INTERCONNECT CABLE TECHNOLOGIES CORPORATION

ICTC USA

Cable & Electronic Assembly & Manufacturing
Brooksville, FL

Quality Assurance Manual

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Revision History		
Revision	**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	
G	07/28/2015	Updated format and quality policy and removed Appendix 2 and QM-002 in the TOC and changed 5.5.2 to ref the Org. chart and not Appendix 2. LCastle
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. EHammond
I	12/6/2016	Updated Quality Manager approval to Ron Cain. Removed staff approvals not required per documentation Approval requirements.

Staff Approval		
President – Sareet Majumdar	COO/CFO Mary Alice Betts	Quality Manager – Ron Cain

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 nature of the organization and its products, 7.3 Product Design is excluded plus sections 7.5.1.2.1, 7.5.1.2.2, 7.5.1.3, 7.5.2.2, 7.5.3.2.2, 8.2.4.2 are not applicable. These exclusions have no negative impact on the organization's ability or responsibility to provide products that meet the Customers', as well as applicable 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

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 "the Standard" applies to the document(s) referenced in Section 2 above.

4. Quality Management System

4.1 General

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.

Associated Documents

ICTC's Operating Procedures

4.2 Documentation Requirements

4.2.1 General

ICTC's quality management system documentation includes:

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

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

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.

Appendix #1 of this document lists the Operating Procedures developed at ICTC.

Level 3 Documentation - Work Instructions

Level 4 Documentation - Records, Forms, and Tags

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.

4.2.3 Control of Documents

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

1. Approve documents for adequacy prior to use.
2. Review, update and, as necessary, re-approve documents.
3. Ensure that changes and current revision status of documents are identified and legible.
4. Ensure that relevant versions of applicable documents are available at points of use.
5. Ensure that documents of external origin determined necessary by the organization are identified and their distribution controlled.
6. Prevent the unintended use of obsolete documents through suitable identification if they are retained for any purpose.

Associated Documents

OP-003 - Control of Documents

4.2.4 Control of Records

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.

Associated Documents

OP-011- Control of Records
Disaster Recovery Plan

5. Management Responsibility

Associated Documents

OP-001 - Management Review
OP-002 - Customer Focus / Requirement Review

5.1 Management Commitment

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

1. Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.
2. Establishment of the quality policy.
3. Ensuring that quality objectives are established).
4. Conducting management reviews.
5. Ensuring the availability of resources.

5.2 Customer Focus

Top management ensures that customer requirements are determined and met through established procedures with the aim of enhancing Customer satisfaction.

5.3 Quality Policy

”ICTC” is committed to meeting our customers’ requirements and exceeding their expectations by continually improving the effectiveness of our quality management system.”

5.4 Planning

Quality Objectives

Top management ensures that Measurable Quality Objectives are established within the organization.

1. Meet or exceed Customer expectations.
2. Provide our Customers high quality products and on time delivery.
3. Effectively manage products, processes and services to provide superior Customer satisfaction.
4. Promote the safety, awareness and well-being of employees through training and education.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

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

CFO/COO - Has the overall responsibility of directing all functions of the facility and acts on behalf of the president in the absence of the president.

Quality Assurance Manager - or designated alternate, has the responsibility for maintaining the quality management system and quality functions.

Divisional Vice President's - Has overall responsibility of directing division manufacturing, purchasing and customer communication functions.

5.5.2 Management Representative

Top management of ICTC has appointed as the management representative, the organization's Quality Assurance Manager who has freedom to resolve matters pertaining to quality.

Refer to ICTC's Organizational Chart.

5.5.3 Internal Communication

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

Associated Documents/Devices

OP-013 - Competence, Training and Awareness
Periodic All Employee Meetings
Posted Charts, Surveys and Report Cards

5.6 Management Review

Associated Documents

OP-001 - Management Review

All personnel affecting the quality of products manufactured by ICTC are responsible to conform to the documented ISO 9001/13485 & AS9100 compliant quality policies and procedures as they pertain to the work they perform. It is the policy of ICTC to conduct periodic, documented management reviews under the chairmanship of the President or a designated alternate.

