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Supplier Quality and Excellence Manual

NOTE: Acceptance of a Medtronic Purchase Order (PO) constitutes acknowledgement that the Supplier has read, understands, and will comply with the expectations of this Manual.

1.0 Introduction

1.1 Medtronic Mission Statement

The Medtronic mission is very important to us as a company. First and foremost, our mission is to alleviate pain, restore health, and extend life. We at Medtronic are committed to fulfilling this mission and expect the same commitment from our Suppliers. Please take time to review and understand the Medtronic mission:

• To contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or applications that alleviate pain, restore health, and extend life.

• To direct our growth in the areas of biomedical engineering where we display maximum strength and ability; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.

• To strive without reserve for the greatest possible reliability and quality in our Products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service.

• To make a fair profit on current operations to meet our obligations, sustain our growth, and reach our goals.

• To recognize the personal worth of employees by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company’s success.

• To maintain good citizenship as a company.

1.2 Purpose and Scope

The purpose of this Supplier Quality Manual is to clearly communicate as One Medtronic the Medtronic Quality Requirements to all new and existing external Suppliers, including raw material, component, Original Equipment Manufacturers (OEM), Contract Manufacturers of Finished Devices, and Service Suppliers associated with Product. These Quality Requirements shall apply to the development and manufacture of all Products supplied to Medtronic. Suppliers are critical to Medtronic’s success in delivering high-quality product to our customers at the right time, therefore it is important for us to set expectations, identify gaps and track progress of gap resolution. Medtronic considers preferential long-term relationships with those Suppliers who have achieved, or who are committed to achieving, these requirements. Quality Requirements may take the form of a separate Quality Agreement, or an exhibit or addendum to, or content in a purchase order or other agreement. They also encompass the requirements set forth in this Manual as well as in other documents such as engineering specifications.

The requirements within this Manual are provided as a supplement, not as a replacement for or altering of the terms or conditions with pre-established agreements, engineering drawings, or specifications.

If conflicting interpretations of the standards arise, the following order of precedence applies unless otherwise noted contractually:

• Agreements (Quality, Supply, etc.)
• Specification Requirements
• Medtronic Purchase Orders
• Supplier Quality and Excellence Manual

Medtronic understands that our business sectors are different in nature and may have unique Supplier quality requirements. However, the processes and tools depicted in this Manual represent the core One Medtronic expectations and requirements. The differences Suppliers may encounter across the Medtronic organization will generally be minimal and driven by customer, product, and/or market specific requirements.
1.3 Medtronic Key Businesses

Cardiac and Vascular Group

• Cardiac Rhythm Disease Management manages the broad spectrum of cardiac rhythm disorders to improve long-term patient care. The solutions developed at Medtronic allow physicians to monitor and treat their patients’ changing cardiac conditions throughout a lifetime. These developments include pacemakers to treat patients with bradycardia (too-slow heartbeat); implantable defibrillators to help patients with tachyarrhythmia (too-fast heartbeat); and diagnostic and monitoring innovations that diagnose heart-related syncope (unexplained fainting), just to name a few.

• CardioVascular develops products that are used throughout the vascular system and those used for arrested and beating heart bypass surgery. The business markets the industry’s broadest line of heart valve products for replacement and repair, plus auto-transfusion equipment and disposable devices for handling and monitoring blood during major surgery, as well as cardiac ablation devices to treat a variety of heart conditions. The business also offers products and therapies that treat a wide range of vascular diseases and conditions. These products include coronary, peripheral and neurovascular stents, stent graft systems for diseases and conditions throughout the aorta, and distal protection systems.

• Physio-Control, a Medtronic wholly-owned subsidiary, for more than 50 years has been on the forefront of developing technologies, services, software, and devices that are widely used by emergency response professionals, clinical care providers and citizens everywhere. The product suite includes renowned external defibrillator/monitor/pacing for in-hospital and out-of-hospital use under the LIFEPAK® brand, automated CPR devices under the LUCAS® brand, and its comprehensive LIFENET® software system to aid in the diagnosis and treatment of individuals prior to in-hospital admission.

Restorative Therapies Group

• Diabetes offers insulin pump therapy, continuous glucose monitoring systems, related disposable product and diabetes management software, making Medtronic a world leader in diabetes management.

• Neuromodulation offers innovative therapies for chronic pain, movement disorders, spasticity, overactive bladder and urinary retention, benign prostatic hyperplasia, and gastroparesis. Medtronic developed and leads the field of neuromodulation, the targeted and regulated delivery of electrical pulses and pharmaceuticals to specific sites in the nervous system.

• Spinal and Biologics offers products that treat a variety of disorders of the cranium and spine, including traumatically induced conditions, deformities and tumors. Through the introduction of INFUSE® Bone Graft and Minimal Access Spinal Technologies, the business has distinguished itself as a global leader in less invasive surgical techniques. It also develops a variety of image-guided surgical navigation systems.

• The Surgical Technologies business is made up of the Ears, Nose and Throat (ENT) and Neurologic Technologies (NT) organization and the Navigation business. ENT/NT is the global leader in providing innovative products and services that offer lifelong solutions for the diagnosis and treatment of chronic diseases and disorders of the ears, nose and throat. Medtronic’s NT business develops and markets surgical devices and implantable products that enhance the treatment of cranial, spinal, and specially small bone conditions. Navigation develops surgical navigation and intra-operative imaging solutions that enable cranial neurosurgery, functional neurosurgery, spinal surgery, ENT, joint replacement, and orthopedic trauma surgeries. In addition, Navigation is expanding its clinical reach to new indications such as cardiac and vascular solutions. Surgical navigation and intra-operative imaging deliver real-time feedback on patient anatomy, instrument position, pathology status, and therapy placement for both procedure planning and intra-operative confirmation.

1.4 Supplier Diversity

A diverse base of high-quality suppliers strengthens our ability to carry out our Mission to alleviate pain, restore health, and extend lives. A diverse supply chain, focused on the highest standards of quality, helps us connect with our patients, physicians, and communities as we work to improve lives.

Our United States Supplier Diversity program encompasses the following classifications.

• Historically Underutilized Business Zone Small Business (HUBZone)
• Minority Business Enterprise (MBE)
• Service-Disabled Veteran-Owned Small Business (SDVOSB)
• Small Business (SB)
• Small Disadvantaged Business (SDB)
• Veteran-Owned Small Business (VOSB)
• Women Business Enterprise (WBE)
• Woman-Owned Small Business (WOSB)

1.5 Continuous Improvement

Medtronic strives for reliability and quality in all of our products. Medtronic recognizes that this cannot be done without the support of a strong supply base. To that end, Medtronic strives to achieve a world-class supply chain utilizing Lean Sigma methodologies. Lean Sigma combines Six Sigma with Lean Manufacturing methodologies. Lean Sigma helps to address the waste and variability in processes and supply chain systems.

Medtronic is dedicated to aligning its continuous improvement strategies with its supply base, namely through two programs: Supplier Development and Supplier Lean Sigma Training.

1.5.1 Supplier Development

The Supplier Development program uses dedicated resources focused on driving continuous improvement in the performance of our supply chain. In other words, Medtronic allocates trained Supplier Development Engineers to help strategic suppliers drive process improvements throughout the value stream that they share with Medtronic.

Both Medtronic and our Suppliers can benefit from Supplier Development. Here are some key outcomes of this process:

• Improved quality
• Improved customer responsiveness (on-time delivery; lead time reduction)
• Cost reductions (inventory, overtime, labor and burden)
• Growth without capital expenditure

To achieve these benefits, Medtronic facilitates specific projects, and coaches suppliers to help develop and implement process improvements into the future.

1.5.2 Supplier Lean Sigma Training

Medtronic also offers Lean Sigma training for select suppliers. Through this program, participants learn the methodology in a formal classroom setting and will be able to apply the knowledge to a project in their organization.

Lean and Six Sigma projects follow the Define, Measure, Analyze, Improve, and Control (DMAIC) roadmap, unifying Lean and Six Sigma toolsets to drive out waste and reduce process variation.

Lean Sigma training is another way by which Medtronic helps strategic suppliers drive process improvements throughout the value stream that they share with us.

For more information, please contact your Medtronic supply chain representative.

1.6 Code of Conduct

1. General Principle: Suppliers’ plants shall operate in full compliance with the laws of their respective countries and with all other applicable laws, rules, and regulations.

2. Environment: Suppliers’ plants must comply with all applicable environmental laws and regulations.

3. Child Labor: Suppliers shall employ only workers who meet the applicable minimum legal age requirement. Suppliers must also comply with all other applicable child labor laws.

4. Forced Labor: Suppliers shall not use any indentured or forced labor, slavery or servitude.

5. Wages and Hours: Suppliers’ plants shall set working hours, wages and over-time pay in compliance with all applicable laws. Workers shall be paid at least the minimum legal wage or a wage that meets local industry standards, whichever is greater.

6. Discrimination: Suppliers shall hire, train, advance, compensate, discipline, and terminate workers on the basis of their ability to do the job, not on the basis of their personal characteristics or beliefs (including race, color, gender, ethnic or national origin, religion, age, maternity, sexual preference or marital status).

