

Stryker Instruments ISO Customer-Specific Requirements

For use with ISO 9001:2000, ISO 13485:2003 or any ISO 9001:2000 sector specific document
January, 2006

1. **Introduction**

Delivering Exceptional Results – A guiding philosophy at Stryker. As a company Stryker sets high standards. We focus on the fundamentals and are relentless in attending to the details. It is these core values that underlie our reason for deciding to require all of our suppliers providing purchased parts, materials and services that affect the quality of our product to become ISO 9000 third-party registered. We are committed to working with our suppliers to ensure customer satisfaction. We, along with our suppliers, jointly contribute to delivering exceptional results.

2. **General**

This document, along with ISO 9001:2000 for our non-OEM suppliers and ISO 13485:2003 for our OEM suppliers, shall define the fundamental quality system requirements for organizations supplying parts, assemblies, finished product, materials, and/or services to Stryker Instruments. Our Stryker Instruments ISO customer-specific requirements are supplemental to ISO 9001:2000, ISO 13485:2003, or any of the other ISO 9001 sector-specific documents, e.g. AS 9100, ISO/TS 16949, etc. These supplemental requirements shall be included in the supplier's certification scope to satisfy Stryker Instruments supplier requirements for ISO 9000 third-party registration.

For all Stryker Instruments suppliers providing purchased parts, materials and services that affect our product, ISO 9000 registration is required by **July 31, 2007**.

All ISO 9001:2000 requirements and the requirements of this document, as well as any exclusions, shall be documented in the supplier's quality management system.

Stryker Instruments ISO Customer-Specific requirements shall be updated from time to time. Our suppliers shall be responsible for managing version control. Upon Stryker's release of an updated version, suppliers shall have 120 days to implement all changes unless specified otherwise by Stryker Instruments.

Suppliers shall maintain ISO certification through their registrar's surveillance audit program and shall notify Stryker Instruments of any changes in their registration status such as an updated certificate, a new certificate number, suspension, revocation, or a switch to another registrar.

Certificate copies shall be submitted to the respective Stryker Instrument's location as follows:

Kalamazoo:	Fax: 1-866-205-0953	Email: InstrumentsAMT@stryker.com
Puerto Rico:	Fax: 1-787-271-5708	Email: Instamt.SPR@stryker.com
Ireland:	Fax: 00 353 21 453 2906	Email: InstrumentsAMT_IRE@stryker.com

Certificate receipt and acceptance shall be communicated to the supplier.

Suppliers not currently ISO third-party registered shall develop an implementation plan and fax or email the plan to one of the faxes or emails listed above by **September 30, 2006**.

Copies of ISO 9001:2000 or ISO 13485:2003 can be obtained from www.ansi.org or www.iso.org

Key Stryker Instruments contacts for questions and comments are as follows:

Stryker Instruments Kalamazoo:

Beth Baker, Supplier Quality, Beth.baker@stryker.com, Ph: 269-323-7700 ext. 4050

Stryker Instruments Puerto Rico:

Milagros Rodriguez, Vendor Mgmt Administrator, Milagros.rodriguez@stryker.com, Ph: 939 307-2610

Stryker Instruments Ireland:

Laura Fiddes, Buyer, Laura.fiddes@stryker.com, Ph: 00 353 21 453 3213

Document Structure

This document is structured as a companion requirements document to ISO 9001 based standards. The paragraphs are numbered to correspond with the paragraphs of ISO 9001:2000. Exceptions to any part of these requirements must be approved in writing by the respective Stryker Instruments purchasing site's Supplier Quality Team.

Consistent with ISO 9001, "shalls" indicate mandatory requirements; "Shoulds" indicate recommendations; and Notes are explanatory.

3. References

- a) ISO 9001:2000, Quality Management Systems - Requirements
- b) ISO 9004:2000, Quality Management Systems – Guidelines for performance improvements
- c) ISO 13485:2003, Medical Devices-Quality Management Systems-Requirements for Regulatory purposes
- d) ISO/TR 14969:2004, Medical Devices-Quality Management Systems-Guidance on the application of ISO 13485:2003
- e) ISO/TS 16949:2002, Quality Management System – Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations
- f) Stryker Instruments Supplier Change Management Guidelines
- g) Stryker Corporation Bar Code Standard
- h) 21CFR820 FDA Quality System Regulation
- i) MDD 93/42/EEC
- j) ISO 11607, Packaging for Terminally Sterilized Medical Devices
- k) ES-0474 (Kal)/ES-0589 (Puerto Rico), General Certification and Packaging Requirements
- l) ES-0180, Tyvek Materials
- m) ES-0273, Blister Trays

4. Quality Management System

4.1. General Requirements

The entire supplier facility shall be registered to an ISO 9000 based standard for Stryker Instruments, ISO 9001:2000 for non-OEM suppliers and ISO 13485:2003 for OEM suppliers. Stryker Instruments ISO Customer-specific requirements shall also be included in the supplier's certification scope. (Also see Original Equipment Manufacturer (OEM) definition).

Process Approach

All work should be viewed as a process, and part of a system. Suppliers should define their organization's key business processes and develop a quality management system based upon those key business processes and the process interfaces with the objective of meeting customer requirements. Key processes should have associated performance metrics. When a process fails to perform up to expectations, action plans shall be developed to improve performance.

Outsourced Operations

Where a supplier chooses to outsource any process that affects product conformity with requirements the supplier shall ensure control over such processes. Control of outsourced processes shall be identified within the quality management system.

4.2. Documentation Requirements

The nature and extent of documentation should satisfy the contractual, statutory and regulatory requirements, and the needs and expectations of customers. Documentation shall be appropriate to the organization.

4.2.2. Quality Manual

All ISO 9001:2000 (non-OEM suppliers) or ISO 13485 (OEM suppliers) requirements and the requirements of this document shall be included in the supplier's quality management system. Exclusions shall be detailed and justified in the quality manual and approved by Stryker.

4.2.3. Control of Documents

The supplier's quality system shall require that sufficient documentation be available to ensure the effective operation of the quality system and the achievement of the required product quality.

The supplier shall have a process to ensure the timely review, distribution and implementation of all Stryker Instruments engineering standards, specifications and engineering changes. Timely review should be as soon as possible, and shall not exceed two working weeks.

The supplier shall maintain a record of the date on which each change is implemented in production. Implementation processes shall include a review of quality management system documentation, and updates to other applicable documents where appropriate.

The quality system should be periodically reviewed for adequacy.

4.2.4. Record Retention

Supplier quality records for parts and materials affecting Stryker Instruments ability to meet government mandated requirements and standards shall be maintained for a minimum of seven (7) years unless otherwise specified by Stryker. Longer retention periods may be specified by the supplier in their procedures. The supplier shall eventually dispose of records.

