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A NEMA Medical Imaging & Technology Alliance (MITA) Division Document
NEMA MITA 2-201X

Requirements for Servicing of Medical Imaging Equipment

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FOREWORD

This standards publication presents the minimum elements of a quality management system for all service providers of medical imaging equipment. This standard provides guidance to multiple stakeholders including, but not limited to, accreditors, manufacturers, provider facilities, and service providers.

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SECTION 1 – GENERAL

1.1. SCOPE

This standard describes and defines the minimum requirements to document service of medical imaging equipment intended to be used on patients to ensure its return to a safe and effective condition, including actions such as repair, rework, update of software/hardware, replacement of parts with qualified parts and the use of test equipment for servicing medical imaging equipment.

This standard outlines the minimum quality management system requirements for servicing that, if followed, will ensure servicers give appropriate consideration to operational, performance and safety factors. This standard applies to any entity that services medical equipment, including healthcare organizations as a whole, divisions and departments within healthcare organizations; and outside vendors such as medical equipment manufacturers, shared service providers, and independent service organizations.

Requirements determined by Authorities Having Jurisdiction (AHJ) take precedence in the event they conflict with this standard.

This standard does not cover refurbishment of medical imaging equipment. NEMA MITA 1- 2015, *Good Refurbishment Practices for Medical Imaging Equipment* covers refurbishment.

1.2. INFORMATIVE REFERENCES

This standard is intended to be used in conjunction with the following publications. The latest edition of the publication applies (including amendments).

IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 62353:2014, Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

IEC PAS 63077:2016, Good refurbishment practices for medical imaging equipment

ISO 13372:2012, Condition monitoring and diagnostics of machines -- Vocabulary

ISO 14971:2007, Medical devices -- Application of risk management to medical devices

United States Code of Federal Regulations Title 21 Part 820, *Quality System Regulation*

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SECTION 2 – DEFINITIONS

For the purpose of this standard the following terms and definitions apply.

2.1. COMPLAINT
Complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device related to the service process.

[SOURCE: 21 CFR 820.3]

2.2. INTENDED USE / INTENDED PURPOSE
Use for which a product, process, or service is intended according to the specifications, instructions and information provided by the manufacturer.

NOTE—Intended use should not be confused with normal use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose but also maintenance, service, and transport.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.44]

2.3. MANUFACTURER
Any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

[SOURCE: FDA 21CFR820.3]

2.4. MEDICAL IMAGING EQUIPMENT
Medical electrical equipment that provides images for clinical applications.

NOTE—See IEC 60601-1:2005+A1:2012 definition 3.63 for a definition of medical electrical equipment.

[SOURCE: IEC PAS 63077:2016, 3.4]

NOTE 2— In addition to medical imaging equipment, this standard applies to equipment such as but not limited to: 1) software, hardware, and systems that make up the device and 2) medical devices supporting medical electrical equipment providing images, that are required to allow the capture of effective images.

2.5. NORMAL USE
Operation, including routine inspection and adjustments by any operator, and stand-by, according to the instructions for use.

NOTE—Normal use should not be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but also maintenance, service and transport.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.71] (modified)

2.6. OBJECTIVE EVIDENCE
Data supporting the existence or verity of something. Objective evidence can be obtained through observation, measurement, testing or other means.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.72] (modified)

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2.7. OPERATOR
Person controlling the acquisition of medical images by handling and operating the medical imaging equipment.

2.8. PATIENT
Living being (person or other mammal) undergoing a medical, surgical, or dental procedure.

NOTE—A patient cannot be an operator of medical imaging equipment.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.76] (modified)

2.9. PREVENTIVE MAINTENANCE (PM)
Maintenance performed according to a fixed schedule, or according to a prescribed criterion, that detects or prevents degradation of a functional structure, system or component, in order to sustain or extend its useful life.

[SOURCE: ISO 13372:2012]

2.10. PROCESS
Set of interrelated or interacting activities which transforms inputs into outputs.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.89]

2.11. PROPERLY INSTALLED
Installed in accordance with the accompanying documentation.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.92]

2.12. QUALIFIED PARTS
Parts that are shown to meet original component qualities and do not change intended system operation.

2.13. QUALITY SYSTEM
The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
[SOURCE: 21 CFR 820.3]

2.14. REPAIR
Means for restoring to a safe, functional, normal condition.

[SOURCE: IEC 62353:2014, 3.39]

NOTE – May occur after fault detection through remote monitoring, customer identification, or other methods.