7. Freedom of Association: Suppliers’ workers are free to join associations of their own choosing, and have the freedom of collective bargaining where the local law confers such rights.

8. Gift Policy: Medtronic employees may not accept gifts from persons or entities who deal with the Company in those cases where any such gift is more than modest in value, or where acceptance of gifts could create the appearance of a conflict of interest.
1.7 Environmental/Social Obligations

At Medtronic, we expect that our suppliers:

- Are aware of how your businesses and products impact the environment
- Commit to continuous environmental improvement
- Know and comply with federal, state and local regulatory requirements
- Notify us of any significant environmental compliance violations
- Comply with current global classifications of hazardous substances
- Supply composition information on parts/components as requested
- Medtronic expects suppliers to be ISO 14001 certified or have a plan to become certified

2.0 Key Roles and Responsibilities

2.1 Medtronic Sourcing Organization

Medtronic understands our business segments are different in nature and in some cases have unique roles and responsibilities. However, the roles and responsibilities represented in this section represent the core of our business and the differences you will see across our organization will be minimal.

**Global Commodity Manager**

Many of Medtronic’s Suppliers are engaged with multiple Medtronic business units. The global commodity manager is responsible for ensuring that there is one face to Medtronic and the Suppliers’ actions support the global strategy by driving cross business unit activities.

**Commodity Manager**

The commodity manager is the Supplier’s primary contact for all business-related issues. The commodity manager is responsible for the relationship with the Supplier, including, but not limited to, issues such as contract, quality, cost, delivery, or health of the business.

**Buyer**

The buyer is the primary contact for all purchasing-related issues. The Supplier must inform the buyer of any issue that impacts delivery, or to request any changes.

**Supplier Quality/Sourcing Continuity**

The supplier continuity/quality function is responsible for the manufacturability, reliability and specification, and quality systems conformance of released supplier provided components, finished devices, and services.

**Technical Sourcing Specialist**

Technical sourcing is the primary integration point linking sourcing with technology and New Product Development (NPD) project teams, aligning Medtronic Product and Supplier Technology Roadmaps and project managing sourced components in support of these efforts.

**Supplier Development**

The supplier development group engages Suppliers to continuously improve process capability, reduce waste and variability, and other activities and projects. The group utilizes Lean Six Sigma, Kaizen, Rapid Improvement Events, Value Stream Mapping, and training as key tools to perform gap analyses, reduce lead times and reduce defects.

**Component/Product Development Engineering**

The component engineering function is responsible for performing component characterization, performing component qualification, and demonstrating component meets reliability expectations.

2.2 Supplier Organization

The Supplier will identify a contact within the Supplier organization to communicate with Medtronic for each function below.

**Customer Representative**

The customer representative to Medtronic is the primary contact within the Supplier’s organization for any key communications with Medtronic, including any quality, delivery, or commercial issue resolution.
Quality Management Representative

The Quality Management Representative within the Supplier’s organization is responsible for the implementation and maintenance of the Supplier’s Quality Management System such as defined by the ISO 9001:2000 or the ISO 13485:2003 series of standards. Reference specific ISO standard requirement in Section 4.1 titled, “Minimum Requirements.”

Executive Representative

A person with executive responsibility or one who reports directly to a person with executive responsibility, will serve as a contact for Medtronic under this Quality Manual, and oversee compliance to the requirements stated in this Manual.

3.0 Supplier Requirements Overview

Suppliers are responsible for ensuring that Products or services meet established Medtronic specifications and Quality Requirements. Audits, approvals or verification by Medtronic of the Supplier’s facility, quality system, process controls, acceptance activities, etc., does not absolve the Supplier of the responsibility to provide acceptable Product, nor will it preclude the subsequent rejection of unacceptable Product.

This Manual contains requirements for all Supplier types: raw and manufacturing material, component, OEM and Contract Manufacturers of medical finished devices, and Service Suppliers.

In reading the requirements in this Manual, it is important to note the following terms:

• Should, may, expect – Action is strongly recommended
• Must, will, shall – Action is required

Additional terms and definitions are listed in Appendix B.

3.1 Quality Agreements

In addition to the requirements contained in this Manual, the Medtronic Sourcing Organization will determine if a Quality Agreement is needed between Medtronic and the Supplier. Once the need is determined, it is our expectation that the Supplier will work with Medtronic to put this agreement in place.

For finished product manufacturing a Quality Agreement must be in place. Quality Agreements outline the Supplier specific quality requirements. Other products will be governed by their respective Quality Requirements which may be in the form of a Quality Agreement, PO, and/or this Manual.

3.2 Environmental Compliance

As a Medtronic supplier we expect that your Products, components or substances supplied to Medtronic will meet the requirements of country, federal, state and local environmental regulations. The list below includes some of the regulations; however, compliance is not limited to these. Additional information may be required such as certification to any of the following or chemical composition of products, components and/or substances. If you suspect that Products, components or substances supplied to Medtronic are not compliant, please contact the appropriate buyer or supply chain representative immediately.

• Battery and Accumulator Directive 2006/66/EC
• Packaging Directives 94/62/EC, 2004/12/EC, COM Decision 97/129/EC
• REACH (Registration Evaluation Authorization and Restriction of Chemicals) Regulation 1907/2006/EC
• RoHS (Restriction of Hazardous Substances) EU 2003/95/EC and China
• WEEE (Waste Electrical and Electronic Equipment) Directive 2001/96/EC

3.3 Import Compliance

As business becomes increasingly globalized, additional documentation and processes are required. If a Supplier is shipping Product to a Medtronic facility within the United States from outside the United States border, there are several key things to know.

Country of Origin as defined by the country of manufacture, production or growth of any article of foreign origin entering the U.S. Further worked or material added to an article in another country must affect a substantial transformation in order to render such a country as the country of origin. Please refer to the following link for more information:


Medtronic requires that unless excepted by law, every article of foreign origin, or its container imported into the U.S. shall be marked in a conspicuous place as legibly, indelibly and permanently as the nature of the article or container will permit.
in such manner as to indicate the country of origin to an ultimate purchaser in the U.S., the English name of the country of origin of the article.

**Commercial Invoices** as defined as the document prepared by the seller which contains the description, value and country of origin of the merchandise being imported into the U.S. It also contains the terms of sale (FOB, CIF, C & F and CFR), the Harmonized Tariff Schedule (HTS) Code and the FDA Product code if applicable.

A commercial invoice signed by the seller, shipper or associated agent is required for Customs entry and is acceptable if prepared in accordance with 19 CFR 141.86 of the customs regulations. Any inaccurate or misleading statement of fact in the commercial document may result in delays in release, detention of goods, increased review by import specialists or penalties against the importer.

Wood Packaging Material is closely regulated as it pertains to importation of goods into the U.S. The Animal and Plant Health Inspection Service USDA, have amended the regulations for the importation of unmanufactured wood articles to adopt an international standard entitled “Guidelines for Regulating Wood Packaging Material in International Trade” that was approved by the Interim Commission on Phytosanitary Measures of the International Plant Protection Convention on March 15, 2002. The standard calls for wood packaging material to be either heat treated or fumigated with methyl bromide, in accordance with the Guidelines, and marked with an approved international mark certifying treatment. This change will affect all persons using wood packaging material in connection with importing goods into the United States. Effective Date: September 16, 2005. Please refer to the following link for more information:


### 3.4 Business Continuity

As a responsible medical device manufacturer, we expect our Suppliers to complete a formal Business Continuity/Disaster Recovery Plan to ensure no interruption in supply to our patients is encountered. While it is apparent that contingency plans cannot be developed for all potential scenarios, we expect our Suppliers to have/maintain robust plans to facilitate rapid response and recovery in the event of disruptions.

Medtronic expects its Suppliers to have a comprehensive crisis management approach to deal with potential disruptions. The approach needs to include plan of action, checklist of activities, communication plans, escalation procedures, and organization of teams, roles, and responsibilities. This plan should address the recovery time needed for a variety of business interruptions, contact information for key locations, supply chain assessment of risk for equipment, material, supplied components and labor, etc. and be specific to Medtronic products and/or services provided.

Upon request, the Supplier shall provide risk management and business continuity plans to Medtronic.

Medtronic expects its Suppliers to develop, deploy, maintain, and adhere to these business continuity planning requirements at all times.

### 3.5 Non-Disclosure Agreements

As a Supplier to Medtronic you may be asked to sign a non-disclosure agreement depending on the level of technology or information disclosed during the course of business. It is our policy to utilize a Medtronic standard form that has been created for this purpose.

Information provided to Suppliers involving various trade secrets, designs, materials and other proprietary information of a secret and confidential nature may include, but are not limited to records, data, schedules, forecasts, formulae, processes, procedures, specifications, developments, designs, inventions, models, techniques, improvements or discoveries, patentable and otherwise.

It is Medtronic’s policy that Suppliers shall not use, transmit or disclose confidential information to any third party except in accordance with the terms of the non-disclosure or any other written agreement. Supplier shall not make any public announcement about or advertise the existence of this agreement, divulge its terms and conditions or any relationship with Medtronic other than with prior written agreement of the other party. Suppliers shall agree not to display or use the Medtronic logo, trade secrets, trademark, or product(s) in any manner without our prior written permission from their Medtronic Supply Chain Representative.