6. Resource Management

Associated Documents

OP-006 - Control of Product Realization

6.1 Provision of Resources

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 and Customer satisfaction.

6.2 Human Resources

6.2.1 General

The 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.

6.2.2 Competence, Training and Awareness

Associated Documents

OP-013 - Competence, Training and Awareness
Training Verification Form(s)

ICTC shall:

1. Determine the necessary competence requirements for personnel performing activities affecting conformity to product requirements.
2. Provide training, where applicable, or take other action(s) to achieve the necessary competence.
3. Evaluate the effectiveness of actions taken.
4. Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives.
5. Maintain appropriate records of education, training, skills and experience.

6.3 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.

6.4 Work Environment

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.

7. Product Realization

7.1 Planning of Product Realization

Associated Documents

OP-006 - Control of Product Realization
OP-015 - Risk Management
IPC 610 - Requirements for Electronic Assemblies
IPC/WHMA-A-620 - Requirements and Acceptance for Cable and Wire Harness Assemblies

Policy

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:

1. The quality objectives and requirements for the product.
2. The establishment of processes, documents and resource provision specific to the product.
3. Verification, validation, monitoring, measurement, inspection and test activities, as well as acceptance criteria specific to the product.

4. Records to provide evidence that the processes and resulting product meet requirements.

Manufacturing processes are planned and controlled through:

1. 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.
2. Suitable equipment and appropriate environmental conditions.
3. Compliance with reference standards/codes, and/or other applicable documented procedures.
4. Monitoring of process and product characteristics during manufacturing.
5. Appropriate evaluation and approval of processes and equipment.
6. Clearly defined product acceptance criteria.
7. Suitable maintenance of equipment to ensure continuing process capability.

7.2 Customer–related Processes

7.2.1 Determination of Requirements Related to the Product

ICTC shall determine:
1. Requirements specified by the Customer, including delivery and post-delivery activities.
2. Statutory and regulatory requirements applicable to the product.
3. Additional requirements considered necessary by ICTC.

Associated Documents

OP-002 - Customer Focus/Requirement Review

7.2.2 Review of Requirements Related to the Product

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

1. Product requirements are defined.
2. Contract or order requirements differing from those previously expressed are resolved.
3. ICTC has the ability to meet the defined requirements.

7.2.3 Customer Communication

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

1. Product information.
2. Enquiries, contracts or order handling (including amendments).
3. Customer feedback (including Customer complaints).

Associated Documents

OP-002 - Customer Focus/Requirement Review
WI-RMA-002 - Work Instruction: Returned Material Authorization

7.3 Design & Development (Excluded)

ICTC only manufactures product to customer design.

7.4 Purchasing

7.4.1 Purchasing Process

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.

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.

Associated Documents

OP-004 - Purchasing and Customer Property
Supplier Questionnaire

7.4.2 Purchasing Information

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.

7.4.3 Verification of Purchased Product

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.

Associated Documents

OP-004 - Purchasing and Customer Property
WI-QA-001 - Inspection Methodology
WI-GEN-001 - General Work Instruction

7.5 Production and Service Provision

7.5.1 Control of production and service provision

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 include:

1. The availability of information that describes the required characteristics of the product.
2. The use of Work Instructions.
3. The implementation of product and process conformance measurement activities.
4. The availability and use of suitable equipment, including monitoring and measuring equipment.
5. The implementation of product release, delivery and post-delivery activities.

Associated Documents

OP-006 - Control of Product Realization
OP-007 - Control of Monitoring and Measuring Equipment
OP-014 - Measurement, Analysis and Improvement
IPC 610-Requirement for Electronic Assemblies
IPC/WHMA-A-620 - Requirements and Acceptance for Cable and Wire Harness Assemblies

7.5.1.2, 7.5.1.3, 7.5.2 – 7.5.1.2.1, 7.5.1.2.2, 7.5.1.3, 7.5.2.2, 7.5.3.2.2, 8.2.4.2 Not Applicable

7.5.3 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.

Associated Documents

OP-004 - Purchasing and Customer Property
OP-005 - Identification and Traceability

Where traceability is a specified requirement, individual product or lots will be uniquely identified to satisfy said requirement.

