INTERCONNECT CABLE TECHNOLOGIES CORPORATION

ICTC USA

Manufacturer of Cables and Electronic Assemblies
Brooksville, FL

Quality Manual

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Approvals	President/CEO, CFO/COO, QA
Notifications	Operations, Quality, Customer Service, Production, Engineering, Supply Chain

Revision	Date	Description of Change
A	02/06/2002	Initial release.
-	12/09/2002	Signatures re-affixed to cover page reflecting staff changes; no substantive alteration to content requiring revision advancement. – T. Baker
B	10/02/2007	Signatures re-affixed to cover page reflecting staff changes; Section 1 amended to reflect scope expansion (the manufacture and distribution of cable, harness and electronic assemblies). – T. Baker
C	10/02/2009	Text amended to conform to ISO 9001:2008 – T. Baker
D	01/06/2014	Update Org Chart, Quality Policy & Added ISO13485 & AS9100
E	05/06/2014	Added exclusions to scope and listed work instructions to appendix
F	08/11/2014	NO DESCRIPTION PROVIDED
G	07/28/2015	Updated format and quality policy. Removed Appendix 2 and QM-002 in the TOC and changed 5.5.2 to ref the Org. chart and not Appendix 2.- L. Castle
H	11/18/2016	Updated cover page with Current ISO Certificate numbers. Revised exclusion: 7.5.1.2 is now 7.5.1.2.1, 7.5.2 is now 7.5.2.2; added 8.2.4.2. – Corrected document number of RMA Work Instruction to WI-RMA-002. E. Hammond
I	12/06/2016	Updated Quality Manager approval to Ron Cain. Removed staff approvals not required per documentation Approval requirements.
J	07/23/2018	Update reflects transition to ISO 9001:2015 and ISO 13485:2016 standards. Approvals maintained electronically – T. Tucker
K	06/18/2019	Update reflects the QMS requirements for regulatory and statutory requirements. Added 13485:2016 clauses omitted in previous release. Update of Appendix A.
L	06/29/2020	Update to reflect new procedures and QMS Interaction Flow Chart
M	08/26/2020	Updated to reflect new procedures, explanations of QMS exemptions and updated quality policy.

Table of Contents

1. Scope

This Quality Manual provides specifics on the policies and procedures used by Interconnect Cable Technologies Corporation (ICTC) to meet ISO 9001/13485 Quality Management Systems requirements for ***the manufacture and distribution of cable, harness and electronic assemblies.***

Due to the limited scope of the organization and its products, the following clauses have been identified as not applicable and listed for exclusion from the Quality Management System:

ISO 9001:2015

8.3 – Design and development of products and services (including all sub-clauses):

Company is a contract manufacturer only; not design responsible.

ISO 13485:2016

7.2.1(d) – Determination of requirements related to the product. User training for medical devices not required;

Not a manufacturer of Medical devices.

7.2.2(d) – Review of requirements related to the product: Not a manufacturer of Medical devices.

7.3 – Design and development (including all sub-clauses): *Company is a contract manufacturer only; not design Responsible.*

7.5.3 – Installation activities: *Does not perform any installation activities.*

7.5.4 – Servicing activities: *No onsite servicing or servicing of medical product.*

7.5.5 – Particular requirements for sterile medical devices: *No sterile product is produced at ICTC.*

7.5.7 – Particular requirements for validation of process for sterilization and sterile barrier system*: No sterile product is produced at ICTC.*

7.5.9.2 – Particular requirements for implantable medical devices: *ICTC is not a manufacturer of implantable medical devices.*

These exclusions do not have a negative impact on the organization's ability or responsibility to provide products that meet customer, statutory and regulatory requirements.

2. Normative Reference

The following normative document(s) contains provisions which, through reference in this text, constitute provisions of ISO 9001/13485. For undated references, the latest edition of the normative document(s) referenced applies.

ISO 9001– American National Standard

ISO 13485 – Medical Device Standard

ISO 14971 – Risk Management

This document outline is based on the ISO 9001:2015 International Standard. Any reference to the requirements of ISO 13485:2016 standard within this document will be highlighted and noted as such.

3. Terms and Definitions

For the purpose of this manual, the term "organization" refers to ICTC. The terms "supplier" and "vendor" are synonymous and refer to external sources used to acquire purchased products and/or services by ICTC. The term "Standard" applies to the document(s) referenced in Section 2 above.

4. Context of the organization

4.1 Understanding the organization and its context

ICTC has established a Strategic Business Plan which identifies and defines its internal and external issues that are relevant to achieve the organization's purpose and strategic direction.