Medtronic values our relationships with our Suppliers and therefore would like to protect it through the use of this formal agreement.

### 3.6 Change Management:

The continuous improvement philosophy encourages process improvements. However, the supplier shall notify Medtronic to collaboratively outline all verification testing prior to any modification including but not limited to
component changes, material or chemical composition changes, process changes, design changes or deviations being implemented. The supplier must complete all verifications and tests to ensure that a new process continues to yield components that meet specification prior to full implementation in production and subsequent production shipments. Approval from Medtronic is required prior to production shipments. The supplier must notify Medtronic prior to implementing any change. See section 7.3.4 for additional detail.

3.7 Sub-Tier Supplier Control:

The Supplier must maintain qualifications for subcontractors and the products purchased through them. It is the Suppliers’ responsibility to ensure and control the quality of all components and raw materials that are purchased to manufacture components and parts for Medtronic.

Suppliers will manage sub-tier suppliers with controls commensurate with those Medtronic applies to direct suppliers. Suppliers are responsible to ensure that product(s) manufactured utilize only authentic, conforming and specified material requirements as stipulated in the BOM. Prior to implementing changes, including changes requested by sub-tier suppliers, Suppliers must notify Medtronic (see section 7.3.4).

3.8 Measurement Systems Analysis (MSA)

Measurement System Analysis (MSA) is recommended in determining whether measurement or test equipment has sufficient accuracy, precision, or resolution to adequately provide information about process performance, or the effects of inherent or applied variation of the process under development. One tool recommended is Gage Repeatability and Reproducibility (Gage R&R or GR&R). Gage R&R using variables data is preferred, although attribute MSA is possible. If performing MSA using attribute measurement (simple pass/fail values), the results of this analysis are limited by the measured item’s values compared with specification requirements. Select test parts which are marginally acceptable and marginally rejectable to criteria to provide meaningful results from this type of analysis. Ideally, as a result of the MSA the total variations should be less than 10% of the tolerance.

3.8.1 General Requirements

The Supplier shall develop or obtain gages to control their processes and to inspect the parts, whenever possible.

Gages used to inspect parts should be variable gages, when possible and feasible, which have been designed to inspect the functionality of the part. If variable gages are not available, then attribute gages (“go” or “no go”) are acceptable for use, but Medtronic approval should be received.

For those characteristics specified by Medtronic, the Supplier must perform a Gage R&R Study using procedures described in Measurement Systems Analysis published by AIAG (Automotive Industry Action Group) or equivalent.

At a minimum, for all special characteristics, a Gage R&R (variable or attribute) is required, unless directed otherwise by Medtronic.

If the Supplier has a number of duplicate custom gages, a gage correlation study must also be completed. For those characteristics specified by Medtronic, the Supplier may need to perform a gage correlation study.

3.8.2 Gage R&R Studies

The recommended requirements for gage R&R studies are as follows:

<table>
<thead>
<tr>
<th>Gage Type</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Three distinct operators measure ten samples three times each.</td>
</tr>
<tr>
<td>Attribute</td>
<td>Attribute Gage Study (long method)</td>
</tr>
</tbody>
</table>
The guidelines for acceptance of Gage R&R (% R&R) are:

<table>
<thead>
<tr>
<th>% Error</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10%</td>
<td>The measurement system is acceptable.</td>
</tr>
<tr>
<td>10 – 30%</td>
<td>The measurement system may be acceptable, based upon the importance of application, cost of gage, cost of repairs, etc. The rational for acceptance must be documented and/or continuous improvement plan documented, as applicable.</td>
</tr>
<tr>
<td>&gt; 30%</td>
<td>The measurement system is not acceptable and issues must be documented and corrected.</td>
</tr>
</tbody>
</table>

### 3.8.3 Gage Correlation Studies

When it is deemed a Gage Correlation Study is necessary, the Supplier will identify, measure, and record a specified number of production parts. If requested, the Supplier may send the parts to Medtronic for measurement, or coordinate with a third party based upon the sourcing strategy and relationship for production of the part in qualification. If the Supplier has a number of like gages, an internal gage correlation study must also be completed and provided to Medtronic. If an acceptable correlation value is not demonstrated, an acceptable rationale must be documented and approved by Medtronic.

### 3.9 Process Capability:

A Statistical Process Control Plan (SPC) and appropriate SPC data for special part and process characteristics will be kept on file as required. All special, significant, or critical drawing characteristics (unless otherwise specified) shall be controlled with SPC and variable gauging as applicable. The capabilities must be identified in the control plan and subsequently followed. This data may be required with each shipment at the discretion of the receiving facility. Special characteristics will be defined in Medtronic specifications when applicable. The minimum expected capability level is \( \geq 1.33 \) Cpk and desired capability is \( \geq 1.67 \) Ppk unless otherwise noted by Medtronic. If a Cpk < 1.33 is found during testing/production then the Supplier should notify Medtronic and receive pre-approval prior to submitting the data package unless otherwise directed by Medtronic. Additional in-process monitoring should be added to the manufacturing process and control plan to assure that conforming Product is being produced unless otherwise noted by Medtronic.

### 3.10 Control Plans

Each Medtronic business unit or geography uses risk assessment to identify the need for a control plan. Special Processes used for the manufacture of any finished device shall be validated and require a control plan. A Control Plan is a documented description of the systems for controlling part and process quality by addressing their key characteristics and engineering requirements. See Appendix C for the Medtronic control plan template.

A. Usage of a control plan:

1. The level of controls for primary and sub-tier suppliers shall be commensurate with the quality and supply risk.
2. The required controls shall be documented and agreed upon with the supplier.

B. Control plans should be written descriptions of the systems for controlling product and processes. The requirements are:

1. Each control plan should describe the actions that are required at each phase of the process including receiving, in-process, outgoing, and periodic requirements.
2. Product and/or process characteristics that are determined to require monitoring based on the risk assessments, should be listed in the control plan and monitored to ensure control. Each of these key characteristics should be identified by an “*” asterisk) in the “Key Process Characteristic” column on the control plan.
3. All special processes will be notated on control plans. A special process is one where the result of a process cannot be fully verified by subsequent inspection and test.
4. A single control plan may apply to a family of products that have commonality and are produced by the same process at the same manufacturing location/source.

5. Each control plan should be maintained and used throughout the product lifecycle.

6. Control plans should be available at all times for all affected operations and, should not be utilized as a substitute for operator work instructions.

C. Sub-tier Control:

A control plan should be generated for all sub-tier supplied Product when the Supplier’s risk assessment process indicates a control plan is required. The Supplier should be responsible for ensuring completion and maintenance of the product/process control plan by the sub-tier or relative to the scope of the outsourced work defined in the Medtronic/Supplier control plan.

D. Retention of Control Plan Records:

1. The Supplier should maintain a Medtronic-approved copy of the current control plan and related product/process approval records as well as all previous approved control plan revisions and related product/process approval records. This should include related records for all sub-tiered work. Quality records should be maintained in accordance with Medtronic requirements found in the Quality Agreement.

2. The Medtronic program quality engineer should be responsible for retention of the current master control plan and all master copies of previous/obsolete revisions in accordance with Medtronic’s Record Retention Policy.

3.11 Cost of Poor Quality (COPQ)

In the event that any Product has been rejected and Medtronic has notified Supplier, Supplier shall replace such Product free of charge and Supplier shall cover expenses (including freight and customs clearance, if any) incurred by Medtronic in connection with (a) shipment of replacement Product to the same location and (b) shipment of the Nonconforming Product back to Supplier (if so requested by Supplier). In the event of a rejection of defective Product, Supplier shall ship replacement Product as soon as practical, but in any event within thirty (30) days of its receipt of a proper rejection notice from Medtronic. Failure to meet such deadline shall result in a 5% decrease in price associated with the replacement Products. Supplier shall also reimburse Medtronic up to an amount equal to scrap and/or rework costs as a result of using the Nonconforming Product in production.

4.0 Quality Management System

4.1 Expected Requirements

The Supplier expectations are dependent on the Supplier type and category, as outlined in the table below:

<table>
<thead>
<tr>
<th>Supplier Type</th>
<th>Supplier Category</th>
<th>Minimum Requirement</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>OEM and Contract Manufacturing of Finished Devices</td>
<td>Both New and Existing</td>
<td>ISO 13485:2003 certified and FDA Registered</td>
<td>N/A</td>
</tr>
</tbody>
</table>

For existing Suppliers that are not certified to the specified ISO standard referenced above, it is preferred that those Suppliers have a plan in place to become certified and can demonstrate progress toward that plan.

Suppliers that are ISO certified must notify Medtronic Supply Chain in writing within five (5) business days if their Quality System certification is suspended, placed on probation, expired, receives any major non-conforming compliance from ISO notified bodies, or if the Supplier has been placed on any special status with their customers or registrars due to quality or delivery issues. The Supplier must also provide immediate notification to Medtronic if it receives a 483 or warning letter from the FDA. New Quality System certification shall be provided where there are mergers, acquisitions, or affiliations associated with Suppliers. Medtronic and its customers reserve the right to verify conformance of Supplier’s Quality System to ISO standard.

