



Quality Systems Manual

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The Quality Systems Manual is intended to be used as an overview of the quality system implemented within EPIC Research & Diagnostics (EPIC). In the case of conflict with specific documents approved and released through the EPIC Documentation System, the specific document will take precedence.

*Reference Documents:

QA-002, Quality Plan

QA-101, Quality System Document Matrix

QA-012, EPIC Research and Diagnostics, Inc. Organization

QA-006, Management Review Policy

1.0 Introduction

EPIC Research & Diagnostics specializes in pioneering diagnostic research for early detection and identification of energetic anomalies in the human body, thereby improving patient therapy outcomes through both early identification and optimization of therapeutic management.

The mission of EPIC is to improve patient outcomes by demonstrating and propagating non-invasive energy analysis capability for use in western medical practices.

- Develop diagnostic methods to broaden the bio-energetic knowledge base.
- To create a bridge between bio-energetic diagnostic research and clinical practice.
- Educate physicians and other healthcare providers in the basic science and clinical applications of bio-energetic diagnostics.
- To disseminate the bio-energetic diagnostics knowledge base to practitioners, educators, researchers, and the public.

EPIC is committed to the highest quality possible in the products and services provided. Additionally, EPIC is dedicated to ensuring that products and services meet or exceed doctor and patient expectations for improved patient therapy outcomes as our goal. In order to accomplish these goals, the quality system has been implemented and maintained to ensure continual improvement to satisfy the diverse and complex customer expectations. Finally, EPIC is continually committed to meeting all regulatory and statutory requirements in order to provide the highest level of quality product for the end user.

2.0 Quality System

2.1 Policy

EPIC is committed to ensuring that a compliant quality system is established and maintained specific to each device designed and/or manufactured. EPIC is committed to ensuring that the quality system meets all rules, regulations, and statutory requirements

that are applicable to each individual device. The quality system is to be understood, implemented, and maintained throughout the entire organization.

EPIC ensures that all contract manufacturers have a quality system established and maintained to ensure that each appropriate step throughout the manufacturing process, and any changes or modifications to the process or product throughout the life cycle are documented and controlled appropriately. EPIC requires all contract manufacturers to have a quality system that meets or exceeds all rules, regulations, and statutory requirements that are applicable to any manufactured product. Contract manufacturers will be required, where appropriate and applicable, to meet all EPIC quality system expectations set forth in this manual during the manufacture of product. EPIC Quality Assurance will periodically review and audit the contract manufacturer to evaluate that their quality system, process and personnel are meeting this requirement.

2.2 Responsibilities

All EPIC employees are responsible for ensuring compliance to the quality system requirements as applicable in their daily functions. Quality Assurance is responsible for monitoring and auditing to ensure that the quality system and any contract manufacturer's quality system is functioning according to the appropriate policy, guidelines and procedures.

3.0 Management Responsibilities

3.1 Policy

All levels of management at EPIC, as defined in the EPIC Research and Diagnostics, Inc. Organization chart, are responsible to ensure compliance with all policies, procedures, objectives, and to maintain the commitment to quality. These responsibilities are understood, implemented, and maintained throughout the organization.

3.2 Responsibilities

All levels of management are responsible for implementing, maintaining and reviewing the quality system as appropriate to their assigned responsibilities. All levels of management have the authority to ensure the requirements of the standards are being met and that personnel are adequately trained.

Executive management is responsible for the overall organization of the quality system by developing a management style, behavior, and attitude that supports the idea that quality is ingrained in the organization, and is the responsibility of all employees. This style focuses on quality and quality improvement.

The Quality Assurance Manager is responsible for reporting on the performance of the

quality system to executive management in Quality System Review meetings as well as ensuring that all Quality Assurance activities are completed as mandated within the quality system.

Quality Assurance is responsible for quality planning which includes the quality practices, resources, activities and procedures relevant to all products designed, manufactured and distributed by EPIC.

4.0 Quality Audits

4.1 Policy

EPIC establishes and maintains procedures to conduct internal audits of the quality system to ensure that the requirements are being consistently achieved. Audit findings are documented and reviewed by the auditor and the department audited for any appropriate corrective and preventive action. Executive Management periodically reviews audit results and corrective and preventive action requests for compliance to the quality system requirements.

