintenance are addressed.

4. Proper selection and accomplishment of design verification or checking processes such as design reviews, alternate calculations, or qualification testing are performed. When a test program is used to verify the adequacy of a design, the prototype is subjected to the most adverse design conditions.

5. Design verification will be conducted by a person other than the original designer.

6. All design and specification changes are subject other same design controls and approvals as the original design.

7. The authority and responsibility of persons performing design reviews and other design verification activities are identified and controlled by written procedures.

Procurement Document Control

1. Procedures are established that clearly delineated the sequence of actions to be accomplished in the preparation, review, approval and control of procurement documents.

2. The procurement documents contain or reference the design technical requirements including the applicable regulatory requirements, and any applicable material and component identifications, drawings, specifications, codes and industrial standards, test and inspection requirements and special process instructions.

3. The procurement documents identify the documentation to be prepared, maintained, and submitted to the purchaser of review and approval.

4. The procurement documentation identifies those supporting records to be retained, controlled, and maintained by the supplier, and those delivered to the purchaser prior to the use of the hardware.

5. Procurement documents contain the procuring agency's right of access to a supplier's facilities and records for source inspection and audit.

6. All changes and revisions to the procurement documents are subject to the same review as the original document.

Instructions, Procedures and Drawings

1. Activities affecting quality are prescribed and accomplished in accordance with documented instructions, procedures or drawings.

2. Procedures are established which delineated the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures and drawings.

3. The Quality Assurance organization outlined in 2 on page 1 (Organization), reviews and concurs with the inspection plans; calibration and special process procedures; drawings and specifications; and changes thereto or acceptable alternatives.

Document Control

1. The review, approval and issue of documents and changes thereto, prior to release, are procedurally controlled to assure that they are adequate and that quality requirements are stated.

2. Changes to documents, including instruction, procedures, and drawings are reviewed by the same organization that performed the original review and approval, or by other qualified, responsible organizations as delegated by IMS.

3. Approved changes are included in instruction, procedures, drawings and other documents simultaneously with implementation of the change.

4. Current issues of applicable documents will be available at the location where an activity is being performed. This will preclude the change.

5. A master list, or equivalent, is established to identify the current revision number of instructions, procedures, specifications, drawings and procurement documents.

Control of Purchased Materials, Parts and Components

1. Qualified personnel evaluate the supplier's capability to provide acceptable quality services and products.

2. The evaluation of a supplier will be based on one or more of the following:

    a. The supplier's capability to comply with the elements of AECB that are applicable to the type of material, equipment or service being procured.

    b. A review of previous records and performance of the supplier on similar articles of the type being procured.

    c. A survey of the supplier's facilities and Quality Assurance procedures to determine his capability to supply a product which meets the design, manufacturing and quality requirements.

3. The results of the supplier evaluations are documented and filed.

4. Surveillance, if required, of suppliers during fabrication, inspection, testing, and shipment of materials, equipment and components is planned and performed in accordance with written procedures to assure conformance to the purchase order requirements.

5. A receiving inspection of the suppler-furnished material, equipment and services is performed to assure:

    a. The material, component or equipment is properly identified and corresponds with the identification on receiving documentation.

    b. Materials, components, equipment and acceptance records are inspected and judged acceptable in accordance with predetermined inspection procedures, prior to installation or use.

    c. Inspection records or certificates of conformance attesting to the acceptance of material and components are available prior to installation or use.

    d. Items accepted and released for use are identified as to their inspection and judged acceptable in accordance with predetermined inspection procedures, prior to installation or use.

Identification & Control of Materials, Parts & Components

1. Procedures are established to identify and control materials parts and components, including partially fabricated sub-assemblies.

2. Procedures are established to ensure that identification of an item is maintained by part number, serial number, or other appropriate means, either on the item or on records traceable to the item to preclude use of incorrect of defective items.

3. Identification of materials and parts important to the function of safety-related systems and components will be traceable to the appropriate documentation, such as drawings, specifications, purchase orders, manufacturing and inspection documentation, deviation reports, and physical and chemical test reports.