These requirements do not supercede any statutory or regulatory requirements. All specified retention periods shall be considered “minimums”.

Device History Records (DHR) – Stryker Instruments OEM Requirement

OEM suppliers shall store and maintain the device history record resulting from product realization for contracted products. The DHR shall include, or refer to the location of the following information: the dates of manufacture, the quantity manufactured, the quantity released for distribution, and any control numbers used. The product DHR shall be properly preserved. A copy of these records shall be provided to Stryker Instruments in either electronic format or hard copy. These records shall be accessible to Stryker within 48 hours.

Device Master Record (DMR) – Stryker Instruments OEM Requirement

OEM suppliers are responsible for generation of the released Device Master Record for each type of device. The DMR shall include, or refer to the location of the following information: released manufacturing procedures, all released drawings and/or product specification documents, including packaging and labeling, for each component, the released Bill of Materials (BOM), released quality inspection procedures, released instructions for use (IFU), and released labels. The DMR shall be prepared, dated and signed by a designated individual(s). Any changes in the DMR shall be authorized in writing by the signature of a designated individual(s). Any approval forms shall be part of the DMR. A copy of this record shall be provided to Stryker Instruments in either electronic format or hard copy and shall be accessible to Stryker within 48 hours.

5. Management Responsibility

5.1. Management Commitment

The quality management system is a set of interrelated processes. Top management shall ensure that processes operate effectively and efficiently.

Consideration should be given to:

- Identifying process owners and delegating responsibility and authority,
- Ensuring that the sequence and interaction of processes are designed to achieve planned results,
- Ensuring that process inputs, activities and outputs are clearly defined and controlled,
- Ensuring that process performance metrics are defined and monitored,

- Monitoring inputs and outputs to verify that individual processes are linked and operate effectively,
- Developing action plans if processes do not achieve process performance metrics,
- Identifying and managing risks, and
- Conducting data collection and analysis to facilitate process improvement.

5.3. Quality Policy

In order to demonstrate that the supplier is committed to implementing its quality policy, the supplier shall identify clear, overall quality goals for the business that are directly relevant to the organization and its customers.

All supplier associates shall understand the company's quality policy, not only how it affects them but also how they contribute to its achievement.

5.4. Planning

Business Plan

The supplier shall develop a formal, documented, comprehensive business plan. The business plan shall be a controlled document not subject to third party audit. The plan should include:

- Market Analysis
- Financial planning
- Projections for Sales and Growth, including capacity planning
- Resource Planning (personnel, plant, equipment, etc)
- Human resource development
- Research & Development plans, industry technology reviews, projections, future project planning
- Quality objectives and Process Improvement Goals
- Customer Satisfaction trends and plans
- Review of key internal process performance metrics
- Health, Safety and Environmental issues

Also see Capacity Planning in section 7.1 of this document.

Methods to track, update, revise and review the plan shall be documented to ensure that the plan is followed and communicated throughout the organization.

5.4.1. Quality Objectives

Top management shall define quality objectives and measurements that shall be included in the company's business plan and used to deploy the quality policy.

Quality Objectives shall be realistic and related to achievable and measurable outcomes, such as:

- Meeting customer, regulatory and other requirements,
- Reducing errors and process variability,

- Reducing internal audit closure times,
- Improving efficiencies,
- Reducing costs,
- Meeting planned schedules, and
- Reducing customer complaints and handling times.

Note: Quality objectives should be achievable within a defined period of time.

5.5. Responsibility, Authority and Communication

5.5.3. Internal Communication

For a quality management system to work effectively, open and active communication is essential. To facilitate top management should define and implement an effective and efficient process for communicating the quality policy, requirements, objectives and accomplishments. Providing such information can aid the organization's performance improvement and directly involve people in the achievement of the quality objectives.

5.6. Management Review

Top management should develop a management review activity beyond verification of the quality management system effectiveness and efficiency into a process that encompasses the whole organization. This meeting or series of meetings should review all facets of the business, including design (if applicable), manufacturing, logistics, customer satisfaction, supplier performance, business information systems, human resources, business development activities, long-term planning, etc.

The management review inputs (ISO 9001:2000, 5.6.2) and outputs (ISO 9001:2000, 5.6.3) shall be documented as part of the supplier's management review quality records.

6. Resource Management

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel for management, performance of work, verification activities, and internal quality audits.

6.2.2. Training

Education and training should emphasize the importance of meeting requirements and the needs and expectations of customers. Training plans shall address new operators, temporary operators, and current operators performing new functions. Training should also cover the potential consequences to the organization and its people when the organization fails to meet customer requirements.

6.3. Infrastructure

The supplier shall utilize a multidisciplinary approach when developing plant, facility and equipment plans. Plant layouts shall optimize material travel, handling and value-added use of floor space.

Manufacturing equipment should be designed, constructed, correctly installed and located to facilitate proper operation, maintenance, adjustment and cleaning.

Documented procedures shall be available for the maintenance, cleaning and monitoring of all equipment used in production, and for the control of the work environment. Appropriate maintenance intervals shall be established and posted on or near the equipment.

Contingency Plans

The supplier shall prepare contingency plans to satisfy Stryker Instruments in the event of an emergency such as natural disasters, utility interruptions, labor shortages or the departure of key personnel, and key equipment failures.

When the supplier knows in advance of an impending production interruption, the supplier shall notify their Stryker Instruments buyer at least 24 hours, if possible, before that interruption. The nature of the problem shall be communicated along with the actions to be taken to assure supply of product to Stryker.

6.4. Work Environment

Cleanliness of Premises

In general, the supplier shall maintain premises in a state of order, cleanliness and repair appropriate for the product(s) manufactured. Premises shall be compliant to all local, state, federal regulations.

Cleanroom Use

If the material supplied requires that a cleanroom be used, then the supplier shall demonstrate compliance to appropriate cleanroom standards applicable for the acceptable level of particles.

7. Product Realization

7.1. Planning of Product Realization

The supplier shall establish and implement a product quality planning process to ensure that Stryker Instruments requirements are determined and understood. Product quality planning should consider the voice of the customer, including prior complaints, defective material reports, recommendations, data and information obtained from internal and/or external customers and lessons learned from similar processes and/or products. The output of the product quality planning process should be a quality plan, a high level document that defines specific quality practices, resources and sequence of activities for a particular product or contract.