Upon request, Suppliers shall forward evidence of their Quality System certification to Medtronic.
4.2 General Requirements for Suppliers

Suppliers are required to establish, document, and implement an effective Quality Management System. The Supplier’s management will ensure that the Quality Requirements, including without limitation, in this Manual, are thoroughly distributed, understood, and maintained, and that adequate levels of authority have been established to ensure the continuous improvement of the Quality System.

4.3 Documentation Required

4.3.1 General

The Quality Management System documentation must include:
• Documented statements of a quality policy and quality objectives
• Documented procedures as required by the Quality Management System
• Documents needed by the organization to ensure the effective planning, operation and control of its processes
• Records required by the Quality Management System

4.3.2 Control of Documents

Supplier must establish, maintain, and document procedures to control all Quality Management System documentation and all data generated under the Quality Management System. The Supplier must have current revisions of documents available at all appropriate locations.

Supplier must have a documented procedure for the control and distribution of drawings and/or standards. Obsolete drawings must be destroyed or appropriately identified as such for limited distribution.

4.3.3 Control of Records

Records must be stored in an environment that will prevent deterioration, damage, or loss, and must be readily accessible to Medtronic upon request.

Supplier will make available any and all quality Records, within two (2) working days, upon request by Medtronic or any regulatory body such as the FDA.

Electronic record approvals and storage should comply with 21 CFR Part 11 requirements.

Record Retention (Applicable to OEM and Contract Manufacturing of Finished Devices)
• All quality Records shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than two (2) years from the date of release for commercial distribution by the manufacturer.

Record Retention (Applicable to Raw Material, Component, and Component Services)
• All quality Records must be kept for at least ten (10) years, or as otherwise required by a Quality Agreement, except internal audit and Supplier audit records, which shall be retained for at least two (2) years. Thereafter, such Records shall be transferred to Medtronic.

4.4 Complaints and MDR Handling

The parties will cooperate in dealing with customer and third party complaints concerning the Product(s) and shall take action to promptly resolve such complaints as may be reasonably requested by the parties.

Supplier shall:
• Give notice to Medtronic by email or by telephone within 24 hours of becoming aware of a Product complaint, with written follow-up within three (3) days.
• Maintain a written Record of all customer and third-party complaints that relate to the Product(s), whether received orally or in writing;
• Establish a tracking system for all Product(s) so as to permit successful tracking in the event of a Recall.
• Maintain complaint Records and files in accordance with Quality System requirements.
Medtronic shall have the sole authority to correspond with all applicable regulatory authorities with respect to complaints about the Product(s).

Medtronic is responsible for complying with all FDA and applicable foreign regulatory requirements pertaining to the reporting of adverse device events, including FDA’s Medical Device Reporting requirements, codified at 21 C.F.R Part 803. Supplier shall reasonably cooperate with Medtronic to enable Medtronic to fulfill such requirements. If Supplier becomes aware of a potentially MDR reportable event, notice of such event shall be given to Medtronic within two (2) business days. If the event may have caused or contributed to a death or serious injury, Supplier shall notify Medtronic within twenty four (24) hours of becoming aware of the issue.

4.5 Recalls

If either party in good faith determines that a Recall or other action involving a Product(s) should be considered, it will immediately notify the other party. Medtronic will have the sole authority to determine whether any action such as a Recall or other action should be undertaken. Supplier will cooperate with Medtronic to implement the Recall once the determination is made.

5.0 Management Responsibilities

Supplier’s senior management will ensure an effective Quality System and maintain an organizational structure which ensures the Product is designed, developed and manufactured to Medtronic requirements, including the Quality Requirements.

Senior management will ensure that appropriate communication is established with Medtronic regarding the effectiveness of and any changes in the Supplier’s Quality Management System.

Senior management is required to take an active role in the Quality Management System. This commitment must address the managerial processes of quality planning, quality control, and quality improvement.
5.1 Management Commitment
A Medtronic Supplier must demonstrate a commitment by senior management to continuous improvement. Senior management must provide documented evidence of its commitment to the development and improvement of the Quality Management System by:
• Communicating to the organization the importance of meeting customer as well as regulatory expectations and requirements
• Establishing the quality policy and objectives
• Conducting regularly scheduled management reviews on the effectiveness of the quality system and taking appropriate action when indicators are unfavorable
• Ensuring the availability of necessary resources

5.2 Customer Focus
Senior management must ensure that customer needs and expectations are identified, converted into requirements, and fulfilled with the aim of achieving customer satisfaction. Medtronic requires that Suppliers conform to design and performance specifications. Suppliers must meet requirements for reliability, delivery, cost management, and technical support.

5.3 Quality Policy
Senior management must endorse a written quality policy that:
• Is appropriate to the purpose of the organization
• Includes a commitment to meeting customer requirements and to continuous improvement
• Provides a framework for establishing and reviewing quality objectives
• Is communicated and understood at all levels in the organization
• Is reviewed for continued appropriateness

5.4 Quality Planning
Senior management must ensure that goals and objectives are established for the appropriate functions and levels. The goals and objectives must be measurable and consistent with the Supplier’s quality policy.

5.5 Responsibility, Authority and Communication
5.5.1 Responsibility and Authority
A Quality Management System must be implemented in order to provide confidence that the organization can satisfy the needs of its customers. The system must be consistent with the Supplier’s size, culture, and products. A Supplier must show evidence of a quality policy emphasizing continuous quality improvement driven by senior management. A long-term quality improvement program must be available for review by Medtronic representatives upon request. Management must define specific quality indicators and goals, as well as have a system in place to track and monitor trends. Improvement activities must be based around these trends.

5.5.2 Management Representative
Senior management must appoint member(s) of management who must have responsibility and authority for the planning, execution, control, and improvement of quality-related activities.

5.5.3 Internal Communication
The organization must ensure that communication takes place between its various levels and functions regarding the processes of the Quality Management System and their effectiveness. This communication may take the form of team meetings, bulletin boards, publications, electronic media, or other techniques.

5.6 Management Review
The Supplier’s management must evaluate the degree of compliance and effectiveness of the quality system. Management Reviews will be held at set intervals with a pre-determined agenda of items for review. The objective of the review must include a conclusion on the effectiveness of the quality system. Metrics presented will have goals set by the department. One of the major constituents of the Management Review is the status of the corrective action process. This formal corrective action process must communicate corrections to deficiencies. Action items will be assigned and recorded in the minutes with follow-up in adjacent management reviews.
6.0 Resource Management

Supplier will provide the resources necessary to implement and maintain an effective Quality Management System and to continually improve its effectiveness. Employees of the Supplier must be qualified for the job they perform through education, training, and/or work experience, and be knowledgeable of appropriate quality tools, defect awareness, and processes that affect the quality of products and services provided to Medtronic. Suppliers shall maintain evidence of required and completed training. Furthermore, employees must be provided with the equipment, facilities, training, and work environment conducive to producing high quality products that consistently meet the Product specifications of Medtronic.

The following requirements shall apply to the Supplier’s work environment:

a) Documents outlining the necessary health, cleanliness and clothing of personnel if contact between such personnel and the Product or work environment could adversely affect the quality of the Product.

b) If work environment conditions can adversely affect product quality, Supplier shall document requirements for the work environment and procedures to monitor these work environment conditions.
c) Supplier shall ensure that all personnel required to work under special environmental conditions are appropriately trained or supervised by a trained person.

If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment, or personnel.

7.0 Product Realization

7.1 Planning of Product Realization

Suppliers shall determine the quality objectives and requirements for the Product by the following:

- Quality Requirements specified by Medtronic, including requirements for delivery and post delivery of Product.
- Additional requirements not stated by Medtronic, but necessary for intended use.
- Statutory and regulatory requirements related to the Product.
- Supplier’s own specifications and quality manual.

Before committing to supply Product to Medtronic, the Supplier will hold a contract review of the requirements related to the Product, stated above, to ensure that Product requirements are defined, order requirements are understood, and the Supplier has the ability to meet the defined requirements.

7.2 Customer Requirements

7.2.1 Design for Reliability and Manufacturability (DRM)

Achieving supplier excellence with DRM practices, methods and tools and integrating into our development process will improve Medtronic’s product performance, reliability, manufacturability and costs. It is our expectation that our Suppliers proactively participate in the DRM process. It is essential that we work together to understand requirements, design for manufacturability principles, and design robust processes where capabilities are understood and effectively controlled.