4. The location and method of identification will not affect the fit, function, or quality of the item being identified.

5. Correct identification of materials, parts and components is verified and documented prior to release for fabrication, assembling and installation.

Control of Special Processes

1. All special processes, such as welding, are procedurally controlled.

2. All procedures, equipment, and personnel connected with special processes are qualified in accordance with applicable codes, standards and specifications.

3. The qualification records of procedures, equipment, and personnel associated with special processes are established, filed and kept current.

Inspection

1. An inspection program which verifies conformance of quality affecting activities with requirements is established, documented and accomplished in accordance with written and controlled procedures.

2. The inspection personnel is independent from the individuals performing the activity being inspected.

3. The inspectors are qualified in accordance with applicable standards and company training programs. Their qualifications are kept current through continued retraining on revised procedures.

4. Modifications, repairs and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

5. Provisions are established that identify mandatory inspection hold points for witness by an inspector.

Test Control

1. A test program to demonstrate that the item or component will perform satisfactorily in service is established, documented and accomplished in accordance with written, controlled procedures.

2. Modification, repairs and replacements are tested in accordance with the original design and testing requirements or acceptable alternatives.

3. Test results are documented, evaluated, and their acceptability determines by a qualified, responsible individual or group.

Control of Measuring & Test Equipment

1. Measuring and test instruments are calibrated at appropriate intervals based on the required accuracy, purpose, degree of usage, stability characteristics and other conditions affecting the measurement.

2. Test equipment is identified and traceable to the calibration test data.

3. Measures are taken and documented to determine the validity of previous inspections performed when measuring and test equipment is found to be out of calibration.

4. Reference and transfer standards are traceable to recognized standards; or, where recognized standards do not exist, provisions are established to document the basis for calibration.

Inspection, Test and Operation Status

1 The appropriate identification of packages as to the status of inspections and testing and therefore the overall operating status of the unit is known by affected organizations.

2. The application and removal of inspection and welding stamps, and status indicators such as tags, markings, labels and stamps are procedurally controlled.

3. The bypassing of required inspections, tests and other critical operations is procedurally controlled.

4. The status of non-conforming, in-operative, or malfunctioning packages or components is clearly indicated is such a manner to prevent their unauthorized use.

Non-Conforming Material, Parts or Components

1. The identification, documentation, segregation, disposition, review and notification to affected organizations, on non-conforming materials, parts components or services are procedurally controlled.

2. Documentation identifies a non-conforming item, describes the non-conformance, the disposition of the non-conformance and the inspection requirements; and includes the appropriate approval signature related to the disposition.

3. Non-conforming items are clearly segregated from acceptable items and identified as discrepant until properly dispositioned.

4. All rework or repair of materials, parts, components and systems is verified by reinspecting and retesting the item as it was originally inspected and tested or as verified by a method which is at least equal to the original inspection and testing method.

Corrective Action

1. The evaluation of conditions detrimental to quality (such as non-conformances, deficiencies, failures, malfunctions, deviations and defective material and equipment) is conducted to determine the need for corrective action in accordance with established procedures.

2. Corrective action is initiated following the determination of a condition adverse to quality to preclude recurrence.

3. Follow-up reviews are conducted to verify proper implementation of corrective actions and to formally close out the corrective action documentation.

Quality Assurance Record

1. Sufficient records are maintained to provide documentary evidence of the quality and safety of items, and the activities affecting quality and safety.

2. The Quality Assurance records maintained for the gauge includes qualification of personnel; procedures and equipment; list of non-conformances; corrective action reports for non-conformance, results of reviews, inspections, test, audits and material analysis; other documentation such as drawings, specifications, procurement documents and calibration procedures.

3. Records are identifiable and retrievable.

4. A list of the required records and their storage locations will be maintained.

5. All design related records (e.g. drawings, calculations, etc.) are maintained for the life of the gauge and all other records are maintained for a minimum of two years.

6. The inspection and test records contain the following where applicable:

    a. A description of the type of observation.

    b. Evidence of completing and verifying a manufacturing, inspection, or test operation.

    c. The date and results of the inspection or test.

    d. Inspector or data recorder identification.

e. Evidence as to the acceptability of the results.