4.2 Responsibilities

The Quality Assurance Department is responsible for conducting and documenting periodic internal audits to the quality system requirements. The identified department in an internal audit is responsible for resolving audit issues and implementing appropriate corrective action and preventive action on a timely basis. Quality Assurance, Executive Management, and the responsible department have the authority to request corrective and/or preventive action for any non-conformance of the quality system.

5.0 Training

5.1 Policy

EPIC establishes and maintains procedures to ensure that hiring practices include activities to determine whether candidates have the necessary education, background and experience to match the requirements outlined in the job description. Additionally, procedures are established and maintained to ensure employee training is conducted, records of the training maintained, and to ensure that all aspects of the quality system are being performed to meet or exceed the requirements within the appropriate department.

5.2 Responsibilities

Each department is responsible for conducting and documenting their specific training or periodic retraining, to meet the quality system requirements. The Human Resources Department is responsible for conducting, coordinating and documenting training related to new employee orientation. Employee qualification documentation and training records will be maintained as a hardcopy by Human Resources.

6.0 Design Control

6.1 Policy

EPIC establishes and maintains procedures to ensure design quality through the documentation of each step of the design process, from the concept to the release for production. Design changes are controlled throughout the product's life cycle to ensure that any changes needed continue to meet the product's requirements. Design History Files (DHF) are maintained for each device developed under Design Controls. Engineering responsibility may be outsourced. As applicable, EPIC will work with the Engineering contractor to develop a design plan that ensures all design history records are maintained within the appropriate DHF until the design transfer phase which will mandate to maintenance of the DHF by EPIC Quality Assurance.

6.2 Responsibilities

The primary responsibility for complying with the quality system requirements throughout the design phase, from formal initiation of the design project through planning, input, output, review, verification, validation, transfer and the development of DHF for each product will reside with the Engineering. EPIC Operations, Marketing, Regulatory, and Quality Assurance are responsible for providing support and assistance to Engineering throughout the design cycle as defined in the Design Control Procedures.

7.0 Document Control

7.1 Policy

EPIC establishes and maintains procedures to ensure that each appropriate step throughout the process, and any changes or modifications to the process or product throughout the life cycle, are documented and controlled appropriately. Quality Assurance is responsible for coordinating document review, approval and maintenance activities in a timely manner.

Documents describing the project initiation through to the device transfer to manufacturing are known as Design History Files (DHF). Documents describing the released device design, manufacturing processes, labeling, packaging, and distribution are known as the Device Master Record (DMR). Documents demonstrating that the finished device was manufactured to the Device Master Records are known as Device History Records (DHR). All of these records pertaining to released product are maintained by Quality Assurance.

7.2 Responsibilities

Quality Assurance is responsible for establishing and maintaining the document control system and for ensuring documents are released, controlled, distributed, changed and

secured to meet the quality system requirements upon device transfer. All users are required to establish, maintain, access, distribute and otherwise utilize all documentation as required within the quality system.

8.0 Purchasing

8.1 Policy

EPIC establishes and maintains procedures to ensure that suppliers and contractors will be qualified, approved, and periodically reviewed to established requirements and to ensure all applicable quality system requirements for quality, reliability, and delivery are met prior to and after providing materials or services to EPIC. Approved Suppliers will be managed using the Approved Suppliers List which is maintained and controlled through Quality Assurance.

8.2 Responsibilities

Operations are responsible for purchasing and/or returning material as required by the quality system. Operations, with support from Quality Assurance and Engineering, are responsible for the selection of suppliers/vendors and subcontractors based on their ability to continually meet all the requirements of the quality system. Vendor and subcontractor performance is gathered through the nonconformance and corrective and preventive action systems, and monitored by Quality Assurance. EPIC reserves the rights to conduct an onsite visit when necessary to discuss quality issues as they occur.

9.0 Identification

9.1 Policy

EPIC establishes and maintains procedures for the identification of components, assemblies, and finished product as appropriate for their purpose, use and life cycle.