As directed by the Stryker Instruments project team, suppliers shall participate in and meet any product quality planning activities deemed necessary for the program, including but not limited to:

- Technical reviews
- Supplier onsite assessments or sub-tier supplier assessments
- Design reviews and/or program reviews
- Development of timing charts and open issues tracking
- Development of prototype samples
- Development of DFMEA (Design Failure Mode and Effects Analysis)
- Development of Process Control Documentation, e.g. Process Flow Charts, PFMEA (Process Failure Mode and Effects Analysis), and Control Plan(s)/travelers/etc. for Stryker review and approval
- Measurement System Analysis (MSA)/Gage Reviews
- Development of Critical Control Point Program
- Pre-Launch or Production Readiness On-site Assessments
- First Article or Part Approvals prior to shipment of production parts

Manufacturing Feasibility

The supplier shall investigate, confirm and document manufacturing feasibility of proposed products during the contract review process. Stryker design-responsibility does not preclude the supplier's obligation to assess the manufacturing feasibility. The supplier shall be satisfied that the proposed product design can be manufactured, assembled, tested, packaged and delivered in quantities requested at an acceptable cost on schedule. Concerns shall be discussed with Stryker Instruments Engineering and Purchasing. As appropriate, consideration should be given to:

- Is the product adequately defined (engineering specifications, functional requirements, quality requirements, etc)?
- Can engineering performance specifications be met as written?
- Can product be manufactured to tolerances specified?
- Is there adequate capacity to produce the product?
- What are the required secondary operations? Can they be performed in-house or will they be outsourced? How will the outsourced operations be controlled?
- Does the design allow the use of efficient material handling techniques?
- Can the product be manufactured without incurring any unusual costs for capital equipment, tooling, or alternative manufacturing methods?
- Is statistical process control required on the product? Is statistical process control used on similar products? Where used on similar products are the processes in control and stable? Are CpK's greater than 1.33?

Capacity Planning

Stryker is a growth company. To support Stryker's on-going growth, suppliers should implement capacity planning tools. Capacity planning shall be included the suppliers business plan.

Acceptance Criteria

Acceptance criteria shall be defined by the supplier and, where required, approved by Stryker Instruments. For attribute data sampling, the acceptance level shall be zero defects.

Confidentiality

The supplier shall ensure the confidentiality of Stryker-contracted products and projects under development and all related product information.

Change Management

The supplier shall not make any changes without prior written notification and approval from Stryker Instruments.



All proposed changes including but not limited to design, process, secondary operation, component, packaging, labeling, sub-tier supplier, equipment, manufacturing location, etc., including changes to a supplier's proprietary design, shall be submitted to Stryker Instruments on a Supplier Change Request Form (SCRF) for written approval prior to implementation. Reference: Stryker Instruments Supplier Change Management Guidelines.


Suppliers shall have a process to control and react to changes that impact product realization. The effects of any change, including those changes caused by any supplier, shall be assessed, and verification and validation activities shall be defined to ensure compliance with Stryker Instruments requirements. Changes shall be validated before implementation. When required by Stryker Instruments, additional verification and product identification requirements such as those required for new product introduction shall be met.

The supplier shall retain approved Supplier Change Request Forms (SCRF) and engineering change orders (ECOs) for a minimum of 7 years. Initial shipments of new or revised material shall be appropriately labeled with the change level.

7.2. Customer-related Processes

Stryker Instruments-designated critical characteristics

Special emphasis and control shall be placed on product characteristics identified by Stryker Instruments with the  symbol. This symbol identifies characteristics that have been designated by Stryker as critical to the parts function and having particular quality, reliability, and durability significance. While all dimensions and specifications included in engineering documents are important, it is recognized that certain dimensions and/or specifications have more significance relative to assuring against product failure or functional dissatisfaction.  characteristics may be susceptible to manufacturing variation and require additional controls to assure performance to specifications and customer satisfaction.

Stryker Instruments designated  characteristics shall be identified on the supplier's process control documentation, e.g. drawings, control plans/product travelers/work orders, inspection sheets, FMEAs, etc. The supplier shall provide documentation showing compliance with these Stryker Instruments specifications as requested.

Critical Control Points

The supplier should establish an effective Critical Control Point (CCP) program within their manufacturing processes to prevent, eliminate or reduce potential manufacturing process failure modes to an acceptable level. The program should be implemented for new product processes and/or existing processes when opportunities for improvement can be attained. The Critical Control Point (CCP) program should include the following steps:

- Conducting a Manufacturing Process Failure Mode and Effects Analysis
- Identification of actions through brainstorming and analysis that could eliminate or reduce the chance of the potential failure from occurring
- Identification of the Critical Control Points, i.e. points, steps, or processes at which control can be applied to eliminate or reduce the failure mode to an acceptable level
- Establishing Critical Control Limits, i.e. the maximum/minimum value to which a product, process or quality parameter shall be controlled to prevent, eliminate or reduce to an acceptable level the potential occurrence of a process failure mode
- Monitoring Critical Control Points
- Establishing reaction plans when the process is performing outside established critical control limits
- Establishing verification procedures, i.e. verifying the critical limits of the control points are accurate; verifying the resulting actions or critical control points impact on the risk associated with the failure mode
- Establishing record keeping and procedural documentation which can be provided to Stryker Instruments as requested

The supplier should select critical control points based on the supplier's knowledge of the product and the production realization process, as well as Stryker's needs and expectations. A preliminary list of critical control points should be developed from, but not limited to the following:

- Product assumptions based on the analysis of customer needs and expectations
- Identification of special process characteristics from the anticipated manufacturing process
- Review of historical data, e.g. complaints, defective material reports, etc., for similar parts
- Similar part Failure Mode and Effects Analyses (FMEAs)
- Identification of reliability goals/requirements

Restricted Substances - Electrical & Electronic Equipment (EEE) and Waste Electrical & Electronic Equipment (WEEE)

EEE/WEEE Compliance Requirements

Suppliers shall mark EEE products as directed by Stryker with an approved, properly sized symbol. This symbol shall be on the product itself (physically on the product, not the packaging or on a removable item from the product) unless specifically authorized by Stryker. In those cases where the product itself is not marked, the next layer of packaging from the item shall be marked with the approved symbol as designated by Stryker.

For suppliers providing finished goods:

- The outer most container shall be marked with the approved symbol.
- The package shall contain an explanation of WEEE in the IFUs. Placing this information on a symbol definition chart shall be acceptable.

- A “Recycling passport” in accordance with current standards shall be provided at the point of initial product delivery.

Suppliers shall provide updated “Recycling Passports” if E.U. or U.S. requirements change.

Suppliers of EEE shall provide a description of all processing agents used in the manufacture, processing, shipping, etc. of the device, which are either on the Restriction of Hazardous Substances (RoHS) List or on the WEEE Selective Treatment List. Descriptions shall be resubmitted if requirements change.

For design-responsible suppliers providing finished goods, the supplier shall provide a design document stating that the device was designed to be as repairable and recyclable as possible without impairing the functionality of the finished device.

All EEE products, including finished goods, subcomponents, subassemblies, individual components or outsourced components, shall be accompanied by a list of all components containing material designed to receive selective treatment by the WEEE directive. This list shall be resubmitted if requirements change.

