* PAY PARTICULAR ATTENTION.

Siemens Medical Solutions USA, Inc.
Med USA Quality Assurance Agreement

Contents

Note: This quality assurance agreement was written so that Article I contains general information to the supplier. Article III states requirements applicable to every supplier regardless of the ***product*** purchased by SMS. Then each of the following articles contains additional requirements depending on the ***product*** purchased.

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Article I. Purpose (Informative)

1. Introduction

Medical device manufacturers, such as SIEMENS MEDICAL SOLUTIONS USA, INC. (SMS), are obligated to follow many regulations and standards relating to quality. The most widely known are:

TITLE 21 Code of Federal Regulations Part 820 – Quality System Regulation

European Medical Device Directive 93/42/EEC

ISO 13485:2003 Medical Device Quality Management System

ISO 9001:2000 Quality Management Systems

In general these regulations prescribe what medical device manufacturers must do during design, manufacturing, and post-manufacturing. While they do not directly apply to suppliers of medical device manufacturers, it is the responsibility of SMS and other medical device manufacturers to assure that only product conforming to specified requirements is used.

These regulations explicitly require that the finished device manufacturer assess the capability of suppliers to provide quality products and services. Because of the complexity of the many parts used in SMS devices, their adequacy cannot always be assured through inspection and testing by Siemens. Quality must be assured through the application of proper quality systems.

As medical device and diagnostics products become more complex and as demand increases, the chance of errors and inconsistencies in manufacturing escalate. Only by implementing systematic processes and quality controls during the product life cycle (e.g.: design, manufacture, installation and service) can manufacturers like Siemens eliminate variability that can lead to regulatory actions, devastating product recalls, and lost market share. Therefore, SMS expects that all of our suppliers will collaborate with SMS and support our effort in meeting our obligations for medical device manufacturers.

2. Quality system requirements in general

SMS requires that our suppliers establish and maintain a quality management system that is appropriate for the specific product being manufactured or the service performed that ensures the users of SMS products – doctors, nurses, and other medical practitioners – receive and operate safe, effective, and reliable medical equipment.

SMS expects its suppliers to have processes that ensure that they meet the quality system requirements specified herein. It also recognized that some suppliers are small businesses while others are large corporations. Exactly how a supplier establishes and maintains their quality system to meet SMS' requirements is dependent upon the supplier's operation and is appropriate for the business size of the supplier provided that quality, reliability, maintainability and regulatory requirements are maintained at the highest level.

In this document a ***requirement*** means a specification or characteristic with which a product, process, service, or other activity being performed for SMS must conform. ***Product*** means component, material, substance, piece, part, software, firmware, assembly, and finished device to be used in or with a finished medical device, or a service performed to design, develop, install, repair, or maintain a finished medical device and its accessories.

These requirements have been established in order to assist SMS in meeting our obligations for safety, quality, and reliability.

3. Notes regarding regulations and standards

A. FDA regulations. Manufacturers that are registered with FDA as a device manufacturer or as a contractor which manufactures and supplies SMS with accessories that function with Siemens equipment are expected to follow all applicable FDA regulations in addition to the requirements herein. Non-medical device manufacturers that supply accessories that function with Siemens equipment or other products are expected to follow all of the requirements herein, as appropriate.

B. Medical Device Directive (MDD). All medical devices sold within the EU member states must meet certain essential safety and administrative requirements, defined in the MDD, before they can be marked with the applicable CE mark by the manufacturer.

C. ISO standards. SMS does not mandate that all of it suppliers be certified to an ISO standard. However, if an ISO certification does exist the supplier shall meet the standard's requirements. The requirements given herein will be used by SMS when evaluating the effectiveness of a supplier's quality management system (QMS).

Article II. Scope

This quality assurance agreement (QAA) applies to the products listed in Annex 1 (Products) which are delivered to SMS by the supplier. When this annex is blank or does not reference the Scope of Work, then this QAA applies to all products procured by SMS from the supplier.

1. Applicable Products

This Quality Assurance Agreement (QAA) applies to the following product(s) delivered by the supplier to SMS. If nothing follows, then the QAA applies to all products ordered by SMS.

2. Additional Requirements Not Stated in the QAA

The following special requirements (barcoding, product labeling, testing, inspection, packaging, documentation, etc.) are in addition to the QAA. If nothing follows, then there are no additional requirements not stated in the QAA.

3. Exclusions to the QAA

The following are exclusions to the QAA as agreed to between SMS and the supplier. If nothing follows, then there are no exclusions to the QAA.