EPIC ensures that products are controlled through the use of alphanumeric part numbers and/or control numbers. Additional identification may be recorded such as serial, batch, and/or trace numbers, as applicable. All incoming, in-process and/or finished device identification requirements will be defined with instructions for execution of this identification throughout processing. Product numbers and control numbers are recorded on appropriate documentation throughout the process as required by standard operating procedures and all records are filed accordingly.

EPIC ensures that all contract manufacturing sites have implemented procedures to ensure the identification of all components, assemblies, and finished product that are handled throughout their specific contract manufacturing site quality system in accordance with the requirements specified in the product specifications and process procedures.

9.2 Responsibilities

Quality Assurance is responsible for controlling and issuing part numbers and control numbers. All requested part numbers/control numbers are maintained on a Master List by Quality Assurance, retained both on hardcopy and electronically (database).

Operations is responsible for ensuring the correct part numbers or control numbers (such as serial, lot, or trace numbers) are used and recorded on the appropriate documentation.

10.0 Traceability

10.1 Policy

EPIC establishes and maintains procedures for the traceability of components, assemblies, and finished product, and ensures that they are controlled through the use of alphanumeric part numbers/control numbers, such as serial, batch, or trace numbers and date received, as applicable. Product numbers and control numbers are recorded on appropriate documentation throughout the process as required by standard operating procedures and all records are filed accordingly.

10.2 Responsibilities

Quality Assurance is responsible for controlling and issuing part numbers and control numbers. All requested part numbers/control numbers are maintained on a Master List by the Quality Assurance department, retained both on hardcopy and electronically (database). Operations and Engineering are responsible for ensuring the correct part numbers and/or control numbers (such as serial, batch, or trace numbers), are used and recorded on the appropriate documentation.

11.0 Production and Process Control

11.1 Policy

EPIC establishes and maintains procedures to ensure processes for the manufacture and/or assembly of EPIC products is documented and controlled to meet the requirements of the quality system. These procedures are intended to provide Operations personnel sufficient instruction to ensure that products are processed uniformly within and between batches to ensure that all quality and customer standards are met or exceeded.

Where necessary, policy and procedures will be created to establish, maintain, and periodically inspect the production/processing and to document the following:

- 11.1.1** The maintenance of the production/process environment as specified and ensure that all personnel who work under special environmental conditions are trained to ensure all necessary precautions are followed.

- 11.1.2** The control of any substance or manufacturing material that could have an adverse effect on product quality. Any manufacturing material that could have an adverse effect on product quality is identified as such and removed according to established procedures.
- 11.1.3** The maintenance of any equipment used in the manufacturing process according to approved maintenance or calibration schedules. These schedules are documented and periodically inspected for adherence to the quality system. Any equipment requiring limitations or allowable adjustments must have those limitations or adjustments visibly posted or readily available to the personnel performing the manufacturing process.
- 11.1.4** When/if computers or automated data processing systems are used as part of the manufacturing process or the quality system, the software used is validated for its intended use. All validation activities and results are documented.

11.2 Responsibilities

It is the responsibility of the appropriate department to document the process, manufacture, and/or change/deviation to the existing process to ensure that the devices and/or product are manufactured conforms to all appropriate specifications, policies, and procedures.

Quality Assurance will be responsible to ensure that all DHRs meet the release requirements prior to releasing finished devices/product for distribution.

12.0 Inspection, Measuring and Test Equipment

12.1 Policy

EPIC establishes and maintains procedures to ensure the use of equipment and software to demonstrate conformance of our products to specified requirements is controlled. This control includes requiring the use of properly calibrated equipment as defined by the quality system, and traceable to the National Institute of Standards and Technology where applicable. Records of these activities are maintained and periodically audited by Quality Assurance.

12.2 Responsibility

The user of the equipment is responsible for ensuring the equipment and/or software used for inspection, measuring, and testing meets or exceeds the tolerance being measured, and the quality system requirements. The user is required to verify calibration and acceptability for use prior to use.

13.0 Process Validation

13.1 Policy

New processes or changes/deviations to existing EPIC processes are verified and/or validated prior to release of the products. Validation requirements are reviewed and addressed for each product to ensure adherence to all proposed uses and functions according to applicable specifications and requirements. Validation is required to be performed and documented for process or design changes except when verification testing is acceptable. Verification testing may be acceptable in such instances as minor component changes or for total label verifications. The decision to perform validation versus verification testing is made on a case-by-case basis and is determined by reviewing the specific changes and its effect on form, fit, function, safety and effectiveness. All decisions regarding validation versus verification will be documented. Approved validation and verification documents are maintained and filed in Quality Assurance.