Restriction of Hazardous Substances (RoHS) Compliance Requirements

Suppliers who contribute to an EEE product shall ensure that their contribution is RoHS compliant. Every supplier who subcontracts out any work or accepts any material from other suppliers, peoples or companies for EEE products, shall ensure that all those contributions are RoHS compliant.

Suppliers, contractors and all others shall provide declaration of RoHS compliance for their products, components, services or operations, for all EEE products. One hundred percent, or 100%, of all work, parts, subparts, finishes, coatings provided by the supplier or outsourced by the supplier shall be declared by the supplier to be RoHS compliant.

Understanding that RoHS requirements may change over time, i.e. concentration values may become more restrictive or other items may be added to the prohibited hazardous substance list (RoHS), the supplier shall have a system in place which can provide certificates of RoHS compliance to any updated new standard within two business weeks.

The system used to create and track RoHS compliance certificates shall be auditable and verifiable by Stryker Instruments.

A list of all materials and their concentrations for supplier parts, operations, etc., shall be made available within two business weeks if requested.

7.3. Design and Development Planning

Multidisciplinary Approach

The supplier shall use a multidisciplinary approach to prepare for product realization, including the development, finalization and monitoring of process controls, e.g. critical characteristics,

critical control points, PFMEAs, including actions to reduce potential risk, and the development and review of process control documentation (control plans/work orders/product travelers, etc.).

Critical Characteristics and Critical Control Points – see section 7.2

Inspection Techniques

The supplier's inspection techniques shall be agreed to by Stryker Instruments. It is the responsibility of both Stryker Instruments and the supplier to come to an agreed upon inspection technique. As requested by Stryker, discrepancies in measurement systems shall be resolved through gage R&R's, correlation studies, etc.

Prototype Program Requirements

As required, prototype requirements shall be documented by the Stryker Instruments Engineer and Buyer.

Delivery date(s) for prototype components shall be established by Stryker Instruments and noted on the purchase order. The delivery date(s) reflect the date(s) parts are to be received at Stryker Instruments delivery docks.

All prototype components and shipments shall be identified as prescribed in relevant documents. The supplier shall submit inspection reports with sample delivery as required. If review of the inspection report indicates that the parts do not agree with the prints or examination of the parts discloses an unsatisfactory condition not covered by the report, it shall be the supplier's responsibility to resolve all discrepancies with the Stryker Instruments Engineer.

If resolution of the discrepancy results in a tooling, material or processing change, the supplier will correct the situation (at the supplier's expense) and resubmit an inspection report on the revised parts.

First Article

The supplier shall comply with Stryker Instruments Production Part Approval process (e.g. First Article (FAR), PPAP, etc.) unless otherwise specified by Stryker Instruments.

Suppliers shall submit first article samples to ensure acceptable product realization results unless specifically exempted by Stryker Instruments. Initial production sample approval is required under the following conditions:

- Initial production of a part
- A new supplier for an existing part
- A significant change to an existing part or to a supplier's process (e.g. new or revised tooling; process method change; moved production location; new plant or supplier; etc). In these instances, the supplier must notify Stryker Instruments of the proposed change and obtain the necessary written approval prior to implementation. (Reference: Stryker Supplier Change Management Guidelines and Supplier Change Request Form).
- A minor engineering revision to an existing part (submission is at the discretion of Stryker Engineering)

First article samples shall be taken from a significant production run, i.e. a production run consistent with the supplier's ongoing production processes. The supplier shall certify that the samples conform to all Stryker drawings and related specifications. Actual inspection and test results documenting conformance to Stryker requirements shall be included.

If tooling involves duplicate fixtures or multiple cavity molds, dies, etc., samples from each shall be submitted. Any layout lines or reference marks used to perform the layout inspection must be left on the submitted samples.

Samples, at the discretion of Stryker Instruments, may either be audited by a Stryker Instruments Quality Assurance Representative at the supplier's plant or shipped to a Stryker Instruments receiving location for validation. Samples that are shipped to a designated Stryker Instruments receiving location for validation shall be shipped in a separate container addressed to the "Receiving Inspection Department" and clearly marked as "First Article Samples." The required First Article forms (06fm004) shall be included with the samples. Validation of initial production samples by Stryker Instruments will not take place without the properly completed forms accompanying the sample.

7.4. Purchasing

Pricing

Supplier pricing shall be competitive. To remain competitive suppliers shall have a continual cost reduction improvement process to manage costs. In addition, suppliers are expected to work with Stryker Instruments buyers toward cost reduction goals. Supplier cost reduction proposals shall be submitted to Stryker Instruments using the Supplier Change Request Form (SCRF). Implementation shall not occur without prior written approval from Stryker Instruments.

Regulatory Conformity

All purchased products or materials used in product shall conform to applicable regulatory requirements.

Material Expectations

Suppliers shall provide samples, testing, and MSDS (Material Safety Data Sheet) information in the timeframe requested. MSDS information shall be required for critical consumables, bulk and raw materials.

Customer-approved sources

Where specified by contract (e.g. Stryker engineering drawing, specification, etc), the supplier shall purchase products, materials or services from customer-approved sources. The use of customer-designated sources, including tooling/gage suppliers, chemical/adhesives, etc. does not relieve the supplier of the responsibility for ensuring the quality of the purchased product.

Sub-tier supplier quality management system development

At minimum, Stryker's suppliers should assess their sub-tier supplier's size, dollar value of the business, type of product supplied and the associated risk, quality management system,

manufacturing and delivery systems capability. Sub-tier supplier performance should be monitored through the following performance indicators:

- Delivered part quality
- Delivery schedule performance
- Customer disruptions

Stryker Instruments suppliers shall take complete responsibility for their sub-tier supplier's quality and delivery performance. When deemed necessary, suppliers shall facilitate Stryker's access to their sub-tier supplier's facility and quality system documents.

7.4.3. Verification of Purchase Product

Incoming Product Quality

Suppliers shall have a process to assure the quality of purchased product utilizing one or more of the following methods:

- Receipt of, and evaluation of, supplier statistical data
- Receiving inspection and/or testing, such as sampling based on performance
- Second-, or third- party supplier on-site audits, when coupled with records of acceptable delivered product quality
- Part evaluation by a designated laboratory
- Another method agreed upon by Stryker

Supplier Monitoring

Stryker Instruments supplier rating system is based primarily on historical performance. The rating system is used to classify suppliers into one of four categories: A (best), B (average), C (worst), or N (new). These classifications can be used to establish payment terms.