Your Role as a Supplier:

- Be active and dedicated throughout the entire process
- Be open to changes
- Look for ways to continuously improve in all aspects of your company

The ten DRM practices include:

- Technology - Strategic technology planning and development with scientific understanding.
- Voice of the Customer (VOC) - describes customers’ and stakeholders’ needs and perceptions of Supplier’s process, product, or service. It includes all aspects of the relationship with the customer with regard to quality, cost, and delivery.
- Concept Engineering - A structured methodology to bridge from the identified customers’ & stakeholders’ needs & perceptions to a number of product concepts designed to meet theses needs.
- Requirements Flow Down - The flow down of functional requirements will evolve to subsystem requirements and to sub assembly requirements and component requirements.
- Robust Design - The state in which the product or service performance is least susceptible and minimally sensitive to variables and factors that could potentially cause performance degradation.
- Use Condition - Understand environments and operating conditions in which a system and its constituent parts are expected to perform.
- Design for Manufacturing & Assembly (DFMA) - A systematic process for product design that enables simplification through component and process step reduction and use of standardized methods, components and materials and promotes Lean Thinking.
- Design for Reliability (DFR) - A design methodology used to assure that the designed product or service will perform the desired function, without failure, for a stated period of time under stated use conditions.
- Capability - The compilation of subsystem and component performance levels to estimate capabilities at the system and customer levels.
- Control - Identification of critical process parameters, product specification, functional performance and their intended behavior [control, mitigation], and requisite activities to sustain the process performance at acceptable levels.
7.2.2 Product Clearances and Approvals (Applicable to OEM Suppliers Only)
Supplier is responsible for obtaining and maintaining regulatory clearance/approval on Product supplied to Medtronic.

7.2.3 Communication to Medtronic
Supplier must identify and implement a communication plan with Medtronic regarding product information, contracts, order handling, and customer feedback and complaints. Supplier will provide prompt notification to Medtronic of any Supplier Product recalls or field actions.
Supplier shall provide Medtronic the documents, paper or electronically, required to determine acceptance of Product during inspection, e.g. certificate of assurance, certificate of compliance, etc.
For questions on whom to contact, see Section 2: Key Roles and Responsibilities.

7.2.4 Supplier’s Obligations for Timely and Proper Notification of Change
7.2.4.1 Changes by Medtronic
The Specifications may be revised by Medtronic. Such revisions may require additional qualification. Medtronic shall notify Supplier of all relevant Specification revisions. Supplier shall implement all revisions by dates specified by Medtronic.
7.2.4.2 Changes by Supplier
Upon approval by Medtronic of the initial design, Component or process changes, design changes or deviations considered by Supplier must be submitted to Medtronic in writing for review and approval prior to making any changes. When Supplier submits changes for Medtronic’s approval, the information submitted must include a complete description of the change and, working jointly with Medtronic, Supplier must determine the effect the change will have on all characteristics of the Product.

Upon request, the Supplier shall submit samples of the proposed Product for evaluation and approval by Medtronic. Supplier shall not implement any such change without Medtronic’s prior written consent. Supplier shall ensure that entities that supply Components follow this same procedure. Additionally, Medtronic requests a minimum of six months notification of change and twelve months in the case of changes where a manufacturing line shutdown or move is involved. It is in both the Supplier’s and Medtronic’s interest to review any potential changes as early in the potential change process as possible.

7.2.4.3 Change/Approval
Medtronic personnel shall review and approve changes that may affect the Product(s), including, without limitation:

All process changes including changes related to:
• Control plan
• Field action
• Product performance issue
• Process validation
• Process deviation
• Process Failure Modes & Effects Analysis (PFMEA)
• Product final acceptance test issue
• Supplier manufacturing site transfers
• Sub-Tier Supplier changes

Material:
• Changes to materials and/or Components
• Change in a supplier of a material or Component

Change in Component or Product requiring:
• Updated component specification
• Updated product specification
• New or alternate Sub-Tier Supplier

CAPA:
• CAPA initiation involving Medtronic products

Change in Supplier:
• Name
• Address

Change in Product design:
• Product
• Labeling
• Packaging

Change to Product part number

Change to Manufacturing, test, or inspection equipment:
• New equipment
• Equipment qualification or validation
• Change from manual to automated process

Facility Changes:
• Move of manufacturing equipment within the same manufacturing facility.
• Facility to facility transfer of manufacturing processes or technology.
• Altering environment specs or conditions in areas used for manufacturing, storage, or test (i.e. microbial/endotoxin/particulate monitor).
In-process and final acceptance test changes related to:

- Test specification
- Test application validation
- Outgoing inspection plan
- Test acceptance requirements
- Products reviewed by Supplier MRB for “Use As Is” disposition

7.3 Design and Development

Supplier may collaborate with Medtronic to ensure a thorough understanding and identification of critical process steps, transfer function relationships, acceptable measurement capability, and process capability of process inputs/outputs related to their impact on the critical design features. Supplier may collaborate with Medtronic to design an appropriate control plan to help ensure the long-term stability and capability of the manufacturing processes with the goal of achieving a high process capability. This control plan shall be documented and approved by Medtronic.

7.3.1 Design and Development Planning

Supplier may establish and maintain plans that:

- Describe or reference the Design and Development activities for the Product
- Identify and describe the interfaces with the groups or activities that provide input to the design/development process for the Product
- Define responsibility for implementation in substantial compliance with Quality Management System Requirements

These plans will be reviewed, updated and approved by Medtronic as design and development evolves.

7.3.2 Design Inputs

Medtronic, through the use of Design for Reliability and Manufacturing methodology, may collaborate with the Supplier to ensure that the design requirements for the Product are appropriate for and address the intended use of the Product. This includes the needs of the user and patient, in compliance with the Quality Management System Requirements. In addition, Medtronic may identify all critical features and/or requirements of the Product that require specific capability and control within the Supplier’s manufacturing process. These will be reported to Medtronic using electronic data collection system or other agreed upon format. The design requirements should be documented and approved by Medtronic and the appropriate Supplier personnel. All approvals should be documented as well.

7.3.3 Design Outputs

Supplier may establish and maintain procedures for defining and documenting Design Outputs in a manner that allows adequate evaluation of the Product’s conformance to Design Input requirements, in substantial compliance with Quality Management System Requirements. The procedures may reference acceptance criteria and may ensure that essential outputs are identified. Supplier may document Design Output.

7.3.4 Design Review

Supplier may establish and maintain procedures to ensure that formal documented reviews of the design for the Product are planned and conducted at appropriate stages in design development, in substantial compliance with Quality Management System Requirements.

7.3.5 Design Verification

Supplier may establish and maintain procedures for verifying the design of the Product, in substantial compliance with Quality Management System Requirements. Design verification may confirm that the Design Output for the Product meets the Design Input requirements and any other Medtronic requirements.

7.3.6 Design Validation

Supplier may establish and maintain procedures for validating the design of the Product. Design validation may be performed under defined operating conditions on initial production units, lots or batches, or their equivalents. Design validation may ensure that the Product conforms to defined user needs and intended uses, and may include testing of the Product under actual or simulated use conditions.
7.3.7 **Design Transfer**
Supplier may establish and maintain procedures to ensure that the design of the Product is correctly translated into production specifications, in substantial compliance with Quality Management System Requirements.

7.3.8 **Design Changes**
Supplier may establish and maintain procedures for the identification, documentation, validation (or where appropriate, verification), review and approval of design changes for the Product before implementation, in substantial compliance with Quality Management System Requirements. Changes to the design will be governed by Medtronic procedures. Supplier may suggest and request design changes to Medtronic, but Supplier shall not implement any design change before receiving updated specifications and appropriate change authorization from Medtronic.

7.3.9 **Control of Design and Development Changes**
Supplier may have procedures for the identification, documentation, and validation of design changes. Supplier shall notify Medtronic, prior to implementation of design changes that may affect the safety, effectiveness, use or performance of the Component or Product. Supplier shall follow all appropriate change control procedures. Any changes to product design require appropriate change authorization from Medtronic.

7.3.10 **Design History File (Applicable to OEM Suppliers Only)**
OEM Suppliers are responsible for maintaining a Design History File (DHF) for the Product. This will contain or reference the records necessary to demonstrate that the design was developed in accordance with the design plan, per the applicable Quality System Requirements.

OEM Supplier shall retain records of the Product DHF for the agreed upon time, as stated in the Quality Management Agreement. Supplier shall grant Medtronic access to the DHF within twenty-four (24) hours of request.

OEM Suppliers shall document results of the design reviews, design verification and the design validation.

7.4 **Purchasing**
Supplier shall establish and maintain controls on the purchase of components used in the manufacture of Product to ensure conformance to specified requirements, including visual inspection of packaging, labeling, or shipping containers, and dimensional inspection or analytical testing.

Supplier shall maintain documentation that clearly describes the quality requirements for components, and shall require component sources to notify Supplier of any proposed changes in the manufacturing of the components prior to making any change. Medtronic shall participate in the review and approval of component source changes.

If necessary, Medtronic may choose to evaluate the Supplier’s component sources to ensure the purchased Product meets specified purchase agreements.

In the event that, with Medtronic’s knowledge and approval, Supplier subcontracts a portion of the manufacture and/or inspection of components to sub-tier suppliers, the requirements defined in this document shall be passed on to those Suppliers through purchase order requirements. Supplier shall remain responsible for all acts or omissions of the sub-tier supplier with whom it contracts.

7.4.1 **Production and Service Provision**
Suppliers must incorporate and document process controls as needed to ensure stable conditions for the manufacturing process. Process controls documents include, but are not limited to, process sheets, inspection and test instructions, test procedures, standard operating procedures, preventive maintenance instructions and process control plans.