13.2 Responsibility

Operations is responsible to ensure that all process validation steps are taken prior to the implementation of a new process or after significant process change. Quality Assurance is responsible to review all process validation documentation to ensure that the quality system requirements have been met taken prior to the implementation of a new process or after significant process change. Engineering is responsible to oversee process validation activities and review results to ensure validation activities are sufficient to technically challenge the process and/or process change.

14.0 Receiving, In-process, and Finished Device Acceptance**14.1 Policy**

EPIC establishes and maintains procedures to ensure inspection and testing is performed on incoming and in-process materials, including finished devices, to the appropriate levels as defined in controlled documentation, to meet the requirements of the quality system and product specifications. Incoming and in-process product is controlled until inspection and test activities have been completed and documented. Finished devices are not released for distribution until the activities required by the Device Master Record are completed and the associated data and documentation has been reviewed. The release of finished devices is authorized by the signature and date of the designated individual(s). Acceptance records include the activities performed, dates, results and the signatures of those individuals conducting the activities and, where appropriate, the equipment used. These records are a part of the Device History Records.

14.2 Responsibilities

Operations and Quality Assurance are responsible for ensuring that personnel performing inspection and testing are appropriately trained to identify acceptable versus non-

acceptable materials using the latest available approved documentation. Quality Assurance is responsible for monitoring the performance of inspection and test results through internal and supplier auditing. Inspection and testing criteria is determined and reviewed periodically by Quality Assurance. Finished device DHRs are reviewed and approved prior to release of product for distribution.

15.0 Acceptance Status

15.1 Policy

EPIC establishes and maintains procedures for identifying the inspection and test status of all components, assemblies, and finished devices throughout the assembly process, packaging, labeling, installation and servicing of the device to ensure that they have passed the required inspections and tests and are identified accordingly.

15.2 Responsibility

Operations and Quality Assurance are responsible for defining the inspection and test points throughout the process and implementing changes or corrective action as required. The department/contract manufacturer recording inspection and test data for DHRs is responsible for documenting the inspection, maintaining the test data and trending the results as well as labeling the product's acceptance status throughout the process. Quality Assurance is responsible for reviewing all DHR documentation before release and monitoring the performance trend data through periodic audits.

16.0 Nonconforming Product

16.1 Policy

EPIC establishes and maintains procedures to ensure components, assemblies and finished devices that do not conform to the quality system requirements at any point throughout the process are identified and segregated until disposition and the person(s) responsible notified accordingly. Records of non-conformances are maintained and reviewed by designated individual(s). Components, assemblies, and/or finished devices will be dispositioned by the appropriate personnel. Any proposed rework is performed to established procedures, reevaluated and retested. All nonconformances will be evaluated for appropriate corrective and preventive action. These records are a part of the Device History Record.

16.2 Responsibilities

Any personnel (either at EPIC or at a contract manufacturing site) identifying non-conforming material are responsible for tagging and segregating the material appropriately. Engineering, Quality Assurance, and Operations are responsible for feedback to suppliers (including contract manufacturers) responsible for non-conforming material or product.

For all contract manufactured products, the contract manufacturer's quality system requirements will be followed for the review, disposition and potential rework of all nonconforming product. Engineering, Operations, and Quality Assurance are required to review and approve of all contract manufacturing proposed approval dispositions and rework requirements for characteristics that affect the form, fit, and/or function of the finished device.

17.0 Corrective and Preventive Action

17.1 Policy

EPIC establishes and maintains procedures to document and investigate non-conformances and determine effective corrective action to prevent reoccurrence, including preventive action when appropriate. This process includes analyzing sources of quality data to identify existing and potential problems, identifying the action(s) needed to correct and prevent recurrence, verifying or validating the corrective and preventive actions to ensure that such action is effective, implementing any suggested changes to the processes, and reviewing and reporting these instances through the appropriate organizational structure with the goal of minimizing nonconformances throughout the process. All activity and results are documented and monitored.