Mission: ***To provide the best customer experience through innovative manufacturing solutions***

Vision: ***Redefine contract manufacturing by being trusted, friendly and flexible.***

ICTC's strategy includes building and sustaining a culture of teamwork, achieving operational excellence, and growing profitability.

The organization will monitor and review information during management review meetings.

4.2 Understanding the needs and expectations of interested parties

In order to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, ICTC shall determine the needs and expectations of interested parties along with the requirements that are relevant to the quality management system.

4.3 Determining the scope of the quality management system

ICTC has considered all applicable requirements within the scope of its quality management system. The organization has taken into consideration the types of products and services provided, external and internal issues, and the requirements of relevant interested parties. The organization has identified the requirements of the standard listed in Section 1 of the Quality Manual as not applicable to the scope.

4.4 Quality Management System and its processes

ICTC documents, implements and maintains a quality management system and continually improves its effectiveness in accordance with the requirements of the ISO 9001/13485 international Standards and corporate policy.

ICTC quality management system is comprised of management processes, product realization processes, and support processes. These processes are outlined in document *285 ICTC process interactions flowchart.*

QMS General Requirements (ISO 13485:2016 – 4.1.6)

The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

5. Leadership

5.1 Leadership and commitment

5.1.1 General

Top management affirms and demonstrates its leadership and commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- taking accountability for the effectiveness of the quality management system;
- ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
- ensuring the integration of the quality management system requirements into the organization's business processes;
- promoting the use of the process approach and risk-based thinking;
- ensuring that the resources needed for the quality management system are available;
- communicating the importance of effective quality management and of conforming to the quality management system requirements;
- ensuring that the quality management system achieves its intended results;
- engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- promoting improvement;
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility;

5.1.2 Customer focus

Top management ensures that customer requirements are determined, understood and consistently met through established procedures along with identifying risks and opportunities that can affect conformity of products and services with the aim of enhancing customer satisfaction.

5.2 Policy

5.2.1 Establishing the quality policy

Interconnect Cable Technologies Corporation is committed to a policy of fulfilling and exceeding our customers' requirements including any regulatory requirements, while maintaining the effectiveness of our quality management system.

5.2.2 Communicating the quality policy

ICTC's quality policy is available and maintained through various forms of documented information. It is communicated, understood, and applied within the organization and available to relevant and interested parties by use of one or more of the following methods:

- Electronic media – monitors throughout the facility;
- Located on reverse of employee identification badges;
- Corporate website;

5.3 Organizational roles, responsibilities and authorities

ICTC Management has assigned responsibilities and authorities for relevant roles throughout the organization. All employees are responsible for ensuring that the quality management system conforms to the requirements of the international standard.

President - Has the overall responsibility for the organization's quality system, setting policy and assigning management responsibilities within the company.

COO - Has the overall responsibility of directing all functions within the organization and ensuring the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Quality Department Head - or designated alternate, has the responsibility for maintaining the quality management system and quality functions; reporting on the performance of the quality management system and on opportunities for improvement.

Department Managers - Have overall responsibility of directing manufacturing, purchasing, planning, and customer communication functions. Ensuring that the processes are delivering their intended outputs and the promotion of customer focus throughout the organization.

6. Planning

6.1 Actions to address risks and opportunities

ICTC's risk management process defines the method(s) to determine the risks and opportunities that need to be addressed. These methods are intended to consider the issues and requirements of the organization in order to:

- give assurance the quality management system can achieve its intended results;
- enhance desirable effects;
- prevent, reduce, undesired effects;
- achieve improvement;

ICTC will plan actions to address these risks and how to integrate and implement the actions into the quality management system as well as evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

6.2 Quality objectives and planning to achieve them

ICTC top management ensures that measurable quality objectives are established including those needed to meet applicable regulatory requirements within the organization at relevant functions, levels, and processes needed for the quality management system to be:

- consistent with the quality policy;
- relevant to the conformity of products and services to enhance customer satisfaction;
- monitored, communicated, and updated as appropriate;

Documented information on the quality objectives will be maintained.

When planning how to achieve its quality objectives, the organization shall determine:

- what will be done;
- what resources will be required;
- who will be responsible;
- when it will be completed;
- how the results will be evaluated;

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner.

The organization shall consider the:

- purpose of the changes and their potential consequences;
- integrity of the quality management system;
- availability of resources;
- allocation or reallocation of responsibilities and authorities;

7. Support

7.1 Resources

7.1.1 General

ICTC has determined and provides adequate resources to implement and maintain the quality management system, continually improve its effectiveness and to perform activities that ensure product quality, regulatory requirements, and customer satisfaction. The organization has considered the capabilities of, and constraints on, existing internal resources; and what needs to be obtained from external providers.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

ICTC maintains comfortable, spacious, well-lighted and clean buildings, workspaces and associated utilities, along with well-maintained process equipment (both hardware and software) and supporting services for transportation of product, communication and information systems needed to achieve conformity.