At the time of Qualification, Supplier will incorporate the foregoing into Quality Control Plan and outgoing lot/batch inspection test plan (“outgoing inspection plan”), which will be mutually agreed upon and approved by Medtronic. Supplier shall provide a measurement system analysis (e.g. gauge repeatability and reproducibility (GRR), for each measurement process utilized in either the quality control or outgoing inspection plans for critical features. These analyses and plans will be filed with the Supplier with a copy sent to Medtronic. On an ongoing basis, the Supplier shall monitor production per the Quality Control Plan and complete inspection of each lot/batch of shipment per the outgoing inspection plan to ensure conformance. The Supplier will include a Certificate of Conformance (COC) for each lot/batch based on conformance to both plans.
Supplier may revise the Quality Control Plan and/or outgoing inspection plan, however, such revisions need to be mutually agreed upon in writing by Supplier and Medtronic. A formal Supplier Change Notification request should be submitted to Medtronic when applicable. See section 7.2.4.

7.5 Identification and Traceability

7.5.1 Identification

Supplier will establish procedures that identify product during all stages of receipt, production, and distribution. Supplier shall have systems in place that provide a means of identifying the status of Product not yet transferred to Medtronic or a contract manufacturer.

At a minimum, identification and segregation is required for:

a) Receiving Inspection
b) Production work in progress
c) Nonconforming Product
d) Reject Product
e) On-hold (quarantined) Product
f) Conforming Product

7.5.2 Traceability

Supplier shall be responsible for setting up and maintaining controlled documentation of product traceability during all stages of receipt, production, and distribution. Traceability and quality records will be maintained throughout the life of the Product, as determined by Medtronic. Traceability requirements include, but are not limited to, the following:

a) Minimum Traceability – All Products and components are traced by lot/batch.
b) Critical Components – Traced according to Medtronic documentation established at the time of qualification.
c) Process Information – Traced to the sub-assembly. At a minimum, this includes the operator, date performed, shift, manufacturing instructions used, use of validated equipment and identification of equipment used, Bill of Material (BOM)/design revision and configuration, resolution of any discrepancies, and record of any rework performed.
d) Raw Materials – Traced to original material manufacturing lot/batch at a minimum.
e) These records will be made available to Medtronic upon request.

7.5.3 Handling, Storage, Distribution, and Installation

Supplier shall establish and maintain procedures for the handling, storage, distribution, and installation of the Product(s) in substantial compliance with the following:

a) Handling: Supplier shall have systems in place to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects do not occur during handling of the Product(s).
b) Storage: Supplier shall control storage areas to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending distribution of the Product(s).
c) Distribution: Supplier shall have systems in place to control distribution of Product(s) so that only Product(s) approved for release are distributed. Supplier shall ensure that no obsolete, rejected, expired, or deteriorated Products are distributed, unless they are distributed to Medtronic at its request.
d) Installation: When a Product requires installation, Supplier shall have adequate installation, inspection, and testing instructions and procedures, where appropriate, which meet Medtronic requirements. Instructions and procedures will include directions for ensuring proper installation. Supplier shall distribute the instructions and procedures with the Product or otherwise make them available to the person installing the Product. The person installing the Product will perform installation, inspection, and testing in accordance with the instructions and procedures.
7.5.4 Control of Monitoring and Measuring Devices

A Supplier must establish and maintain documented procedures for the calibration, control, and maintenance of measuring, inspection, and test equipment used to ensure that products and processes conform to applicable requirements. A Supplier must calibrate these devices at consistent periodic intervals against applicable standards traceable to NIST (National Institute of Standards and Technology), and safeguard the devices against adjustments that would invalidate the calibration. If a Supplier finds that a gauge is not calibrated correctly and it has been used to verify parts for Medtronic, the Supplier must notify Medtronic.

8.0 Measurement, Analysis, and Improvement

8.1 General

Measurement, analysis, and improvement are the processes of planning, defining, and using performance metrics for products delivered to Medtronic. These performance metrics determine the current level of performance, drive continuous improvement activities, and monitor performance levels. Statistical tools must be applied to measure the performance metrics on processes and products, but also to measure supply chain performance. Supplier must define, plan, and implement measurements where processes affect the quality of products or services that Medtronic receives.

8.2 Production and Process Control

Supplier will have systems in place to define and maintain the manufacturing process and associated controls so that all Product conforms to their specifications, including, but not limited to:

a) Approved and documented production processes, instructions, and methods that define and control the manner of production.

b) Monitoring and control of process parameters and component and device characteristics during production.

c) Compliance with specified reference standards or codes.

d) Approval of processes and process equipment.

e) Criteria for workmanship, which shall be expressed in documented standards or by means of identified and approved representative samples.

Supplier will monitor and control the manufacturing process using industry standard tools, such as: in-process inspection; control plans; validation; and Statistical Process Control.

At a minimum, Special Processes used for the manufacture of any finished device shall be validated and require a control plan. This includes any process that may be performed by sub-tier suppliers. Validation plans and reports should be reviewed and approved by Medtronic.

Supplier will identify and document key manufacturing process steps that affect product performance. Medtronic will aid Supplier in such identification as it relates to product or device performance.

In the event that any of the manufacturing process steps are out-of-control or manufacturing yields decline considerably, Supplier will take appropriate corrective and preventive actions to rectify the situation, while documenting actions taken.

8.3 Audits

Medtronic may choose to audit the Supplier or sub-tier Supplier’s manufacturing and Quality Systems. To ensure compliance to Quality Requirements, it is expected that during these audits, Medtronic shall have reasonable access to observe and inspect Supplier’s:

• Facility, manufacturing, and quality control processes
• Manufacturing and quality control records
• Quality Systems and all analytical and manufacturing documentation related to Product

Supplier will conduct internal audits to ensure compliance with its Quality System and this Quality Manual. Upon request, the Supplier will provide audit results and conclusions to Medtronic.
8.4 Monitoring and Measurement

8.4.1 Incoming Acceptance
Supplier shall have procedures for acceptance of incoming product, including inspection, testing, and verification as conforming to Medtronic specifications. Supplier will document acceptance or rejection of incoming product. Certified Components that are received shall include a certificate of compliance to Supplier’s specification.

8.4.2 In-Process Acceptance
Supplier shall have in-process acceptance procedures to ensure that in-process Product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received.

8.4.3 Final Acceptance
Supplier shall have procedures for finished Product acceptance to ensure that each production unit, lot, or batch of finished Product meets Medtronic’s acceptance criteria. Finished Product shall be adequately controlled until released. Suppliers who are identified in the DRM program to electronically submit data on critical parameters, must have passing shipment data to control limits.

8.5 Control of Nonconforming Product
Supplier will establish and maintain procedures to control Product that does not conform to Medtronic specifications. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of Nonconforming Product, including the need for an investigation, which shall be documented.

8.5.1 Material Corrective Action Request/Supplier Corrective Action Request (SCAR)
Where a Product is identified by Medtronic as Nonconforming Product, Supplier shall cooperate with Medtronic in working toward closure of the Medtronic Corrective Action Request associated with the Product(s).

8.5.2 Product Performance
Nonconforming Product may be returned to Supplier for investigation and analysis by Medtronic, a third party, or through Supplier’s own vigilance. In the latter two, Supplier shall promptly notify Medtronic when Nonconforming Product is returned. Supplier and Medtronic shall agree on the necessary analysis to be performed by Supplier. Supplier shall follow their own failure analysis protocol in performing root cause analysis, if available.

8.5.3 Production Defects
Production defects that exceed established process control/action limits shall be investigated within Supplier’s CAPA system. Production defects shall be tabulated and analyzed for trends in order to identify need for further CAPA.

8.5.4 Escapes
Supplier shall have control systems in place to prevent Nonconforming Product from being integrated with conforming Product. In the event these systems fail, Supplier shall immediately notify Medtronic by telephone and email of escapes of Nonconforming Product, to allow Medtronic to investigate and take containment action. Supplier shall fully cooperate in any investigation of containment action.

8.5.5 Disposition of Nonconforming Product
Supplier shall have procedures covering disposition of Nonconforming Product, including review and documentation of decisions. Medtronic and Supplier shall jointly determine the procedures for rework, retest, and re-evaluation of Nonconforming Product to ensure Product meets specifications. Supplier shall document rework activities in the Device History Record (DHR) or equivalent and submit rework report to Medtronic, upon request.
8.6 Corrective and Preventive Action (CAPA) System

Supplier will establish and maintain procedures for implementing a CAPA system in substantial compliance with the industry standards and Quality Management System requirements. Medtronic and the Supplier shall collaborate to determine the division of responsibility for implementation of the CAPA system depending upon the nature of the quality problem and the proposed solution.