17.2 Responsibility

Any individual or department may request corrective or preventive action. Quality Assurance is responsible for coordinating the review of corrective or preventive action with the responsible departments, implementation of corrective and/or preventive action, and periodic review of the effectiveness of implemented corrective/preventive action as appropriate. Each department is responsible to respond to corrective action requests and, where appropriate, take necessary action.

18.0 Labeling

18.1 Policy

EPIC establishes and maintains procedures to ensure that documents and labels are handled, stored and distributed with appropriate measures taken to ensure their integrity and protect them from physical damage. Labels and labeling are distributed in a controlled manner to ensure that only approved labels and labeling are released and utilized.

18.2 Responsibilities

Quality Assurance will coordinate with Regulatory staff to identify the labeling requirements. Executive Management, Operations, and Quality Assurance are jointly responsible for establishing the procedure for controlling the labeling process and

ensuring that the Quality System requirements are met. EPIC Operations and/or the contract manufacturer are responsible for affixing labels in a controlled manner. Quality Assurance is required to perform all established release requirements as required.

19.0 Handling, Storage, Packaging and Delivery

19.1 Policy

EPIC establishes and maintains procedures to ensure components, assemblies and finished devices are handled, stored and distributed with appropriate measures taken to protect them from physical and/or non-visual damage. Finished devices/product is distributed in a controlled manner to ensure only approved devices are released.

19.1.1 Handling: Handling and movement of material is done in such a way as to prevent damage to the packaging and to the material.

19.1.2 Storage: Production material is stored in designated, well secured and covered areas and warehouses in order to prevent deterioration and loss. Verification that no deterioration and loss has occurred to either in-process materials or finished goods is done during as a part of inventory management. Warehouse and manufacturing personnel and Supervisors inspect their respective areas for damaged packaging, unsafe stocking, and general housekeeping. Material is consumed, stored, and shipped on a first-in-first-out basis. Issuance of material into and out of material control is done using a standard procedure established to protect the product and prevent deterioration and loss.

19.1.3 Packaging: Packaging of finished product is done in accordance with documented work instructions.

19.1.4 Preservation: Products with environmental requirements are stored in such a manner as to preserve the integrity of the material.

19.1.5 Delivery: To ensure preservation of product, transportation methods are established and documented. Records of shipment and distribution are maintained.

19.2 Responsibility

Engineering is responsible for identifying the requirements for handling, storing, and packaging and preservation. Operations, Engineering, and Quality Assurance are jointly responsible for establishing the procedure for all devices/product labeling and shipment. Operations is responsible to work with the contract manufacturer to ensure that packaging and shipment of contract manufactured product to EPIC for distribution is conducted according to established policy and procedures.

20.0 Customer Contract Review

20.1 Policy

EPIC establishes and maintains procedures for the review and coordination of customer contracts and purchase orders to ensure all Quality System requirements have been met.

20.2 Responsibilities

Customer Service and Sales are responsible for the review and coordination of customer contracts and purchase orders. Other departments will be involved as defined in the appropriate Contract Review Procedures.

21.0 Installation**21.1 Policy**

EPIC establishes and maintains procedures to ensure that adequate installation and inspection is performed on the devices prior to use. These procedures detail the instructions and procedures that must be utilized during the installation.

21.2 Responsibilities

Clinical, Wellness and Training is responsible to identifying and documenting the requirements for proper installation including generating instructions and procedures to be used by all personnel during installation. These procedures will provide, as applicable, instructions and procedures for proper installation to ensure the installed device is safe, performing satisfactorily and is ready for use. Additionally, any safety and set up verifications required before use will be documented and distributed with the device or otherwise made available to the person installing the device and the end user. As appropriate, an installation checklist and required test documentation or other installation records will be established and maintained.

22.0 Quality Records**22.1 Policy**

EPIC establishes and maintains procedures to ensure quality records are developed, used, collected, and stored in a manner which meets the quality system requirements. Quality records are stored and maintained in a suitable environment to minimize deterioration or damage, and are readily retrievable. Record retention periods for all types of records will be established. The main types of quality system records are:

Device Master Record (DMR): Device Master Records for any EPIC device including device, process, quality, packaging, labeling, maintenance and servicing specifications and procedures are maintained and controlled through Quality Assurance.