Audits

1. Audits are performed in accordance with pre-established written procedures or check lists and conducted by personnel not having direct responsibilities in the area being audited.

2. The results of audits are documented and reviewed with responsible management of areas audited.

3. The responsible management takes the necessary action to correct deficiencies revealed by the audit on a timely basis.

4. Deficient areas will be re-audited on a timely basis to verify implementation of corrective actions to minimize recurrence of deficiencies.

5. Audits of the Quality Assurance Program are preformed at least annually, based on the safety significance of the activity audited.

6. The audit plan includes:

   a. Purpose or objective of audit.

   b. Scope.

   c. Specific organizations to be audited.

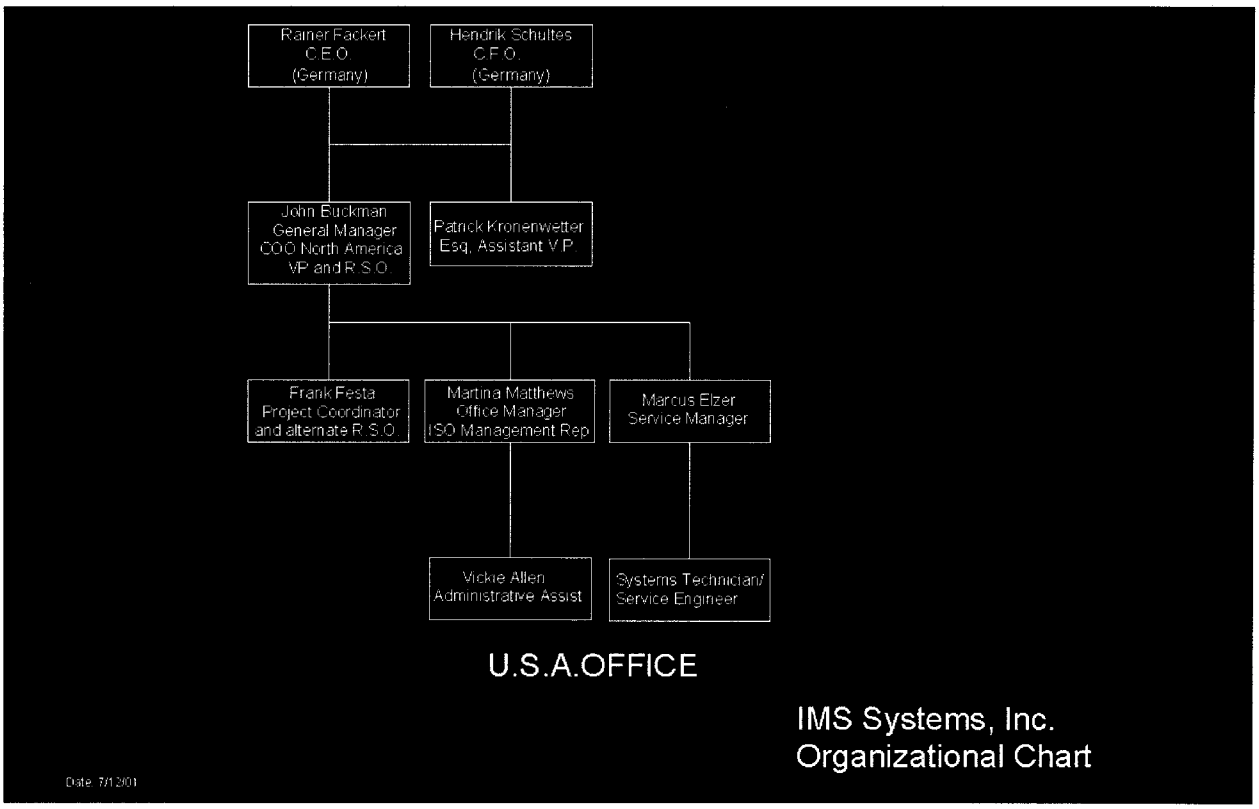
   d. Names of team members and team leaders.

   e. Approximate schedule.

   f. Written notification to audited organization.

   g. Post audit conferences.

   h. Method of reporting and evaluating findings.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Organizational Chart
Date: 7/1/2001