Article III. Quality Assurance Requirements Applicable to All Suppliers

1. Quality system

A. Establishment. It is expected that the seller has established and is maintaining a quality management system that is commensurate with the *product* being provided to SMS or in support of SMS' business. It is further expected that the supplier's quality system has been established to ensure that all SMS requirements are understood and are being met.

For the exchange of quality-relevant information between the parties via e-mail, appropriate software for electronic signature and encryption has to be used, where appropriate.

B. SMS requirements. The supplier is required to ensure that it has received and understands all requirements from SMS, stated or implied. The supplier is responsible for addressing any incomplete, ambiguous, or conflicting requirements received from SMS prior to commencing performance.

The product shall be in compliance with the agreed quality (e.g. description, specifications, data sheets, drawings, product samples). Unless otherwise agreed, such a description and product samples do not rank as guaranteed product features. In each and every case, the supplier shall check without delay whether a description provided by SMS is in any way obviously incorrect, unclear, incomplete, or not in compliance with the product sample. If the supplier realizes that this is the case, it shall forthwith give notice in writing to SMS.

C. Deviations. The supplier shall receive written authorization from a representative of SMS prior to making any changes to any SMS requirement, including the requirements herein. Failure to comply with this SMS requirement could have a serious impact resulting in the SMS medical device becoming adulterated within the meaning of U.S. Federal Regulations.

D. Process plan. The supplier shall: (a) define and document (i.e. in a process map, in a flow diagram, or etc.) the processes it uses, from order receipt to order fulfillment, necessary to provide the product for SMS; (b) verify that these processes are effective in producing the desirable product for SMS, (c) establish the methods to appropriately monitor, measure and control these processes to ensure that product requirements are consistently meeting SMS' expectations; and (d) provide, when appropriate, for a means to analyze process trends and take prompt action to correct any unfavorable trend.

E. Quality system procedures. The supplier shall have documented procedures and instructions to effectively implement the established quality system and support the process plan.

F. Siemens owned property. The supplier is responsible for identifying, controlling, maintaining, storing, and, where appropriate, calibrating Siemens owned property. The supplier is required to timely notify SMS in the event that any Siemens property is lost or damaged, or that its continued use could result in nonconforming product.

This includes, but not limited to, meters, gages, tools, fixtures, instruction manuals, installation aids, and software provided by SMS to the supplier to provide product to SMS.

The use of such property is limited to making/providing product for SMS and may not be used by the supplier for any other purpose without written approval from an agent of SMS.

G. Complaints from Siemens customers. While it is reasonable to expect that the supplier will have some interaction with a customer of SMS, the supplier is required to have a written procedure for forwarding to a representative of SMS, without undue delay, any written, electronic, or oral communication from a customer of SMS that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of any of Siemens equipment.

H. Complaints from Siemens. The supplier is to establish a process for receiving a complaint from SMS alleging nonconformity of the supplier's product and providing timely feedback to SMS reporting on the corrective action it has taken or rationale for not taking corrective action.

The supplier shall have a written procedure describing the corrective action process. The procedure is to include:

1. the department or staff responsible for receiving, reviewing, evaluating and coordinating complaints from SMS
2. documenting oral complaints upon receipt,
3. processing complaints in a timely and uniform manner,
4. the investigation process to determine the root cause of the problem,
5. evaluating the need for action to ensure that the problem does not recur,
6. determining and implementing the action needed to provide a solution to the problem,
7. action on product already delivered and/or other sites or systems that could be affected by the nonconformity,
8. verification of activities to show that the actions taken were effective,
9. management review and approval of the action taken, and
10. maintaining records of corrective actions. Corrective action records are to be made available to SMS upon request.

I. Management representative. The executive management is to appoint a member of management who, irrespective of other responsibilities, is the supplier's management representative for quality. This manager shall have the overall responsibility and authority to

4. Calibration of inspection, measurement and test equipment

A. Calibration requirements. Any equipment used to establish product specifications during design and development, used to determine process parameters, or used to judge the acceptability of a product specification shall be maintained under a calibration program.

B. Calibration procedures. Procedures shall be established and maintained to ensure that inspection, measuring, and test equipment (IM&TE) used to determine the acceptance or rejection of process or product requirements during design, production, installation or service are calibrated, inspected, checked and maintained in accordance with the manufacturer's recommendations. Calibration procedures shall include specific directions and limits for accuracy and precision. Calibration standards used for IM&TE must be in conformity to national or international standards.