Stryker Instruments supplier performance criteria shall include but not be limited to:

- Quality (FPY, PPM, or DMR history)
- On-time Delivery
- Cost Reductions
- R&D Support
- Technology Capability
- Process Control
- Responsiveness

Zero defects is the expectation. Suppliers are expected to produce objective evidence of continuous improvement efforts towards this goal. Failure to meet this goal may result in a request for corrective action.

Stryker Instruments shall perform supplier on-site audits as deemed necessary. Conditions which warrant onsite audits include the following:

- Quality issues
- Engineering Changes
- Process Changes

- Plant Location or Equipment Changes (e.g. tool transfer, etc)
- Product Launches
- Etc.

7.5. Production and Service Provision

Process Control Documentation (Control Plans/Travelers/Work Orders, etc.)

Supplier process control documentation shall include:

- Part name and part number
- Current engineering level and date
- Tools, gages and other equipment
- Material identification and disposition instructions
- Controls used for manufacturing process control
- Customer and supplier designated critical characteristics and critical control points, as appropriate
- Methods for monitoring the control exercised over critical characteristics or critical control points as defined by Stryker Instruments and the supplier
- SPC requirements, as specified by Stryker
- Inspection and test instructions
- Specified reaction plan(s) when the process becomes unstable or not statistically capable
- Other Stryker-required information, if any
- Tool change intervals and setup instructions

Process Control Documentation shall be reviewed and updated when any change occurs affecting the product, manufacturing process, measurements, logistics, sub-supplier sources, or similar products, etc.

Critical Characteristics

The supplier's process control documentation, e.g. control plan/traveler/work order etc., shall be used to define the method and means of control of critical characteristics or critical control points during production. A critical characteristic does not necessarily require the use of ongoing SPC, or other equivalent monitoring techniques. However, unless otherwise specified by Stryker, short-term capability must exceed 1.67 CpK after the supplier has demonstrated a stable process. Long-term capability must achieve 1.33 CpK. When the process has demonstrated capability with these targets, the frequency and quantity of samples should be reflected on the process control documentation.

Work Instructions

The supplier shall prepare documented work instructions for all employees having responsibility for processes that impact product quality or traceability. These instructions shall be accessible for use at the work station.

Production Scheduling

The supplier shall schedule production in order to meet Stryker Instruments requirements. If for any reason the supplier is unable to meet the schedules communicated the supplier shall notify the

Stryker Instruments buyer immediately and receive authorization for the under-shipment. If necessary, the suppliers shall make up all under-shipments via supplier paid premium freight.

Verification of Job set-ups

Job set-ups shall be verified whenever performed, e.g. an initial run of the job, material change over, or job change. Set-ups shall be done only on qualified machines. Work instructions shall be available for set-up personnel. The supplier shall use statistical methods of verification where contracted by Stryker.

Management of Production Tooling/Gauging

Where appropriate, the supplier shall provide resources for tool and gauge design, fabrication and verification activities.

Preventive and Predictive Maintenance

The supplier shall identify key process equipment and provide resources for equipment maintenance and develop an effective planned preventive maintenance system. The system should include:

- Planned maintenance activities
- Packaging and preservation of equipment, tooling and gauging
- Availability of replacement parts for key manufacturing equipment
- Documenting, evaluating and improving maintenance objectives

Sterilization Processes

The degree of documentation required shall depend on how the product is provided to Stryker.

Products supplied to Stryker not for re-labeling as a Stryker part, but for inclusion in a Stryker product or accompanying a Stryker product, can be accepted with routine supplier auditing.

Products supplied to Stryker complete for use, but release requirements of the sterilization process not completed, shall have configuration documentation of how the product was shipped to the sterilization facility, including the quantities, part numbers, and any other testing required for verification of that configuration for release and post-sterile release procedures.

Products supplied to Stryker complete and released as sterile, bearing the Stryker label and manufacturing address, shall have sterilization certification accompanying the product. If this is not possible, then documentation shall accompany the product from the supplier that strictly states that the involved product is sterile and has completed all release criteria acceptable to the supplier.

In addition, the monitoring testing shall be supplied. This shall include: copies of audits of the suppliers contract sterilizer conducted in accordance with the supplier's procedures. A copy is required of the products initial validation. Also, copies of dose auditing results for irradiation sterilization, or re-qualification data for gas sterilization of the product are needed. If copies of the actual data are deemed to be proprietary, then minimally Stryker will accept a communication in writing that the appropriate testing has been completed and passed, and clearly states the date samples were sent from testing and the results. This type of information shall be physically audited at the supplier by a member of Stryker's microbiology staff annually.

Supplier Parts for use in an Environmentally Controlled Area (ECA)

When component parts are supplied to Stryker for use in an environmentally controlled production area, the supplier shall comply with Stryker's "General Certification and Packaging Requirements"; ES-0474 (Kalamazoo) and ES-0589 (Puerto Rico). These specifications cover certification, packaging and standard requirements for parts utilized in an ECA. Copies can be obtained from your Stryker buyer.

Material Cleaning Requirements

If the material supplied requires that a cleaning step be performed, such cleaning shall have demonstrated testing to prove the required level of cleaning is attained as well as documented procedures to ensure continued compliance with cleaning requirements.

Clean Parts Requirements

If the material supplied requires that it be manufactured and supplied to Stryker as a clean part, the supplier shall have documented procedures to ensure an appropriate level of cleanliness acceptable to Stryker.

Certificate of Compliance

As directed by Stryker, suppliers shall submit Certificates of Compliance.

Packing Slip - General Requirements

Each package sent to Stryker Instruments shall include the following packing slip information:

- Supplier Name
- Stryker Instruments Purchase Order Number
- Stryker Part Number
- Quantity shipped
- Items backordered
- For blanket parts, the release of the purchase order
- If reworked product, the DMR purchase order numbers
- If shipping per iSupply, include the invoice number/packing slip referenced on the advanced shipping notice (ASN)

OEM Packaging – Guidelines for Terminally Sterile Medical Device Packaging

When products are packaged by an OEM supplier, the supplier shall comply with ISO 11607, "Packaging for Terminally Sterilized Medical Devices". For new product introductions or any initial packaging operation, the OEM supplier shall outline the following items for review and approval by the Stryker Instruments R&D Packaging Engineer:

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Process Qualification (PQ)
- Process Validation
- Shelf life studies
- Package integrity testing

Sterile Product Packaging Materials

Suppliers shall use the guidelines outlined below for sterile product packaging:

- Maintain product traceability records of each lot back to the raw material used, for a period of three years from date of manufacture. All correspondence regarding product shipped by the supplier shall reference the lot number(s).
- Supply a Certificate of Compliance with each shipment which must be signed by authorized personnel and retained in the supplier's device master records.
- "Bulk pack" the packaging materials in two individually closed plastic bags (one inside the other) that are free from dust, particulate and fiber. The double bagged contents shall be packed in a suitable corrugated container unless specified otherwise.
- Not change the manufacturing process, manufacturing location, raw material or raw material supplier for packaging materials per original validations unless approved in writing by Stryker Quality Assurance. (see Supplier Change Management Guidelines under section 7.1)
- Label each shipping container as outlined Section 7.5.3.