7.1.4 Environment for the operation of processes

ICTC manages the physical work environment in such a fashion, through conditioned climate and clean, comfortable surroundings, as well as promoting an environment of mutual dignity and respect among members of the organization, so as to achieve consistent quality output and conformity to product requirements.

Work environment (ISO 13485: 2016 – 6.4.1)

The organization shall:

- *document requirements for health, cleanliness and clothing of personnel if contact between such*
- *personnel and the product or work environment could affect medical device safety or performance;*
- *ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person*

Contamination control (ISO 13485:2016 – 6.4.2)

As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

ICTC determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity to requirements. ICTC has established processes to ensure that monitoring and measurement can be and is carried out in a manner consistent with requirements.

7.1.5.2 Measurement traceability

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified, or both, at specified intervals, or prior to use, against standards traceable to national or international measurement standards; where no such standard exists, the basis used for calibration or verification is recorded.
- Identified in order to determine its calibration status.

7.1.6 Organizational knowledge

Any personnel performing work affecting conformity to product requirements, including those performing any task within the quality management system, shall have demonstrated the requisite proficiency to carry out their assigned tasks.

7.2 Competence

The organization shall:

- determine the necessary competence requirements for personnel performing activities affecting conformity to product requirements;
- provide training, where applicable, or take other action(s) to achieve the necessary competence;
- evaluate the effectiveness of actions taken;
- ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives;
- maintain appropriate records of education, training, skills and experience;

7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

- the quality policy;
- relevant quality objectives;
- their contribution to the effectiveness of the quality management system, including the benefits of
- improved performance;
- the implications of not conforming with the quality management system requirements;

7.4 Communication

Top management has implemented processes, determined to be appropriate to the organization, through the establishment of dedicated areas for posting QMS information, periodic production and staff meetings and training that communicate the policies and effectiveness of the quality management system.

7.5 Documented information

7.5.1 General

ICTC's quality management system documentation includes:

- Documented statements of a quality policy and quality objectives.
- A quality manual.
- Documented procedures and records required by the Standard.
- Documents, including records, needed by the organization to ensure the effective planning, operation and control of its processes.
- Regulatory documents where required.

Medical Device File (ISO 13485:2016 – 4.2.3)

For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of the International Standard and compliance with applicable regulatory requirements.

The content of the file(s) shall include, but is not limited to:

- *general description of the medical device, intended use/purpose, and labelling, including any instructions for use;*
- *specifications for product;*
- *specifications or procedures for manufacturing, packaging, storage, handling and distribution;*
- *procedures for measuring and monitoring;*
- *as appropriate, requirements for installation;*
- *as appropriate, procedures for servicing*

7.5.2 Creating and updating

ICTC has established and maintains a quality manual and supporting documentation as defined by four tiers which includes:

Level 1 Documentation - Quality Manual

Level 2 Documentation - Operating Procedures

Level 1 and Level 2 documentation is subject to copy and review by second and third parties and shall by such definition be considered uncontrolled upon distribution.

Level 3 Documentation - Work Instructions

Level 4 Documentation - Records, Forms, and Tags

Appendix A of this document lists the Operating Procedures/Work Instructions developed at ICTC.

The set of records, forms, tags and/or labels which complement the record keeping necessary for maintenance of the quality system.

Level 3 and Level 4 documentation provide the information used in decision-making pertinent to the effectiveness of processes and the quality of product and shall by such definition be controlled throughout its life cycle.

7.5.3 Control of documented information

Documents required by the quality management system shall be controlled. A documented procedure is established to:

- Approve documents for adequacy prior to use.
- Review, update and, as necessary, re-approve documents.
- Ensure that changes and current revision status of documents are identified and legible.
- Ensure that relevant versions of applicable documents are available at points of use.
- Ensure that documents of external origin determined necessary by the organization are identified and their distribution controlled.

- Prevent the unintended use of obsolete documents through suitable identification if they are retained for any purpose.

Records are defined as documents which provide evidence of conformity to requirements and of the effective operation of the quality management system. ICTC has an established, documented procedure for the control, identification, storage, protection, retrieval, retention and disposition of records. Records shall remain readily identifiable, legible and retrievable

Control of records (ISO 13485:2016 – 4.2.5)

The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

8. Operation

8.1 Operational planning and control

ICTC's planning of product realization is consistent with the other processes of the quality management system. In planning product realization ICTC determines that which is appropriate to:

- The quality objectives and requirements for the product.
- The establishment of processes, documents and resource provision specific to the product.
- Verification, validation, monitoring, measurement, inspection and test activities, as well as acceptance criteria specific to the product.
- Records to provide evidence that the processes and resulting product meet requirements.