C. Suitability of equipment. Suppliers shall ensure that all IM&TE, including mechanical, automatic, or electronic inspection and test equipment, are suitable for their intended use and capable of producing valid results. Controls shall be in place to ensure that IM&TE maintain their suitability while in-use, in transit, or in storage.

D. Calibration labeling. A label is to be affixed on or, if appropriate, near the IM&TE. This is to inform the user of the IM&TE that the IM&TE is under the calibration program. The label is to include: (a) date IM&TE was calibrated, (b) who performed the calibration, and (c) the due date of the next calibration.

E. Calibration records. Supplier is responsible for maintaining records to provide objective evidence that IM&TE are being maintained and calibrated. These records shall be made available to Siemens upon request.

F. Notification to Siemens. The supplier shall notify SMS without undue delay when the supplier becomes aware of the use of any inappropriate or out-of-calibration inspection measurement and test equipment so that SMS can evaluate the effect of its use and any necessary corrective or other action, up to and including reworking at the supplier's expense.

G. Use of calibration lab. When the supplier uses the services of an outside calibration service, it is the responsibility of the supplier to ensure that the service provider meets any and all requirements for the service provided.

5. SMS right to inspect (Audit)

A. Supplier's executive management responsibility. To ensure the effectiveness of the supplier's quality system to deliver conforming product, SMS may require representatives of SMS to perform quality system audits at the supplier's facility. The supplier's executive management shall support such audits and ensure that prompt corrective actions are taken to address any discrepancies found.

B. SMS Audits. The supplier shall at reasonable intervals allow SMS to check the compliance with this quality assurance agreement. The supplier shall therefore, after prior agreement of the parties on the date of such an inspection, grant SMS reasonable access to its business premises and shall make available a duly qualified member of its staff for the duration of the inspection visit. SMS may be denied access to and inspection of classified manufacturing methods and other industrial secrets.

This described right of SMS includes the right to inspect the existing documentation and to participate in quality checks carried out by the supplier. The checks may be carried out by way of quality audits (e.g. audits involving the systems, products or processes) and via inspections.

C. Third party audit. An audit or regulatory inspection may also be required from time to time. This may involve the authority having jurisdiction over SMS according to the European Medical Device Directive 93/42/EEC or any other regulatory authority (e.g., US Food and Drug Administration) or authorized organization or by third parties commissioned by SMS.

6. Corrective and preventive action (CAPA)

A. Basic CAPA requirements. The suppliers shall establish procedures for implementing corrective and preventive action. The procedures shall include requirements for:

1. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed, where necessary, to detect recurring quality problems;
2. Investigating the cause of nonconformities relating to product, processes, and the quality system;
3. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
4. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
5. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
6. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems;
7. Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review; and
8. Ensuring that all activities required under this section, and their results, are properly documented.

7. Miscellaneous

A. Termination. SMS shall have the right to terminate any and all agreements with supplier or revoke any purchase order issued to supplier if at any time SMS determines that supplier is not in compliance with the Quality System Requirements.

B. Liability and Indemnification. The supplier shall be liable for, and shall indemnify, protect and defend SMS, its directors, officers, employees and agents from and against, any and all claims, causes of action, damages, penalties, judgments, costs and expenses (including reasonable attorney's fees) arising from, related to or caused by (i) the failure of the supplier, its employees and agents, to comply with the Quality System Requirements; (ii) the negligent or intentional acts or omissions of the supplier, its employees and agents; (iii) the breach of any of its representations, warranties or obligations under any agreement between supplier and SMS; and (iv) the failure of supplier, its employees and agents, to comply with applicable laws, rules and regulations.

Annex I. Specific Requirements to Design and Development

NOTE: These requirements also apply when the supplier *integrates* by the selection of various parts by the supplier, as well as hardware and software, as applicable, which result in a product meeting SMS requirements.

A. Design and development planning. The supplier is required to have written procedures for the design and development activities and define responsibilities and authority for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design development evolves.

B. Design input. The supplier shall have written procedures to ensure that the SMS design requirements for the product are complete, understood and include, where applicable:

1. functional, performance, and safety requirements,
2. applicable statutory and regulatory requirements,
3. other requirements essential for design and development
4. application of risk management (see ISO 14971 for guidance)
5. provisions which address the intended use of the device, including the needs of the user and patient.

The supplier's procedure is to include a mechanism for addressing incomplete, ambiguous, or conflicting requirements from SMS. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s) of SMS and the supplier. The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

C. Design output. The supplier shall have written procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to SMS design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved by supplier before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented. Where required, the approval shall include an authority from SMS.