7.5.3.2.2 – Not Applicable – No implants are manufactured

7.5.4 Customer Property

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.

Associated Documents

OP-004 - Purchasing and Customer Property
OP-010 - Preservation of Product

7.5.5 Preservation of Product

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.

Associated Documents

OP-010 - Preservation of Product

7.6 Control of Monitoring and Measuring Equipment

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. Where necessary to ensure valid results, measuring equipment is:

1. 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.
2. Identified in order to determine its calibration status.

Associated Documents

OP-007 - Control of Monitoring and Measurement Equipment
- Maintenance Records
- Calibration Certificates

8.2 Monitoring and Measurement

8.2.1 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.

Associated Documents

OP-002 - Customer Focus/Requirement Review
WI-RMA-002 - Returned Material Work Instruction
Customer survey

8.2.2 Internal Audits

ICTC conducts internal audits at planned intervals to determine if the quality management system is:

1. Conforming to planned arrangements, to the requirements of ISO 9001/13485 & AS9100 and to quality management system requirements established by the organization.
2. Effectively implemented and maintained.

Associated Documents

OP-012 - Internal Audits

8.2.3 Monitoring and Measurement of Processes

ICTC applies suitable methods for the monitoring and, where applicable, measurement of the quality management system process. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is applied as appropriate.

8.2.4 Monitoring and Measurement of Product

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

Associated Documents

OP-006 - Control of Product Realization
OP-008 - Control of Nonconforming Product
OP-014 - Measurement, Analysis and Improvement

Manufacturing Traveler

8.3 Control of Nonconforming Product

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. Product may require Adverse Effect documentation.

Associated Documents

OP-008 - Control of Nonconforming Product
OP-009 - Corrective and Preventive Action
WI-MRB-001 - Material Review Board Instruction
WI-RMA-002 - Returned Material Instruction
IPC 610 - Requirements for Electronic Assemblies
IPC/WHMA-A-620 - Requirements and Acceptability for Cable and Wire Harness Assemblies

8.4 Analysis of Data

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:

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

Associated Documents

OP-006 - Control of Product Realization
OP-012 - Internal Audits
OP-014 - Measurement, Analysis and Improvement

8.5 Improvement

8.5.1 Continual Improvement

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.

8.5.2 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.

Associated Documents

OP-009 - Corrective and Preventive Action
OP-008 - Control of Nonconforming Product

8.5.3 Preventive Action

ICTC determines actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. Documented procedures are established to define requirements.

Associated Documents

OP-006 - Control of Product Realization
OP-008 - Control of Nonconforming Product
OP-009 - Corrective and Preventive Action
OP-013 - Competence, Training and Awareness

Appendix # 1

Operation Procedure/ Work Instruction Index

SOP/Work Inst. #	Title
OP-001	Management Review ***Ref. 5.6***
OP-002	Customer Focus/Requirement. Review ***Ref. 7.2***
OP-003	Control of Documents ***Ref. 4.2.3***
OP-004	Purchasing and Customer Property ***Ref.7.4***
OP-005	Identification and Traceability ***Ref. 7.5.3, 7.5.5***
OP-006	Control of Product Realization ***Ref. 7.1, 6.3***
OP-007	Control of Monitoring and Measuring Equipment ***Ref. 7.6***
OP-008	Control of Nonconforming Product ***Ref 8.3, 7.2.3, 8.2.1***
OP-009	Corrective & Preventive Action ***Ref 8.5.2 & 8.5.3, 8.2.1***
OP-010	Preservation of Product ***Ref. 7.5.5***
OP-011	Control of Records ***Ref. 4.2.4***
OP-012	Internal Audits ***Ref.8.2.2***
OP-013	Competence, Training and Awareness ***Ref. 6.2.2, 5.5.1***
OP-014	Measurement, Analysis and Improvement ***Ref. 8.2, 8.4***
OP-015	Risk Management ***Ref. 7.1***
WI-ESD-001	Electrostatic Discharge ***Ref 6.4***
WI-SFP-001	Shop Floor Packet ***Ref 7.5.1.1***
WI- EN-001	Red Line Deviation ***Ref 4.2.3***
WI-QA-001	Inspection Methodology ***Ref 8.2.4.1***