2.15. REWORK
Action taken on a nonconforming part so that it will fulfil the specified requirements before it is released for distribution.

[SOURCE: FDA 21 CFR 820.3(x)] (modified)

2.16. RISK
Combination of the probability of occurrence of harm and the severity of that harm.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.102]

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2.17. SERVICE
Maintenance or repair of a finished device after distribution for purposes of verifying its adherence to safety and performance specifications and/or returning it to the safety and performance specifications (including original manufacturer device labeling, serial numbers, etc.) established by the manufacturer and to meet its original intended use. Maintenance or repair cannot change the intended use(s) of the device from the original purpose(s).

[SOURCE: FDA 81 FR 11477] (modified)

2.18. SERVICE PERSONNEL
Individual(s) or entity(ies) that install, assemble, maintain or repair medical imaging equipment.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.102] (modified)

2.19. TRAINING
Activities that ensure the necessary education, background, and experience are acquired to adequately perform all assigned activities.

NOTE—Training can be in a formal classroom, hands on, online, virtual, or OJT (on the job training), it is not limited in any way - other than it must be comprehensive enough to allow for the safe and effective service of the device, as determined by the owner of said device.

2.20. VALIDATION
Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

[SOURCE: 21 CFR 820.3(z)]

2.21. VERIFICATION
Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

NOTE—The term “verified” is used to designate the corresponding status.

NOTE 2—Confirmation can comprise activities such as:
- performing alternative calculations;
- comparing a new design specification with a similar proven design specification;
- undertaking tests and demonstrations;
- reviewing documents prior to issue.

[SOURCE: ISO 14971:2007 , definition 2.28]

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SECTION 3 – QUALITY MANAGEMENT SYSTEM FOR SERVICERS OF MEDICAL IMAGING EQUIPMENT

3.1. QUALITY POLICY

Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization that provide service for medical imaging equipment. Management with executive responsibility are those with the authority to establish and make changes to the company quality policy.

3.2. ORGANIZATION

Each service provider shall establish and maintain an adequate organizational structure to ensure that medical imaging equipment is maintained and serviced in accordance with the requirements of this part.

3.2.1.Responsibility and authority

Each service provider shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

3.2.2.Resources

Each service provider shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this section.

3.2.3.Management representative

Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:

a. Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and
b. Reporting on the performance of the quality system to management with executive responsibility for review.

3.3. MANAGEMENT REVIEW

Management with executive responsibility shall review the suitability and effectiveness of the quality system, at defined intervals and with sufficient frequency, according to established procedures, to ensure that the quality system satisfies the requirements of this part. Management with executive responsibility shall review for suitability and effectiveness the service provider's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

3.4. QUALITY PLANNING

Each service provider shall establish a quality plan which defines the quality practices, resources, and activities relevant to the medical imaging equipment that it services. The service provider shall establish how the requirements for quality will be met.

3.5. QUALITY SYSTEM PROCEDURES

Each service provider shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.

3.6. AUDITS

Each service provider shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have

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direct responsibility for the matters being audited. Corrective action(s), including a re-audit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and re-audit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and re-audits shall be documented.

3.7. DOCUMENT CONTROL

Each service provider shall establish and maintain procedures to control all documents that are required by this standard. The procedures shall provide for the following:

a. Document approval and distribution. Each servicer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this standard. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this standard shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.
b. Document changes. Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each servicer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

3.8. SERVICE PROCESS CONTROL

Each servicer shall develop, conduct, control, and monitor service processes to ensure that medical imaging equipment conforms to its available specifications. Where deviations from available equipment specifications could occur as a result of the servicing process, the servicer shall establish and maintain process control procedures that describe any process controls necessary to ensure system performance. Where process controls are needed they shall include but are not limited to:

a. Documented instructions, standard operating procedures (SOPs), and methods that define and control the manner of service;
b. Monitoring and control of process parameters and component and medical imaging equipment characteristics during service;
c. Compliance with specified reference standards or codes;
d. The approval of processes and process equipment; and
e. Criteria for workmanship which shall be expressed in documented standards

3.8.1.Test equipment, tools, parts and supplies

The service provider shall

a. Maintain sufficient inventory or access to types and quantities of test equipment, tools, parts and supplies to enable the staff to deliver the requisite medical equipment maintenance services
b. Ensure that test equipment, tools, parts and supplies are

    - maintained in good condition,
    - properly clean/disinfected,
    - packaged, stored, and transported in a proper environment and that they are used only by staff who have been appropriately trained in their use

c. Establish and follow a calibration schedule for any test equipment determined to require regular calibration
d. Establish and follow a policy/procedure for mitigating problems that might arise from the use of test equipment that was found to be out of calibration

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e. Monitor the test equipment performance and recalibrate, repair or replace equipment as appropriate if determined not to be accurate
f. Validate that the system is returned to appropriate operating parameters when replacing parts

3.8.2.Personnel
Each service provider shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of its personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on service quality. The servicer shall ensure that its personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual.