Also reference ES-0180 (Tyvek Materials) and ES-0273 (Blister Trays) for details pertaining to these specific packaging materials.

Feedback from Service

The supplier shall establish and maintain a process for communication of service concerns to manufacturing, engineering and design activities.

7.5.3. Identification and Traceability

When specified, or as customary, traceability for components and subcomponents shall be maintained.

Labels – General Requirements

The marking and labeling of materials shall be legible, durable and in accordance with Stryker specifications. Identification shall remain intact from the time of initial receipt to delivery to the final destination. Marking shall be adequate to identify a particular product in the event of a recall or special inspection becomes necessary.

Supplier Bar Code Label Program

As directed by Stryker those suppliers participating in the Bar Code Label Program shall label product with bar codes meeting the agreed to Stryker Corporate Bar Code Standard criteria. At a minimum, bar code labels shall include:

- Stryker's Part Number
- Human readable digits directly beneath the bar code
- Quantity - the standard packaged quantity shall be reviewed and approved by Stryker
- Date - the date printed on label is at the supplier's discretion, but the standard date format, e.g. the date of shipping, the date of manufacture, etc. shall be consistently applied in the supplier's process.

Prior to the initial release of bar code labeled product, suppliers shall obtain approval from Stryker Instruments for:

- Label stock and label format
- Label validation test protocol
- Label validation results

Once the supplier's labeling process is validated and approved, proposed process changes or deviations shall be submitted to Stryker for approval using a Supplier Change Request Form (SCRF). Receipt of improperly bar coded product, product with missing labels, improperly packaged parts, etc. shall result in a supplier nonconformance and shall require corrective action.

7.5.4. Customer Property

Stryker Instruments-owned tools, manufacturing equipment, inspection tooling, etc. shall be permanently marked so that the ownership of each item is visible and can be easily determined.

7.5.5. Preservation of Product

To detect deterioration, the supplier shall assess the condition of product in stock at appropriate planned intervals.

Inventory Management

The supplier shall use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first-in-first-out" (FIFO). Obsolete product shall be controlled in a similar manner to nonconforming product.

7.6. Control of Monitoring and Measuring Devices

7.6.1. Measurement Systems Analysis

As required, the supplier shall conduct statistical studies to analyze the variation present in the results of each type of measuring and test equipment system. If required, this requirement shall apply to the measurement systems referenced on Stryker product process control documentation.

7.6.2. Calibration/Verification Records

The supplier shall maintain records of calibration/verification activities for all gauges, measuring and test equipment, including employee- and customer-owned equipment, needed to provide evidence of product conformity to determined requirements. The process shall include:

- Equipment identification, including the measurement standard against which the equipment is calibrated,
- Revisions following engineering changes,
- Any out of specification readings as received for calibration/verification,
- An assessment of the impact of out-of-specification condition,
- Statements of conformity to specification after calibration/verification, and
- Notification to Stryker if suspect product or material has been shipped.

8. Measurement, Analysis and Improvement

Identification of statistical tools

Basic statistical concepts such as variation, control (stability), and process capability shall be understood and utilized.

Statistical methods should be used to understand product and process variation in order to proactively prevent non-conformances. Suppliers should establish appropriate Statistical Process Control (SPC) or equivalent methods for critical characteristic(s) and critical control points.

For plastics suppliers critical characteristics are identified on drawings. Suppliers should complete short-term capability studies for critical characteristics:

- before a part goes into production
- when an engineering change is made that affects a critical characteristic, or
- when a major tool maintenance/repair occurs that affects the characteristics.

8.2.1. Customer Satisfaction

Customer satisfaction shall be monitored through continual evaluation of performance of the product realization processes. Performance indicators shall be based on objective data and include, but not be limited to:

- Delivered part quality
- Delivery schedule performance
- Stryker disruptions, and
- Stryker notifications related to quality or delivery issues.

Trends in quality system performance and customer satisfaction should be compared to those of competitors, or appropriate benchmarks, and reviewed by top management on a regular basis. When a supplier fails to meet performance objectives action plans shall be developed to achieve desired results.

8.2.2. Internal Audit

Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan. The schedule should be a living document, updated as appropriate to address internal/external nonconformities and customer complaints.

Internal audit corrective actions shall be timely and appropriate to the magnitude of the problem.

8.2.3. Monitoring and Measurement of Processes

As directed by Stryker the supplier shall maintain manufacturing process capability or the performance levels specified. The supplier shall ensure that the process control documentation is implemented, including adherence to the specified

- measurement techniques,
- sampling plans

- acceptance criteria, and
- reaction plans when acceptance criteria are not met.

Significant process changes, such as a tool change or machine repair, shall be recorded.

The supplier shall initiate a reaction plan when product characteristics are either not statistically capable or unstable. These reaction plans shall include containment of product and 100% inspection as appropriate. A corrective action plan shall then be completed by the supplier, indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable.

Layout Inspection and functional testing

A layout inspection and a functional verification of applicable Stryker engineering material and performance standards shall be performed as specified by Stryker. Records shall be available for Stryker Instruments review.

8.3. Control of Non-conforming Product

Control of reworked product

The supplier shall have instructions for rework, including re-inspection. Instructions shall be accessible to and utilized by personnel performing the rework and any rework re-inspection.

Customer information

The supplier shall promptly inform Stryker Instruments in the event that nonconforming product has been shipped.

Customer Waiver/Deviation

The supplier shall obtain a Stryker waiver/deviation prior to further processing whenever the product or manufacturing process differs from that which is approved or validated by Stryker.

The supplier shall maintain a record of the expiration date or quantity authorized. The supplier shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on a waiver/deviation shall be clearly identified on each shipping package/container.

8.4. Analysis of Data

Analysis and use of data

The supplier shall track trends in quality and operational performance as well as progress toward objectives. Actions should support the following:

- Development of priorities for prompt solutions to customer-related problems;
- Determination of key customer-related trends; and
- Decision-making and longer term planning.