Manufacturing processes are planned and controlled through:

- Documented Shop Floor Control Quality Plans, defining the manner in which processes are performed to ensure that quality objectives and requirements for the product are met.
- Suitable equipment and appropriate environmental conditions.
- Compliance with reference standards/codes, and/or other applicable documented procedures.
- Monitoring of process and product characteristics during manufacturing.
- Appropriate evaluation and approval of processes and equipment.
- Clearly defined product acceptance criteria.
- Suitable maintenance of equipment to ensure continuing process capability.

8.2 Requirements for products and services

8.2.1 Customer communication

ICTC establishes and implements effective arrangements for communication with customers in relation to:

- product information;
- inquiries, contracts or order handling (including amendments);
- customer feedback (including Customer complaints);
- *advisory notices (ISO 13485:2016 – 7.2.3.d)*

8.2.2 Determining the requirements for products and services

ICTC shall determine:

- requirements specified by the Customer, including delivery and post-delivery activities;
- statutory and regulatory requirements applicable to the product;
- additional requirements considered necessary by ICTC;
- *applicable regulatory requirements related to the product (ISO 13485:2016 – 7.2.1.c)*

8.2.3 Review of the requirements for products and services

ICTC conducts reviews of requirements related to the product prior to the organization's commitment to supply a product which includes:

- product requirements are defined;
- contract or order requirements differing from those previously expressed are resolved;
- ICTC has the ability to meet the defined requirements;
- *applicable regulatory requirements are met (ISO 13485:2016 – 7.2.2.c)*

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services – (NOT APPLICABLE)

8.4 Control of externally provided processes, products and services

8.4.1 General

It is the policy of ICTC to purchase goods and services from approved sources. This approval is established by the customer, from our own assessment of the supplier or from references.

8.4.2 Type and extent of control

A listing of approved suppliers shall be maintained, reviewed and updated. Continued approval status shall be contingent upon ongoing assessment of delivery, service, and quality performance.

ICTC has established and implements inspection or other activities necessary to ensure that purchased product meets specified requirements. Where ICTC or the Customer intends to perform verification at the supplier's premises, such arrangements are planned and implemented.

8.4.3 Information for external providers

All Purchase Orders shall be reviewed and authorized prior to release. Purchase Orders shall ensure a clear, unambiguous definition of the goods and/or services required and, where appropriate, include or reference documentation, specifications, and inspection requirements.

8.5 Production and service provisions

8.5.1 Control of production and service provisions

ICTC's commitment to the Customer is to take immediate corrective action to resolve any defect, functional or cosmetic, in goods produced. ICTC carries out production processes under controlled conditions which includes the:

- availability of information that describes the required characteristics of the product;
- use of Work Instructions;
- implementation of product and process conformance measurement activities;
- availability and use of suitable equipment, including monitoring and measuring equipment;
- implementation of product release, delivery and post-delivery activities;

8.5.2 Identification and traceability

Where appropriate, ICTC identifies product, with respect to monitoring and measurement status, by suitable means throughout product realization. Where traceability is a specified requirement, ICTC controls and records the unique identification of the product.

8.5.3 Property belonging to customers or external providers

ICTC exercises all due care with customer property while it is in use or under the control of the organization. ICTC identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. Should customer property become lost, damaged or otherwise be found unsuitable for use, it is reported to the customer and records maintained.

8.5.4 Preservation

ICTC preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, this preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider:

- statutory and regulatory requirements;
- the potential undesired consequences associated with its products and services;
- the nature, use and intended lifetime of its products and services;
- customer requirements;
- customer feedback

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

Reporting to regulatory authorities (ISO 13485:2016 - 8.2.3)

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities.

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

ICTC monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with planned arrangements. Evidence of conformity with acceptance criteria and records indicating the person(s) authorizing the release of product are maintained.

8.7 Control of nonconforming outputs

ICTC ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained. When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to requirements.

9. Performance evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

The organization shall determine:

- what needs to be monitored and measured;
- the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- when the monitoring and measuring shall be performed;
- when the results from monitoring and measurement shall be analyzed and evaluated

The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction

As one of the measurements of the performance of the quality management system, ICTC monitors information relating to customer perception as to whether the organization has met customer requirements. Methods for obtaining this information are determined through customer feedback/surveys and customer service/sales feedback derived from customer interaction.