Note: Each service provider will have established procedures and retain documentation of adherence to such, to provide for training of service personnel with operator's requirements for safety and security. All service providers shall be cleared by appropriate security, or appropriate vendor credentialing services, badging will be displayed when appropriate, and service providers shall not enter areas for which there is no direct correlation for imaging service or permission has not been granted.

3.8.3.Contamination control
Each service provider shall establish and maintain procedures to reduce the risk of contamination of equipment or product during the process of servicing by substances that could reasonably be expected to have an adverse effect on product quality.

3.8.4.Buildings
If medical imaging equipment is serviced in the service provider's buildings, the areas where service is performed in the building shall be of suitable design, including environmental controls and contain sufficient space to perform necessary operations, prevent errors, and assure orderly handling.

3.8.5.Equipment
Each service provider shall ensure that all equipment used in the service process meets specified requirements and is appropriately designed, constructed, placed, and properly installed to facilitate maintenance, adjustment, cleaning, and use.

a. Maintenance schedule. Each service provider shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure proper operation. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.
b. Inspection. Each service provider shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.
c. Adjustment. Each service provider shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.
d. Risk Management. The service provider shall establish a policy to address how to mitigate and respond to risk associated with equipment used in the service process that does not meet specified requirements.

Note: Where applicable, all test equipment shall meet requirements of authorities having jurisdiction.

3.8.6. Software-based service processes
When non-original manufacturer software or another device is added or connected to the system for servicing purposes the service provider shall validate the computer software or other device for its intended use according to an established protocol. All software changes shall be validated before

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approval and issuance and meet the requirements of the AHJ. These validation activities and results shall be documented.

3.9. CYBERSECURITY CONSIDERATIONS

Cybersecurity activities related to service shall be documented. See Annex A for additional information.

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SECTION 4 – PURCHASING CONTROLS

Each service provider shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

4.1 EVALUATION OF SUPPLIERS, CONTRACTORS AND CONSULTANTS

Each service provider shall establish and maintain the requirements, including quality requirements, which shall be met by suppliers, contractors, and consultants. Each service provider shall:

a. Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
b. Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
c. Establish and maintain records of acceptable suppliers, contractors, and consultants.

4.2 PURCHASING DATA

Each service provider shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the service provider of changes in the product or service so that service provider may determine whether the changes may affect the quality of a finished device.

4.3 IDENTIFICATION

Each service provider shall establish and maintain procedures for identifying parts during all stages of receipt, storage, repair, service, distribution, and installation to prevent loss or substitution of a defective or non-conforming part.

4.4 PART REPLACEMENT

Regardless of the part being original manufacturer or non-manufacturer-sourced, the parts shall be demonstrated and documented through appropriate validation and verification as a qualified part.

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SECTION 5 – TRAINING

5.1. GENERAL

Each service provider shall have sufficient personnel with the necessary documented qualifications to assure that all activities required by this standard are correctly performed. The qualifications may include a background in medical imaging equipment technology, clinical application and use, associated components, systems, and appropriate regulatory compliance knowledge. Individuals providing service shall possess qualified knowledge of the equipment for which they perform maintenance, including safe practices to perform such service (e.g., radiation safety) and be trained for the requirements in the quality management system. As part of their training, personnel shall be made aware of system errors, parts defects, compliance issues, and potential risks to their person, others, the equipment, or facility in the form of safety: to include but not limited to electrical, radiological, and hydraulic risks. Assessment of the performance of these activities and competence are key components in an applicable audit or certification program. Additional training and competency checks shall occur as dictated by the applicable quality management plan or as equipment evolves.

5.2. PROCEDURES

Each service provider shall establish procedures for specifying competence requirements and identifying training needs and ensure that all personnel providing medical imaging equipment maintenance or support are trained to adequately perform their assigned responsibilities. Training shall be documented. As part of their training, personnel shall be made aware of system errors, parts defects, and compliance issues which may occur from the improper performance of their specific jobs.