The CAPA system shall include, at a minimum, the following requirements:

- Analysis of quality data (e.g., manufacturing processes, operations, quality audit records and reports, complaints, returned Product) to identify root causes of Nonconforming Product or other quality problems
- Investigation of the causes of nonconformities
- Identification of the actions needed to correct the nonconformance and to prevent reoccurrence
- Verification or validation of the corrective and preventive action
- Documentation of changes implemented to methods and procedures to correct and prevent quality problems
- Implementation of and recording changes to methods and procedures needed to correct and prevent quality problems. Prior notification and approval may be required by Medtronic pursuant to Section 7.2.4 (Supplier’s Obligations for Timely and Proper Notification of Change)
- Documentation that information regarding quality problems or Nonconforming Product is disseminated to appropriate quality personnel
- Submission to management of relevant information regarding quality problems, plus corrective and preventive action
- Documentation of activities under the CAPA system
- Effectiveness verification of corrective and preventive action

Supplier shall resolve and document any product quality, Quality System, or performance issues within the CAPA framework. Supplier will:

- Review nonconformities, including customer complaints
- Perform failure/root cause analysis
- Evaluate the need for action to ensure that nonconformities do not recur
- Determine and implement action needed
- Record the results of any investigation and action taken
- Review the corrective action taken to ensure its effectiveness

Supplier shall provide action plans including responsible personnel and targeted completion dates for all corrective action requests within thirty (30) days of notification, unless otherwise noted in a Medtronic contract or agreement. Action plans shall be verified and/or validated to ensure effectiveness without an adverse affect on Product or process. To eliminate the possibility of human error, mistake-proofing will be incorporated when and where possible. Supplier shall meet commitment dates to ensure timely resolution of all identified issues.

Supplier shall notify Medtronic in writing within two (2) working days after learning of any actual or potential problems relating to the performance of any Product manufactured for Medtronic that does not meet specification.
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOM</td>
<td>Bill of Material</td>
</tr>
<tr>
<td>CAPA</td>
<td>Corrective and Preventive Action</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>COPQ</td>
<td>Cost of Poor Quality</td>
</tr>
<tr>
<td>Cpk / Ppk</td>
<td>Process Capability Indices</td>
</tr>
<tr>
<td>DHF</td>
<td>Design History File</td>
</tr>
<tr>
<td>DHR</td>
<td>Device History Record</td>
</tr>
<tr>
<td>DRM</td>
<td>Design for Reliability and Manufacturability</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FMEA</td>
<td>Failure Mode and Effect Analysis</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standard Organization</td>
</tr>
<tr>
<td>MSA</td>
<td>Measurement System Analysis</td>
</tr>
<tr>
<td>NPD</td>
<td>New Product Development</td>
</tr>
<tr>
<td>OEM</td>
<td>Original Equipment Manufacturer</td>
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<tr>
<td>PO</td>
<td>Purchase Order</td>
</tr>
<tr>
<td>SCAR</td>
<td>Supplier Corrective Action Request</td>
</tr>
<tr>
<td>SPC</td>
<td>Statistical Process Control</td>
</tr>
</tbody>
</table>
APPENDIX B: Terms and Definitions

Business Continuity Management: A holistic management process that identifies potential impacts that threaten an organization and provides a framework for building resilience with the capability for an effective response that safeguards the interests of its key stakeholders, reputation, brand and value creating activities.

Capability: Quantified by the index Cpk; can be determined only after the process is in statistical control.

Cpk (Capability Index): A process capability calculation which considers both the normal process variation and the measure of central tendency for that process. It is calculated by dividing 3 sigma into the lesser of the Upper Specification Limit (USL) minus the process grand average (average of subgroup averages), or the process grand average minus the Lower Specification Limit (LSL). Cpk can be calculated only when data from the study indicate that stability has been achieved.

Certificate of Conformance (COC): A document, signed by an authorized representative of Supplier, attesting that a particular Product is Manufactured or Serviced in accordance with applicable Quality Management System requirements, the Specifications or the Quality Agreement. This may also be referred to as a Certification of Compliance and Certification of Analysis.

Certified Component: A component from a particular supplier that has undergone the Medtronic Certification process and been granted a certified status. The process includes the particular supplier having accepted tactical responsibility for completing the ongoing actions necessary to mitigate the risks associated with eliminating or reducing receiving inspection at Medtronic.

Control Plan: A document that identifies key Manufacturing process steps, critical inputs to and critical variables of such steps, and that defines process monitoring control strategies and tools.

Corrective and Preventive Action (CAPA): A corrective action and preventive action system for identifying and preventing or eliminating the cause of an existing or potential nonconformity, defect, or other undesirable situation in order to prevent occurrence or recurrence.

Contract Manufacturer: A contractor that manufactures Finished Devices distributed by Medtronic and where Medtronic maintains control/approval of the Specifications. The finished Product may be supplied to Medtronic for final packaging and labeling or be labeled by the contractor with the Medtronic name and brand. Contract manufacturing may include sterilization, packaging, labeling, or servicing activities.

Critical Component: A component of a finished device, which if fails could result in a hazard to a patient and/or user and/or is identified in the product development process as being part of a critical feature or function of the device.

Customer: Medtronic or the customers of Medtronic.

Critical Feature: The process specified by Medtronic for identifying features requiring control.

Design and Development: Activities conducted pursuant to applicable Quality Management System requirements, including FDA’s Quality system requirements, ISO 13485, or both, to design and develop the Product for Manufacture.

Design History File (DHF): A compilation of Records that describes the design history of a finished device.

Device History Record (DHR): A compilation of Records containing the production history of the Product(s).

Design Input: The physical and performance requirements of the Product(s) that are used as a basis for device design.

Design Output: The results of a design effort at each design phase and at the end of the total design effort. The finished Design Output is the basis for the DMR. The total finished Design Output consists of the device, its packaging and labeling, and the DMR.

Design Review: A documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, the capability of the design to meet these requirements, and the presence of any problems.

Design Validation: Objective evidence that confirms the device Specifications conform with user needs and intended use(s).

Design Verification: Confirmation by examination and provision of objective evidence that specified design requirements have been fulfilled.

Finished Device: Any Product that constitutes a device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Gauge Repeatability and Reproducibility (GR&R or GRR): Statistical measure to analyze how much variation exists in a gauge, measurement or test equipment.


Lot: One or more products manufactured under essentially the same conditions that are intended to have uniform characteristics and quality within specified limits.

Manual: This quality manual and its appendices.

Medtronic Contract/Agreement: Medtronic documents including purchase orders, purchasing terms and conditions, engineering drawings, Specification requirements, and contracts (quality, supply, development, etc.).

Nonconforming Product: Product or material that does not meet specified requirements, such as:
- Material built to an incorrect configuration
- Material built with nonvalidated process parameters or material processes outside of approved parameters
- Material built with unapproved components, counterfeit components, or components not meeting Specification

OEM Supplier: Supplier that manufactures Medical Finished Devices used and/or sold by Medtronic, in which the Supplier holds legal title, design, manufacturing, and regulatory responsibility.
APPENDIX B: Terms and Definitions (continued)

Ppk (Performance Index): A calculation which considers both the normal variation (performance) of the process and the measure of central tendency for that process. It is calculated by dividing 3 sigma into the lesser of the Upper Specification Limit (USL) minus the process grand average (average of subgroup averages), or the process grand average minus the Lower Specification Limit (LSL). Ppk can be calculated only when data from the study indicate that stability has been achieved.

Product: All goods supplied by Supplier to Medtronic on or after the Effective Date of this Quality Agreement.

Qualification: Activity and analysis performed to demonstrate adherence to predetermined criteria. Qualification for a Product means Product testing or inspection conducted according to an approved and controlled protocol to ensure the Product meets Specifications.

Quality Control Plan: A document that identifies key Manufacturing process steps, critical inputs to and critical variables of such steps, and that defines process monitoring control strategies and tools.

Quality System or Quality Management System: The regulatory requirements for the methods used in, and the facilities and controls used for, the design, manufacture, packing, labeling, storage, installation, and servicing of Finished Devices, as codified in 21 CFR Part 820 or embodied in ISO 13485/ISO 9001.

Records: Written or electronic accounts, notes, data, record of, and information and results obtained from performance of Services of all work done under the Quality Management System, this Manual, or Quality Agreement.

Recalls: Any recall, market withdrawal, stock recovery, safety alert, correction, removal, or field action.

Specification: All applicable specifications, protocols and other documents relevant to the design, physical characteristics, function, performance, Manufacture, packaging, labeling and quality of the Product(s) communicated in writing by Medtronic.

Special Process: A process where the result of a process cannot be fully verified by subsequent inspection and test.

Supplier: A provider of goods or services to Medtronic.

Statistical Process Control (SPC): Application of statistical methods such as control charts to analyze a process and determine appropriate actions to take to achieve and improve statistical capability.