Device History Record (DHR): DHRs for each device manufactured are maintained and controlled through Operations and/or the contract manufacturer(s) and Quality Assurance.

Design History File (DHF): Approved and Released for manufacture devices will have their Design History Files for any EPIC device developed under design controls maintained through Quality Assurance. Devices currently under development may have their DHF maintained by contract design and development firms. These DHFs are controlled as outlined in the Design Control documentation.

Complaint Record: Complaint Records are maintained and controlled through the Quality Assurance department.

Quality System Record (QSR): Other Quality System Records are maintained and controlled through the Quality Assurance department as defined in the appropriate policy and procedure.

Employee Training Record: Employee Training Records are maintained and controlled through Human Resources and individual department management.

22.2 Responsibilities

Each department and/or contractor is responsible for ensuring that record keeping methods meet the requirements of the quality system. Quality Assurance will oversee the identifying, indexing, filing, storing, maintaining, and disposing of records as defined by the appropriate departmental procedures.

23.0 Quality System Record

23.1 Policy

EPIC establishes procedures for and maintains any other Quality System Record (QSR) required. The QSR includes and refers to the location of quality system procedures and records.

23.2 Responsibilities

Each department is responsible for ensuring that their quality system procedures and records are in keeping with the requirements of the quality system. Quality Assurance will oversee the identifying, indexing, filing, storing, maintaining, and disposing of procedures and records as defined by the appropriate departmental procedures.

24.0 Complaint Files

24.1 Policy

EPIC establishes procedures for and maintains complaint files for any devices manufactured by EPIC. These procedures are intended to ensure that complaints regarding products, devices, and services are processed in a timely manner while ensuring uniform handling during receiving, reviewing and evaluating complaints. The evaluation of a complaint will include an assessment of whether an investigation is necessary, the reasoning behind these decisions and a determination regarding the necessity of filing the event under FDA 21 CFR part 803 or 804. A record of the investigation shall be maintained by Quality Assurance in accordance with policy and procedure outlined within the quality system.

24.2 Responsibilities

Each department is responsible for ensuring that complaints are handled in keeping with the requirements of the quality system. Quality Assurance will oversee corrective action and the identifying, indexing, filing, storing, maintaining of complaint files, and for identifying potential reportable events. Engineering is responsible for assisting Quality Assurance in determining the need to report and for submitting reports when necessary.

25.0 Servicing**25.1 Policy**

EPIC establishes and maintains procedures to ensure that finished devices under warranty or contract are serviced appropriately to meet specifications and provide customer satisfaction. This includes instructions for the end user, supplier, and/or distributors. Customer product experience reports are documented, reviewed and analyzed to determine whether they are complaints or non-complaints, corrective action is implemented when required, trends are identified, and reportable events are managed under the quality system requirements. Service records are filed as part of the Device History Record for each device.

25.2 Responsibilities

Customer Service is responsible for receiving and documenting customer requests for service or product experience. Quality Assurance and Engineering are responsible for determining whether or not a product experience is a complaint or a non-complaint, including reviewing and approving the analysis and any possible recommendation for corrective action prior to complaint closure. Executive Management is responsible for reviewing complaints for reportable events. Operations and Engineering are responsible for performing, servicing and complaint/failure investigation. Quality Assurance will oversee, maintain, and periodically report the activities of the complaint system. Quality Assurance analyzes service records with appropriate statistical methodology for corrective and preventive action reporting.

26.0 Statistical Techniques**26.1 Policy**

EPIC establishes and maintains procedures to incorporate statistical techniques where appropriate, to determine and control the acceptability of components, assemblies, finished devices, and process capabilities. Valid statistical techniques are based on available industry standards, and are implemented as appropriate for the application.

26.2 Responsibilities

Engineering, Operations and Quality Assurance are responsible for establishing sampling plans and/or levels to be used on a product or process. Quality Assurance is responsible for review and approval of all sample plans/levels being implemented or changed, and has the authority to request changes or modifications, whether temporary or permanent. Engineering, Operations, and Quality Assurance will periodically review statistical data for trending analysis and determine corrective action as required.

Document Revision History

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