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SECTION 6 – ACCEPTANCE ACTIVITIES, INSPECTIONS, AND CHECKS

6.1. CONTROL OF NON-QUALIFIED PARTS AND MATERIALS

Each service provider shall establish and maintain procedures to control parts and materials that are not qualified. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of non-qualified parts and materials. The evaluation of qualification shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the non-qualification. The evaluation and any investigation shall be documented.

If rework is done to a part or material, the service provider shall establish and maintain procedures for rework, to include retesting and reevaluation of the part or material after rework, to ensure that the part or material meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the part, shall be documented.

6.2. ACCEPTANCE ACTIVITIES

Each service provider shall establish and maintain procedures for acceptance activities for parts and materials. Acceptance activities include inspections, tests, or other verification activities.

6.3. CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT/FIXTURES

Each service provider shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment and fixtures, is suitable for its intended purposes and is capable of producing valid results. Test equipment shall be maintained as documented in section 3.8.1.

6.4. CALIBRATION OF TOOLS FOR INSPECTION, MEASUREMENT AND TEST EQUIPMENT

Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the medical imaging equipment's quality. This shall include a review of medical imaging equipment that has been impacted by the out-of-specification equipment. These activities shall be documented.

Documentation of calibration shall be maintained. Documentation of use of calibrated tools shall also be maintained. The service provider shall establish a policy to address how to mitigate and respond to risk associated with equipment used in the service process that is found to be out of calibration.

6.4.1. Calibration standards

Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the service provider shall use an independent reproducible standard. If no applicable standard exists, the servicer shall establish and maintain an in-house standard.

6.4.2. Calibration records

The equipment identification, calibration dates, the individual or provider performing each calibration and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available.

6.5. PROPER INSTALLATION

Service personnel shall establish, maintain, or acquire instructions and procedures for performing and verifying that the installation, inspection, and any required tests meets the equipment specifications.

The service personnel installing the medical imaging equipment shall ensure that the installation, inspection, and any required testing are performed. The service personnel shall document the inspection

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and any test results to demonstrate proper installation in accordance with the accompanying documentation which should be preserved on site with the equipment for the life of the current installation.

If the service provider supports relocation of medical imaging equipment, (e.g. moving the equipment from one healthcare facility to another) they shall provide information to the manufacturer as necessary to allow for recalls and updates.

For installations involving radiation emitting products, the service provider shall comply with all applicable reporting requirements.

6.6. PREVENTIVE MAINTENANCE (PM)

The medical and test equipment included in the scope of this standard have varied minimum PM requirements. PMs shall be performed according to the individual medical imaging equipment's PM checklist and schedule. The PM checklist and schedule for medical and test equipment shall be made available to the owner of the equipment, including any updates to the checklist or schedule. The equipment owner shall retain these records.

The specific work performed and the results thereof during PMs shall be documented to demonstrate compliance with preventive maintenance requirements. This documentation shall be made available to the owner of the equipment upon the completion of service.

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SECTION 7 – SERVICING

7.1. INSTRUCTIONS

Each service provider shall establish, maintain, or acquire instructions and procedures for performing and verifying that the servicing meets the specified requirements of the equipment.

7.2. SERVICE REPORTS

All Service activities shall be documented and shall include:

a. The name of the medical imaging equipment serviced;
b. Any unique device identifier (UDI) or universal product code (UPC), and any other medical imaging equipment identification(s) and control number(s) used;
c. The date of service;
d. The individual(s) servicing the medical imaging equipment;
e. The service performed;
f. The applicable test and inspection data;
g. Specific documentation for the medical imaging equipment as required under applicable laws (e.g., radiation emitting products);
h. Service reports shall be provided to the owner of the equipment or their agent upon completion of the service.

If service reports are captured in an electronic format, they should be in a protected, searchable format. All documents required by this standard shall be retained for a minimum of five years from time of service or for the length of time as required by AHJ, contract or business needs..

7.3. ANALYSIS OF SERVICE REPORTS

Each service provider shall analyze service reports with appropriate statistical methodology in accordance with Section 9.3. to identify trends and determine the root cause of reoccurring service problems.