Validation or “Validate”: Confirmation by examination and provision of objective evidence that the applicable requirements can consistently be fulfilled.
### APPENDIX C: Control Plan Template

<table>
<thead>
<tr>
<th>Control Plan Number</th>
<th>Control Plan Type</th>
<th>Pre-Production</th>
<th>Production</th>
<th>Control Plan Original Date</th>
<th>Control Plan Revised Date</th>
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<td>Part Number/Rev Level</td>
<td>Part / Process/Project Name or Description</td>
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<td>Medtronic Quality</td>
<td>Medtronic Team Members</td>
<td>Medtronic Approval(s)/ Date</td>
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<td>Contact Address/Phone</td>
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<td>Medtronic Plant Location</td>
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<tr>
<th>Part/ Process Number</th>
<th>Process Name / Operation Description</th>
<th>Machine Device, Art Tools for Mfg</th>
<th>Characteristics</th>
<th>Special Class / Class</th>
<th>Spec/Work Instruction # / Revision</th>
<th>Methods</th>
<th>Responsible Party</th>
<th>Reaction Plan</th>
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### Control Plan Change Log

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<tr>
<th>Revision</th>
<th>Document Change No.</th>
<th>Revision Date</th>
<th>Description of Change</th>
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<tbody>
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</tbody>
</table>
### APPENDIX C: Control Plan Template

<table>
<thead>
<tr>
<th>Control Plan Content</th>
<th>Content Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Plan Number:</td>
<td>Enter the control plan document number used for tracking, if applicable.</td>
</tr>
</tbody>
</table>
| Control Plan Type: (pre-production or production)        | Indicate the appropriate category.  
- Pre-Production: A description of the dimensional measurements, material and performance tests that will occur prior to normal production.  
- Production: A comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems occurring during normal production. |
| Control Plan Original Date:                              | Enter the date that the original control plan was compiled.                                                                                                                                                             |
| Part Number & latest revision level:                     | Enter the number of the system, subsystem or component being controlled. When applicable, enter the latest engineering change level and/or issue date from the drawing specification.                                              |
| Part/Process/Project Name & Description:                 | All steps in the manufacturing of a system, subsystem, or component are described in a process flow diagram. Identify the part/process/project name that best describes the activity being addressed.                               |
| Control Plan Revised Date:                               | Enter the date of the latest Control Plan updates.                                                                                                                                                                     |
| Medtronic Purchasing Contact/Address/Phone: Medtronic Plant Location | Enter the name and telephone number of the primary Medtronic contact responsible for the control plan. Enter name of the Medtronic facility receiving the supplier product or service.                  |
| Medtronic Quality Contact/Phone:                         | Enter the name and telephone number of the primary Medtronic Quality contact responsible for the control plan.                                                                                                           |
| Medtronic Team member:                                   | Enter the name and telephone number of the primary Medtronic Team member responsible for the control plan.                                                                                                               |
| Medtronic Approval/Date:                                 | Obtain the responsible Medtronic quality representative approval (if required).                                                                                                                                       |
| Supplier Purchasing Contact/Address/Phone: Supplier Plant Location | Enter the name and telephone number of the primary supplier purchasing contact responsible for the control plan. Enter name of the supplier manufacturing plant where the product is produced and where the control plan will be executed. |
| Supplier Quality Contact/Phone:                          | Enter the name and telephone number of the primary supplier quality contact responsible for the control plan.                                                                                                          |
| Supplier Team Member:                                   | Enter the name and telephone number of the primary Supplier Team member responsible for the control plan.                                                                                                              |
| Supplier Approval/Date:                                  | Obtain the responsible supplier manufacturing plant approval (if required).                                                                                                                                             |
| Part/Process Number:                                     | This item number is usually referenced from the Process Flow Chart. If multiple part numbers exist (assembly), list the individual part numbers and their processes accordingly.                                              |
| Process Name/Operation Description:                      | All steps in the manufacturing of a system, subsystem, or component are described in a process flow diagram. Identify the process/operating name from the flow diagram that best describes the activity being addressed.                   |
| Machine Device. Jig Tools for Mfg:                       | For each operation that is described, identify the processing equipment, e.g., machine, device, jig, or other tools for manufacturing, as appropriate.                                                                     |
| Characteristics:                                         | Definition: A distinguishing feature, dimension or property of a process or its output (product) on which variable or attribute data can be collected. Use visual aids where applicable.                                 |
| Number                                                   | Enter a cross reference number from all applicable documents such as, but not limited to, process flow diagram, numbered blue print, FMEA’s and sketches (computer generated or otherwise), if required.               |
| Product                                                  | Product Characteristics are the features or properties of a part, component or assembly that are described on drawings or other primary engineering information. The Core Team should identify the Special Product Characteristics that are a compilation of important Product Characteristics from all sources. All special characteristics need to be listed on the Control Plan. In addition, the manufacturer may list other Product Characteristics for which process controls are routinely tracked during normal operations. |
## APPENDIX C: Control Plan Template

<table>
<thead>
<tr>
<th>Control Plan Content</th>
<th>Content Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process</strong></td>
<td>Process Characteristics are the process variables (input variables) that have a cause and effect relationship with the identified Product Characteristic. A Process Characteristic can only be measured at the time it occurs. The Core Team should identify process Characteristics for which variation should be controlled to minimize product variation. There could be one or more Process Characteristics listed for each Process Characteristic. In some processes one Process Characteristic may affect several Product Characteristics.</td>
</tr>
<tr>
<td><strong>Special Char. Class.</strong></td>
<td>Use the appropriate classification as required by the OEM, to designate the type of special characteristic or this field can be left blank for other undesignated characteristics. Customers may use unique symbols to identify important characteristics, such as those that affect customer safety, compliance with regulations, function, fit or appearance. These characteristics are variously termed, “Critical”, “Key”, “Safety”, or “Significant.”</td>
</tr>
<tr>
<td><strong>Spec/Work Instruction # and Revision</strong></td>
<td>Enter the number and revision level of the specification referenced.</td>
</tr>
<tr>
<td><strong>Methods:</strong></td>
<td>Definition: A systematic plan using procedures and other tools to control a process.</td>
</tr>
<tr>
<td><strong>Product/Process Specification Tolerance</strong></td>
<td>Specifications/tolerance may be obtained from various engineering documents, such as, but not limited to, drawings, design reviews, material standard, computer-aided design data, manufacturing, and/or assembly requirements.</td>
</tr>
<tr>
<td><strong>Evaluation Measurement Technique</strong></td>
<td>This column identifies the measurement system being used. This could include gages, fixtures, tools and/or test equipment required to measure the part/process/manufacturing equipment. An analysis of the linearity, reproducibility, repeatability, stability and accuracy of the measurement systems should be done prior to relying on a measurement system and improvements made accordingly.</td>
</tr>
<tr>
<td><strong>Sample Size</strong></td>
<td>When sampling is required, list the corresponding sample size.</td>
</tr>
<tr>
<td><strong>Sampling Freq.</strong></td>
<td>When sampling is required, list the corresponding frequency.</td>
</tr>
<tr>
<td><strong>Control Method</strong></td>
<td>This column contains a brief description of how the operation will be controlled, including procedure numbers where applicable. The control method utilized should be based on effective analysis of the process. The control method is determined by the type of process that exists. Operations may be controlled by, but are not limited to, Statistical Process Control, inspection, attribute data, mistake-proofing, (automated/non-automated), and sampling plans. Refer to the examples for how typical processes are controlled. The Control Plan descriptions should reflect the planning and strategy being implemented in the manufacturing process. If elaborate control procedures are used, the plan will typically reference the procedure document by a specific identification name and/or number. The method of control should be continually evaluated for effectiveness of process control. For example, significant changes in the process and process capability should lead to an evaluation of the control method.</td>
</tr>
<tr>
<td><strong>Responsible position</strong></td>
<td>Person responsible for ensuring the control methods are employed.</td>
</tr>
<tr>
<td><strong>Reaction Plan</strong></td>
<td>The reaction plan specifies the corrective actions necessary to avoid producing non-conforming products or operating out of control. The actions should normally be the responsibility of the people closest to the process, the operator, job setter or supervisor, and be clearly designated in the plan. Provisions should be made for documenting. In all cases, suspect and nonconforming products need to be clearly identified and quarantined, and disposition made by the responsible person designated in the reaction plan. This column may also refer to a specific reaction plan number and identify the person responsible for the reaction plan.</td>
</tr>
</tbody>
</table>

### Control Plan Change Log

<table>
<thead>
<tr>
<th>Control Plan Change Log</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revision #</strong></td>
<td>Enter the revision number of the control plan</td>
</tr>
<tr>
<td><strong>Document Change #</strong></td>
<td>Enter the documentation supporting the referenced change, if applicable.</td>
</tr>
<tr>
<td><strong>(ECO or DCR #)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Revision Date</strong></td>
<td>Enter the documentation supporting the referenced change, if applicable.</td>
</tr>
<tr>
<td><strong>Description of change</strong></td>
<td>Enter a description of the change.</td>
</tr>
</tbody>
</table>
APPENDIX D: Revision Record

The master copy of this document is controlled and maintained by the Medtronic Corporate Quality Group.

This Manual will be modified based on opportunities for continuous improvement. Any changes to this document must be approved by and coordinated through the Quality group. Revision levels and the corresponding detailed modifications will be updated in the table below.

All printed and downloaded copies are for reference only. Suppliers are responsible for obtaining and using the current version of this document. Contact your Medtronic Supply Chain Representative to get the current version.

<table>
<thead>
<tr>
<th>Revision Level/Version</th>
<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Initial Version</td>
</tr>
<tr>
<td>2.0</td>
<td>First Released Version</td>
</tr>
<tr>
<td>3.0</td>
<td>Updated The Version In The Footer To The Current Version</td>
</tr>
<tr>
<td>4.0</td>
<td>Updated The Version In The Footer To The Current Version</td>
</tr>
</tbody>
</table>