8.5. Improvement

Problem solving

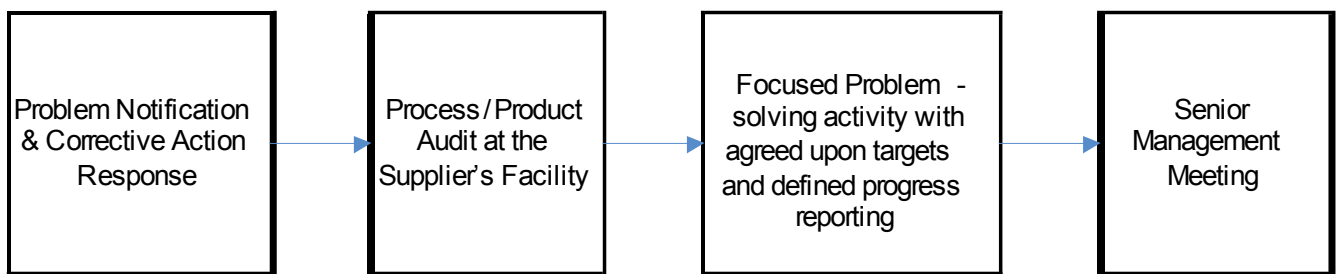
The supplier shall have a defined process for problem solving leading to root cause identification and elimination.

Corrective Action Plan

Written corrective action plans shall be submitted to Stryker Instruments as requested.

The supplier shall apply to other similar processes and products the corrective action, and controls implemented, to eliminate the cause of nonconformities.

In the event that on-going quality problems are experienced with a supplier, Stryker Instruments corrective action process may escalate through several phases depending on the supplier's responsiveness and corrective action effectiveness. The typical escalation path is as follows:



It should also be noted that the escalation path may also go straight from problem notification to a Senior Management meeting depending on the problem severity and urgency. Throughout the escalation process, senior management shall monitor the progress. If the problem results in the final step in the escalation phase, management shall be prepared at this meeting to commit resources to resolve the issues. Failure to follow through with appropriate commitments would be grounds for Stryker Instruments to initiate re-sourcing to look for an alternative source.

Rejected product test/analysis

The supplier shall analyze parts rejected by Stryker Instruments and initiate corrective action to prevent recurrence. Records of these analyses shall be kept and made available upon request.

Additional requirements:

Certified suppliers

Suppliers currently certified to ISO 9001:2000 or ISO 13485:2003 have until July 31, 2007, to include Stryker Instruments ISO Customer-Specific Requirements in their certification scope. Planning consideration shall be given to the frequency of your company's surveillance audit process, i.e. annual surveillance audits versus semi-annual surveillance audit programs.

Consultants

Organizations that have provided quality management system consulting services in the past two years to the supplier are not acceptable as the certification body/registrars for that supplier, nor may they supply auditors. This restriction includes subsidiaries or affiliates of the same parent organization.

Multi-site/Corporate Registration Certificates

Multi-site/Corporate registrations are when multiple sites are assessed and a single certificate is provided. Multi-site/Corporate registration schemes are permissible but each site must be audited; "sampling" of sites is not permitted.

Registrar Oversight

Stryker Instruments shall be allowed to accompany Accreditation Bodies on witness audits of registrars as "Technical Expert Observers", if client (supplier) permission is obtained, and if all potential issues regarding "confidentiality" and "conflict of interest" have been resolved.

Supplier Certification Audit Reports/Certificates

The certification body/registrar's report shall be made available to Stryker Instruments upon request. Requests for the report can be made through the supplier, or the supplier may authorize the certification body/registrar to provide the report. The report should not contain any proprietary information outside of the results of the ISO 9001:2000 or ISO 13485:2003 system audit. A supplier can request that any proprietary information be removed.

Definitions

Accreditation Body - An organization with authority, typically from the national government, to accredit bodies such as certification bodies/registrars for quality system certification, environment quality system certification, test laboratory certification, etc.

Calibration - A set of operations which compare values taken from a piece of inspection, measuring and test equipment or a gage to a known standard under specified conditions.

Capability - The total range of inherent variation in a stable process.

Capacity - The highest number of units that can be consistently produced in a given period of time generally expressed in time increments of both straight time and maximum sustainable overtime levels.

Certification Body/Registrar/Notified Body - A qualified organization accredited by a national accreditation body to perform audits to ISO 9001 and to register the audited facility for a given scope.

Control Plans – Written descriptions of the systems for controlling parts and processes. They address the important characteristics and engineering requirements of the product. Each part has a Control Plan, but “family” Control Plans can cover a number of parts produced using common processes.

Consulting - Consulting is the provision of training, documentation development, or assistance with the implementation of a quality system. If these activities are open to the public, advertised, and not customer-specific, they are considered training rather than consulting.

Corrective Action - Action taken to eliminate the causes of an existing nonconformity or other undesirable situation in order to prevent recurrence.

Corrective Action Plan - A document specifying actions to be implemented to correct a process or part quality issue, and includes assignment of responsibilities and target dates.

Critical Characteristic – Product requirements (dimensions, performance, etc) or process parameters in which deviations from specifications are likely to adversely affect product performance, safety and efficacy.

Critical Control Point - A point, step, or procedure at which control can be applied and it is essential to prevent, eliminate or reduce a hazard to an acceptable level.

Critical Control Limits - A maximum/minimum value to which a product, process, or quality parameter must be controlled to prevent, eliminate or reduce to an acceptable level the potential occurrence of device hazard.

Design Failure Mode and Effects Analysis (DFMEA) - A FMEA used as a tool to help identify and prevent product failures that are related to the product design.

Device History Record (DHR) - Compilation of records (or references to the locations of records) documenting dates and quantities of manufacture, quantity released for distribution, acceptance records demonstrating that the device was manufactured in accordance with the Device Master Record, the primary identification label and labeling used for each finished goods unit and any identification(s) and control number(s) used.

Device Master Record (DMR) - All documentation, or reference there of, required to manufacture devices that comply with company and Quality System Regulations (QS Regulations).

Dose - Quantity of radiation energy absorbed per unit of mass.

ECA - Environmentally Controlled Area - A room in which the concentration of airborne particles is controlled to specific limits.

EEE - Electrical and Electronic Equipment

Failure Mode and Effects Analysis (FMEA) - A systemized group of activities intended to:

- Recognize and evaluate the potential failure modes of a product/process and their effects.
- Identify actions through brainstorming and analysis that could eliminate or reduce the chance of a potential failure from occurring.
- Document the process through application of industry accepted standards.

FAR - First Article Report

FPY - First Pass Yield (FPY)

Functional Verification - testing to ensure the part conforms to all customer and supplier engineering performance and material requirements.

IFU - Instructions for use

Initial Process Study - Initial process studies are short-term studies conducted to obtain early information on the performance of new or revised processes relative to internal or customer requirements.

Installation Qualification (IQ) - Establishing objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer's approved specification.

Label - Graphics, stencils, cord tags, specification labels, face plates, container labels and other various components which may be directly attached to the product or its packaging and whose function may be other than identification of the product.

Layout Inspection - Layout inspection is the complete measurement of all part dimensions.

Level 1 Supplier – a Stryker Instruments supplier that provides purchased parts, materials or services included or intended to be included in the Stryker Bill of Material.