7.4. SERVICE ACTIVITIES

Defective parts shall be replaced. Worn, but still operational parts shall be assessed for replacement. If a worn part is likely to lead to failure of the medical imaging equipment before the next scheduled preventative maintenance, or if failure presents a safety risk to any party or may cause harm directly or indirectly to the patient, the worn part shall be proactively replaced. Contaminated parts shall be replaced unless they can be cleaned or disinfected effectively. Issues that are not repaired at the time of servicing shall be documented as an incomplete repair and reported to the operator. In the event an incomplete repair presents a safety risk to any party or may cause harm directly or indirectly to the patient, the operator shall be notified and the system shall not be returned to active use until the repair can be properly completed.

7.5. OPERATIONAL TESTING

Upon completion of service, the medical imaging equipment shall be checked for functional operation and calibrated if required. The operational testing shall be documented within the service record. Local regulations or policy may require additional evaluation before returning the medical imaging equipment to service.

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SECTION 8 – COMPLAINTS

8.1 CUSTOMER FEEDBACK

The service provider shall have in place a system for managing customer feedback relating to the service of the device. The service provider shall develop a mechanism to evaluate customer feedback relating to the service of the device to ensure appropriate corrective action and facilitate overall trending for quality monitoring.

8.2 COMPLAINTS

The service provider shall have in place a system for managing complaints relating to the device if such information is received. A system for managing complaints relating to the device shall include a mechanism for sharing such information in a timely manner to appropriate parties (e.g. manufacturers, operator). The information shared with appropriate parties shall include the details listed in Section 8.3

8.3 RECORD

When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in section 8.1. The record of investigation shall include:

a. The name of the medical imaging equipment;
b. The date the complaint was received;
c. Any unique device identifier (UDI) or universal product code (UPC), and any other medical imaging equipment identification(s) and control number(s) used;
d. The name, address, affiliation, and phone number of the complainant;
e. The name, address, affiliation, and phone number of the investigator;
f. The nature and details of the complaint;
g. The dates and results of the investigation;
h. The relationship, if any, of the device to a reported incident or adverse event;
i. Any corrective action taken; and
j. Any correspondence relevant to the complainant.

NOTE: For all service providers not servicing their own equipment, sharing of customer data may require the approval of the hospital as many hospitals and systems consider this their own proprietary data. Normally this does not prohibit sharing service data as long as it is redacted appropriately.

8.4 CORRECTIVE AND PREVENTATIVE ACTION

Each service provider shall establish and maintain procedures for implementing corrective and preventive action related to service activities. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
b. Investigating the cause of nonconformities relating to product, processes, and the quality system;
c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
d. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
f. Ensuring that information related to quality problems is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
g. Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

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SECTION 9 – OTHER/MISCELLANEOUS

9.1 CONTROL OF DESIGN AND DESIGN CHANGES

Servicing activities shall be evaluated to determine if they are design changes. Service providers shall review, verify, and validate potential design changes to ensure that the safety and effectiveness requirements of the equipment are not changed from its original or applicable market authorizations. All design changes, including parts, shall be evaluated to determine if the servicing activity has become a manufacturing activity and therefore falls under regulations of the AHJ.

Service activities that replace parts with validated replacement parts, with the intention of returning the unit to installation specification, do not need to be evaluated for consideration regarding if the service provider is now the manufacturer.

9.2 RISK MANAGEMENT

Risk management principles shall be applied as applicable across all aspects of servicing.

9.3 STATISTICAL TECHNIQUES

Each service provider shall establish and maintain procedures for identifying valid statistical techniques as required for establishing, controlling, and verifying the acceptability of service activities.

Sampling plans, when used, shall be written and based on a valid statistical rationale. Each service provider shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

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ANNEX A: Cybersecurity Considerations

Cybersecurity is a shared responsibility between all stakeholders, including, but not limited to manufacturers, operators, service personnel, and others. For guidance on cybersecurity considerations, please refer to the following materials:

ISO/IEC 27000 family, Information security management systems

ISO 27799:2016, Health informatics -- Information security management in health using ISO/IEC 27002

ISO/TR 11633-1:2009, Health informatics -- Information security management for remote maintenance of medical devices and medical information systems - Part 1: Requirements and risk analysis & Part 2: Implementation of an information security management system (ISMS)

ISO/TR 21089:2004, Health informatics -- Trusted end-to-end information flows

NIST SP 800-43 Rev.2, Telework, Remote Access and BYOD Security

HN 1-2013, Manufacturer Disclosure Statement for Medical Device Security (MDS^2)

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