I.S. EN ISO 13485:2016
I.S EN ISO 9001:2015

Quality Management System

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Revision History:

Date	Change Notice	Change Description
6-28-2013	CN-2013-015	Original Release
12-10-2013	CN-2013-060	Updated ISO standards, Quality Policy & Scope. Per Stage 1 Audit # MD19.4820.
3-10-2015	CN-2015-001	Updated the QP & Scope (incorporated each certification scope).
3-2-2017	CN-2017-005	Updated per I.S. EN ISO 13485:2016
10-23-2018	CN-2018-004	Updated the QMS Scope Exclusion Table charts description Non Applicable Activities & added "relevant interested parties" information to scope section (sec 1) and sub clause 4.1.1

Approvals:

Management Representative (Eric J. Straka)

President and CEO (Dave Mochi)

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CFA Focus on Solutions
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Introduction:

General:

Controls For Automation is the fastest growing Fluid Power distributor in New England. We have serviced the needs of New England based manufacturers for over 35 years with a full range of over 40 pneumatic product lines recognized and available worldwide.

CFA is located in Taunton, Massachusetts, in the heart of the territory we support and service, with representatives in all six New England states. Our representatives are highly experienced sales engineers who can help and support our customers from the design and engineering phase all the way through production. Our theme of "Focus on Solutions" has been the foundation for our growth in such industries as Medical, Packaging, Semiconductor, Custom Machine building, Printing, BioChem and many other technologies.

In addition to representing the highest quality products in the world, our contract fabricating and assembly department can provide you with a turnkey solution of a fully assembled and tested sub assembly ready to be installed on your machine. From installing special seals in an air cylinder, to complete assembly of your product, CFA can do it all.

You don't have to go out of the region or out of the country to get the Best Products, Best Delivery, and Best Service. **The best little company in the world is right in your own backyard!**

Controls For Automation

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Process Approach:

This Manual has adopted the process approach to quality management. Figure 1 is a conceptual illustration of the process approach of the system aimed towards Consistent Compliance to the Standard and it illustrates the process linkages presented in clauses 4 to 8 of I.S. EN ISO 13485 and I.S. EN ISO 9001. References to procedures are made as applicable or to the section of the manual that applies to that activity.

1 Scope:

Controls For Automation Inc. hereinafter referred to as "CFA.", developed and implemented the Quality Management System (QMS) described in this manual to help CFA operate with increased effectiveness, consistency and to;

- Demonstrate our ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services to regulatory requirements per I.S. EN ISO 13485, and to
- Enhance customer satisfaction through the effective application of the system. Including processes for continual improvement of the system and the assurance of conformity to customer, relevant interested parties and applicable regulatory requirements per I.S. EN ISO 9001 where practical or applicable.

Scope of Registration:

I.S. EN ISO 13485:2016:

The manufacture and distribution of components and assemblies for the medical device industry.

I.S. EN ISO 9001:2015:

The manufacture and distribution of components, manufactured products and assemblies for various industries that include medical and as applicable, our relevant interested parties.