9.1.3 Analysis and evaluation

ICTC determines, collects and analyzes data to demonstrate the suitability and effectiveness of the quality management system, and to evaluate continuous improvement effectiveness. The analysis of this data provides information relevant to:

- Customer satisfaction;
- Conformity to product requirements;
- Characteristics and trends of process and products, including opportunities for preventive action, and suppliers.

9.2 Internal audit

ICTC internal audits will be scheduled and conducted at planned intervals to determine if the quality management system is conforming to:

- planned arrangements, to the requirements of ISO 9001/13485
- quality management system requirements established by the organization

ICTC shall:

- plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- define the audit criteria and scope for each audit;
- select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- ensure that the results of the audits are reported to relevant management;
- take appropriate correction and corrective actions without undue delay;
- retain documented information as evidence of the implementation of the audit program and the audit results

9.3 Management review

9.3.1 General

All personnel affecting the quality of products manufactured by ICTC are responsible to conform to the documented ISO 9001/13485 compliant quality policies and procedures as they pertain to the work they perform. It is the policy of ICTC to conduct documented management reviews under the chairmanship of the President or a designated alternate no less than once per calendar year.

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

- the status of actions from previous management reviews;
- changes in external and internal issues that are relevant to the quality management system;
- information on the performance and effectiveness of the quality management system, including trends in:
  - customer satisfaction and feedback from relevant interested parties;

- the extent to which quality objectives have been met;
- process performance and conformity of products and services;
- nonconformities and corrective actions;
- preventative actions;
- monitoring and measurement results;
- audit results;
- the performance of external providers;

- the adequacy of resources;
- the effectiveness of actions taken to address risks and opportunities;
- opportunities for improvement;

Review input (ISO 13485:2016 - 5.6.2)

- *complaint handling;*
- *reporting to regulatory authorities;*
- *applicable new or revised regulatory requirements*

9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

- opportunities for improvement;
- any need for changes to the quality management system;
- resource needs;

Review output (ISO 13485:2016 - 5.6.3)

- *changes needed to respond to applicable new or revised regulatory requirements;*

The organization shall retain documented information as evidence of the results of management reviews.

10. Improvement

10.1 General

ICTC continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, and audit results, analysis of data, corrective actions, preventive actions and management reviews.

10.2 Nonconformity and corrective action

ICTC takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. A documented procedure is established defining requirements.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

11. Appendix A- Operational Procedure / Work Instruction Index

ICTC OP/WI #	Title	ISO 9001	ISO 13485
OP-001	Management Review	9.3	(5.6)
OP-002	Customer Focus/Requirement Review	5.1.2	(5.2)
OP-003	Control of Documents	7.5.3	(4.2.4)
OP-004	Purchasing and Customer Property	8.4	(7.4)
OP-005	Identification and Traceability	8.5.2	(7.5.8)
OP-006	Control of Product Realization	8.1	(7.1)
OP-007	Control of Monitoring and Measuring Equipment	7.1.5	(7.6)
OP-008	Control of Nonconforming Product	8.7	(8.3)
OP-009	Corrective & Preventive Action	10.2	(8.5.2)
OP-010	Preservation of Product	8.5.4	(7.5.11)
OP-011	Control of Records	7.5.3	(4.2.5)
OP-012	Internal Audits	9.2	(8.2.4)
OP-013	Competence, Training and Awareness	7.2/7.3	(6.2)
OP-014	Measurement, Analysis and Improvement	9.1	(8.2)
OP-015	Risk Management	6.1	(8.5.3)
OP-016	ITAR Compliance	8.5.5	(8.2.3)
OP-017	Counterfeit Avoidance Policy and Procedure	8.4	(7.2.3)
OP-021	Regulatory Requirements	8.5.5	(8.2.3)

OP-020	Equipment Validation	8.5.1	7.5.6
OP-022	Software Validation	4.4	(4.1.6)
OP-023	New Product Introduction	8.1	(7.1)
OP-024	Context of the Organization	9.3	(5.6)
OP-025	Material Review Board (MRB)	8.7	(8.3)
OP-026	Supplier Selection and Approval	8.4	(7.4)
WI-ESD-001	Electrostatic Discharge	7.1.4	(6.4)
WI-QA-001	Inspection Methodology	9.1.3	(8.4)
WI-RMA-002	Returned Material	8.5.5	(8.2.2)
IPC-A-610	Requirements for Acceptability of Electronic Assemblies	8.2/8.6	(7.5)
IPC/WHMA-A-620	Requirements/Acceptability for Cable and Wire Harness Assemblies	8.2/8.6	(7.5)