D. Design review. At suitable stages or milestones, and as defined in the design plan, a systematic review of the product design and development is to be performed to evaluate whether the results of the design and development to meet SMS requirements, and to identify any problems, potential or real, and propose necessary actions. Participants at each design review include representatives of all functions concerned with the design stage being reviewed, representative(s) from SMS, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented.

E. Design verification. The supplier is responsible for design verification activities in accordance with the approved design and development plan to ensure that the design outputs meet all of the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented.

F. Design validation. When the product being designed by the supplier is the finished medical device and/or a stand-alone accessory to a finished medical device capable of operating independently, the supplier shall have written procedures for validating the product design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that product conforms to defined user needs and intended uses and shall include testing of production units under

actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented.

G. Design transfer. As appropriate, the supplier shall ensure that the final design output is correctly translated into production specifications.

H. Design records. The supplier shall establish and maintain a design history file (DHF) for the product designed and developed for SMS. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and meets SMS requirements. In cases where the supplier receives SMS engineering drawings and then redraws them into the supplier's engineering drawing format, confidentiality of both sets of drawings is to be maintained in the DHF. The entire DHF is the property of SMS.

Annex II. Specific Requirements for Manufacturing

NOTE: This section applies to suppliers producing, assembling, fabricating or processing product for SMS.

1. Receiving, receiving inspection, and storage

A. Authorized receipts. The receiving function shall ensure that only deliveries from 3rd party suppliers that are listed on the supplier's approved supplier list are accepted and processed. Articles leaving the receiving function must be clearly labeled or otherwise identified so as to preclude mix-ups and unintentional use. Nonconforming articles are to be clearly labeled and separated from all other articles.

B. Direct to stock receipts. When received articles bypass receiving inspection and go directly to storage or to their point-of-use, controls must be in place to avoid mistakes and the unintentional acceptance of articles.
1. The acceptance of these articles must have some form of prior documented approval, including the rationale, to bypass receiving inspection.
2. The receiving function shall record the acceptance of the articles after verifying they meet predetermined requirements.

C. Receiving inspection. Receiving inspection activities shall be established and maintained in a written procedure. These activities are to confirm or to otherwise verify that incoming articles conform to specified requirements. When other than 100% inspection is performed, the sample size is to be determined based on the risk of accepting the lot when it should have been rejected. Only published sampling plans may be used (i.e., ANSI/ASQC Z-1.4). Receiving inspections are to be recorded and include (1) the inspection/tests performed, (2) date inspection/tests were performed, (3) results –acceptance or rejection, (4) the signature of the inspector, and (5) where appropriate, the test equipment used. Articles leaving the receiving function must be clearly labeled or otherwise identified so as to preclude mix ups and unintentional use. Nonconforming articles are to be clearly labeled and separated from all other articles.

D. Storage. Stockrooms, where materials and parts are stored for later use in production, are to be kept orderly and well maintained. Only items that have been accepted for use are to be stored in the stockroom. All bins, cartons, or other containers holding the items in storage are to be labeled with the item's part number and be of such design as to preclude mix ups. Controls are to be in place to prevent damage and deterioration while items are in storage. Controls for temperature sensitive and limited shelf life materials must be considered.

2. Production and process controls

A. Engineering drawings. In cases where the supplier receives SMS engineering drawings and then redraws them into the supplier's engineering drawing format for internal use, confidentiality of both sets of drawings is to be maintained. Both sets of drawings are to remain the property of SMS.

B. Inspections and tests. Whether required by SMS or not, the supplier is responsible for conducting all appropriate inspections and tests that are necessary to confirm that the product made for SMS meets all of its specified requirements and quality attributes.

C. Standard operating procedures. Production operations are to be defined, conducted, controlled, and monitored to the extent necessary to ensure that the product made for SMS conforms to its specifications. This is to be documented in standard operating procedures (SOP's).

D. Production controls. A process control plan (or similar document) shall be established and maintained that outlines the various production operations and the process controls necessary to manufacture acceptable product for SMS, if not already detailed and included in the process plan. The following is a list of items that must be considered for inclusion in the process control plan, dependent upon, and where appropriate for, the complexity of the process(es) used to manufacture product for SMS.