Level 2 Supplier – a Stryker Instruments supplier that provides purchased parts, materials or services that affect the quality of the products/processes in the Stryker Bill of Material/Routing.

Measurement Systems Analysis (MSA) - a process to determine that measurement systems are capable of measuring to the desired accuracy and repeatability.

Multidisciplinary Approach - An activity where a group of individuals from different functions is consulted to complete a task or activity. A multidisciplinary approach seeks to have all relevant knowledge and skills available to the decision making process. The term multi-disciplinary is synonymous to “cross-functional.”

OEM - Original Equipment Manufacturer is considered to be the developer/producer of a finished device (a device suitable for use or capable of functioning, whether or not it is packaged, labeled or sterilized.) An OEM may or may not: have the 510(k); “Own” the design and/or specifications; distribute the finished device; or provide the same device to a competitor.

Operational Qualification (OQ) - Establishing by objective evidence that the process will produce acceptable results and establishing process control limits and action levels for process parameters.

Packaging Integrity Testing - Test shipments (where feasible) and test methods to assess the protection of the product from normal transportation damage and adverse environment factors.

Parts Per Million (PPM) - a method of stating the performance of a process in terms of actual nonconforming material. PPM data can be used to prioritize corrective actions.

Performance qualification (PQ) - Establishing by objective evidence that the process, under anticipated conditions, consistently produces product which meets all predetermined requirements.

Preventive Action - Action taken to eliminate the cause of a potential nonconformity or other undesirable situation in order to prevent occurrence.

Problem Solving - A disciplined approach to analyze problems to determine and eliminate root causes.

Process Characteristics (Critical Control Points) - 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. Process characteristics can cause variation and must be controlled to minimize product variation. There can be one or more process characteristics for each product characteristic.

Process Flow Chart - A depiction of the flow of materials through the process, including any rework or repair operation.

Process FMEA (PFMEA) - A FMEA used to identify and prevent failures that are related to the manufacturing or assembly process for a specific component/assembly or for a family of components/assemblies. Additionally, PFMEA is used to identify process controls needed to ensure that special (and some critical) processes stay in control over time.

Process Parameters – see process characteristics

Process Validation - Process validation entails demonstrating that when a process is operated within specified limits, it will consistently produce product complying with predetermined (design and development) requirements. It is the mechanism or system used by the manufacturer to plan, obtain data, record data, and interpret data. This activities may be considered to fall into three phases: 1) an initial qualification of the equipment used and provision of necessary services – also known as installation qualification (IQ); 2) a demonstration that the process will produce acceptable results and establishment of limits (worst case) of the process parameters – also known as operational qualification (OQ); and 3) and the establishment of long term process stability – also known as performance qualification (PQ).

Process Validation Plan - A document stating how validation will be conducted, including test parameters, product characteristics, manufacturing equipment, and decision points on what constitutes acceptable test results.

Product Characteristic - Features or properties of a part, component or assembly that are described on drawings or other primary engineering information.

Product Realization - An ISO term used to describe the processes starting with planning and proceeding through:

- the determination of customer requirements and customer communication
- design and development
- purchasing
- production and servicing
- control of monitoring and measuring devices, and
- delivery

Product Validation Testing - Production validation testing refers to engineering tests that validate that products made from production tools and processes meet customer requirements.

Quality Plan - A document setting out the specific quality practices, resources and sequence of activities relevant to a particular product. While control plans are quality plans, the quality plan is a broader concept.

Quality Planning - Quality planning is a structured process for defining the methods (i.e. measurements, tests, inspections) that will be used in production of a specific part or family of parts. Quality planning embodies the concepts of defect prevention and continuous improvement as contrasted with defect detection.

Reaction Plan - plans that specify the corrective actions that are initiated to avoid producing nonconforming products or operating out of control. The actions should be the responsibility of the people closest to the process or operation and be clearly defined in the plan. Provisions should also be made for documentation.

Repair - Action taken on nonconforming product so that the product will fulfill the intended usage although the product may not conform to the original requirements.

Rework - Action taken on nonconforming product so that it will meet the specified requirements.

Restricted Substances - See WEEE and RoHS

RoHS - Restriction of Hazardous Substances in Electrical and Electronic Equipment (EEE). Directive 2002/95/EC of the European Parliament: 27-Jan-2003. Per the directive, six items measured as a percent by weight of homogeneous material can not be used in EEE: Mercury, .1%; Cadmium, .01%; Hexavalent Chromium, .1%; PBB (Poly-brominated biphenyls: flame retardant), .1%; PBDE (Poly-brominated diphenyl ethers: flame retardant), .1; and lead, .1%. See Restricted Substances, section 7.2.

Root Cause - The source of the nonconformance. Valid root causes are specific and correctable. The action required to prevent recurrence of the nonconformance should be implied by the root cause.

SCRF - Supplier Change Request Form – (Stryker 06fm055) - a supplier must notify and receive written approval from Stryker Instruments for any design, material, and process change prior to implementation. The SCRF shall be submitted to the Stryker Instruments buyer for processing and approval. Note: The SCRF should also be used to submit supplier cost savings suggestions and ideas.

Shall - The word “shall” indicates a mandatory requirement

Should - The word “should” indicates a recommendation.

Special Process (SP) - Processes in which the product quality cannot be fully verified in the finished product (e.g. adhesives, welding, sterile package seals etc.).

Statistical Process Control (SPC) - The use of statistical techniques such as control charts to analyze a process or its outputs so as to take appropriate actions to achieve and maintain a state of statistical control and to improve the process capability.

Sub-tier Supplier - Providers of production/assembly materials, production or service parts, assemblies, heat-treating, welding, anodizing, or other finishing services directly to a Stryker Instruments supplier. Note: In ISO 9001:2000 the term “supplier” is equivalent to the term “subcontractor.”

Supplier - Providers of production/assembly materials, production or service parts, assemblies, heat-treating, welding, anodizing, or other finishing services directly to Stryker Instruments. Note: In ISO 9001:2000 the term “organization” is equivalent to the term “supplier”.

Third-Party Registered Quality System – Certification/registration by an independent registrar, certification body or notified body, qualified by a national accreditation body to perform ISO 9001 based audits and register the audited facility for a given scope.

Tool - Tools (or tooling) is used in process machinery to transform raw material in to a finished part or assembly.

Validation - Confirmation by examination and provision of objective evidence that particular requirements for a specific intent use are fulfilled.

Verification - Follow-up action taken to measure the effectiveness of actions taken and requirements have been fulfilled.

WEEE - Waste Electrical and Electronic Equipment – a European Parliament Directive 2002/96/EC, this directive aims to reduce waste, increase recovery and recycling and improve the environmental performance of producers of EEE.