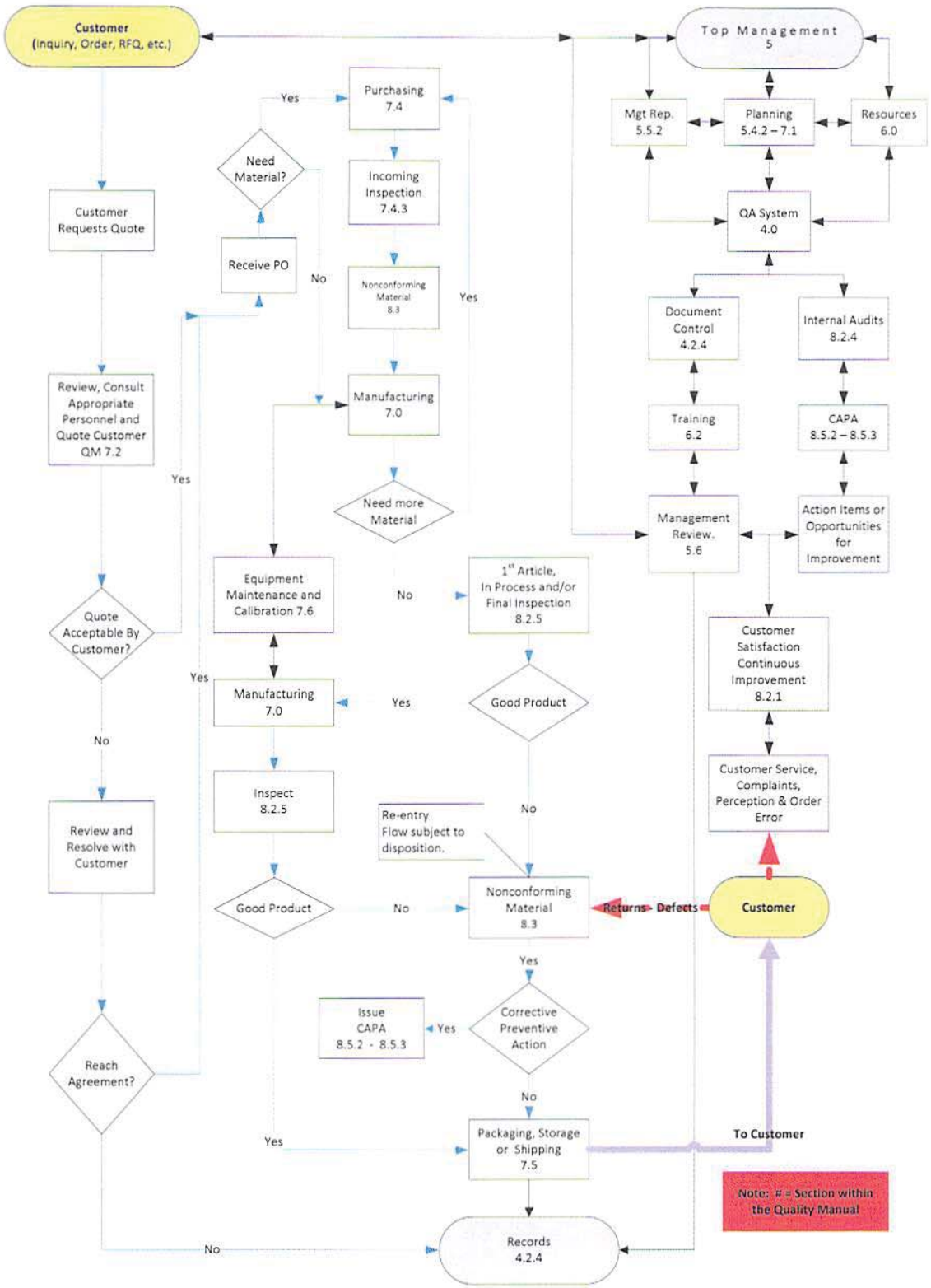
CFA has developed and implemented the Quality Management System (QMS) described in this manual to help CFA operate with increased effectiveness, consistency and customer satisfaction. Our QMS utilizes the process approach and quality management principles contained in the international I.S. EN ISO 13485 and I.S. EN ISO 9001 standards to both create a customer focus while consistently meeting customer, our relevant interested parties and regulatory requirements and to enhance our ability to continually improve as applicable.

Our QMS encompasses all operations at our facility. The following table identifies requirement(s) not applicable to CFA and provides a brief narrative justifying their exclusion from the scope of our QMS:

QMS Scope Exclusion Table:

Clause or Sub-clause:	Non Applicable Activities:	Justification:
7.3	Design and Development	CFA builds product to customer's specifications.
7.5.3	Installation Activities	CFA Does not perform Installation Activities.
7.5.4	Servicing Activities	CFA does not perform Servicing Activities after the sale of products.
7.5.5	Particular Requirements for Sterile Medical Devices	CFA does not manufacture Sterile Medical Devices.
7.5.7	Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems	CFA does not Sterilize or produce any Sterile Barrier Systems.
7.5.9.2	Implantable Devices	CFA does not Manufacture Implantable Devices

Figure 1: CFA's Process Interrelationship:



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