1. The controls to assure only accepted process inputs are used. Inputs are the materials and parts needed to make the product.
2. Clear identification (labeling) and separation of the materials and parts stored on the production floor in order to prevent mix ups and their unintended use.
3. Controls to prevent the use of materials that have exceeded or are nearing their expiration date.
4. The process to ensure the production line has been cleared of inputs from previous production runs for a different product (i.e., a "line clearance").
5. The assignment of a unique lot or batch number, or date code, to the production run for future reference and record keeping.
6. The manufacturing steps required (i.e., the use of a route tag).
7. The criteria for workmanship, including representative samples.
8. The process characteristics (parameters) to be controlled during production.
9. The means, such as SPC, for the continuous monitoring and control of critical-control-points in the production processes.
10. The in-process product attributes that are critical to quality are monitored during production.
11. The defined acceptance and rejection criteria of the process output to ensure that they are correctly inspected/tested by qualified individuals.
12. Controls for the handling and reworking of in process nonconformances.
13. The final inspection and test methods to be used for product release.
14. Handling procedures to assure that personnel handling and moving both in-process and final product do not inadvertently cause nonconformances.
15. The procedure for adequately packaging the product for shipment to SMS so that it is reasonable to expect that product quality will not be affected during transportation.
16. The method for recording process data and inspection/test results either electronically or on paper forms.

E. Automated test systems. Software controlled and/or automated test systems used to determine the acceptance or rejection of incoming product, in-process product or final product are to be validated or otherwise verified to assure that consistent and repeatable results are obtained and that the system is fit for its intended use.

F. Process validation. Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated. Processes that typically require validation include, but are not limited to:

- Reflow & wave soldering
- Injection molding
- Plating
- Bonding
- Sterilization

G. In-process rejects. Supplier is to establish and maintain procedures to ensure that the causes of internal, in-process rejects are identified and corrected so as to prevent their recurrences. Where appropriate, supplier shall monitor (i.e., trend chart analysis) production operations to enable the early detection of problems and correct them in order to prevent rejects from occurring.

H. Statistical applications. Valid statistical techniques shall be used, where appropriate, for the verification of the acceptability of incoming product, process characteristics, and product release.

I. Environmental controls. Where environmental conditions (temperature, humidity, ESD, etc.) could reasonably be expected to have an adverse effect on quality, the supplier shall establish and maintain procedures to adequately control these environmental conditions. Maintenance schedules and activities must be documented.

J. Equipment maintenance. Production equipment is to be maintained to ensure its continuing suitability and capability to manufacture acceptable output.

K. Final acceptance activities. Product shall not be released for shipment until all requirements have been confirmed as being satisfactorily completed, unless otherwise approved in writing by SMS. Records shall include the signature of the person(s) authorizing release of the product. Prior to shipment, the supplier shall confirm and document that the product meets all of its requirements. This verification is to include the following items.
1. The SMS part number and revision level to be shipped is what was ordered.
2. The process control plan was followed. All in-process inspection and tests and final inspections and tests were completed and their results are acceptable.
3. All required forms and other documents are available and correctly completed.
4. Any necessary documents to be shipped with the product, such as a certificate-of-conformance, are complete and ready to go.

L. Production history records. Records, including route tags, process forms, inspection forms, and test data forms, are be maintained to demonstrate that the product was produced according to the production control plan.

3. Storage, packaging and transport

The supplier shall ensure that sufficient protection is given for storage on its own premises, in particular against damage and environmental influences.

To the extent the parties do not have any other agreement relating thereto, the products shall be packaged and transported in a defined and reproducible manner at the supplier's responsibility. The supplier shall thereby ensure that the packaging units are clean, that there is sufficient protection in place against damage and that the transport security in place is capable of maintaining the quality requirements.

As far as possible, the environmental impact of packaging and transportation of newly produced products by way of coordinated forwarding concepts with multiple and/or shuttle packaging, the reduction of the packaging volume and use of environmentally friendly packaging materials, as well as the costs of packaging and disposal, are to be optimized.

With regard to packaging repaired used products and spare parts, single shipment packages are to be used that can only be opened by way of a sealed closure, and which are suitable with regard to providing effective protection against transport-related changes in the case of worldwide shipment. The possibilities with regard to reducing the amount of packaging, and the use of environmentally friendly materials and reusable packaging, are to be utilized insofar as such course of action is also possible within this framework.

4. Nonconformances

A. Control of nonconforming articles. Nonconforming articles (raw materials, parts, piece parts, in-process work, etc., used to produce product for SMS that do not meet specified requirements) are to be rejected, labeled as such, and separated to preclude their accidental use.

Nonconforming articles can only be used to produce product for SMS after they have been reworked to meet original specifications, or with written (e.g., deviation) authorization from SMS.

B. Control of nonconforming product. Product made for SMS that failed to meet its specified requirements and quality attributes shall be rejected, labeled as such, and separated so as to prevent it from being shipped to SMS. Supplier shall not knowingly ship nonconforming product to SMS without first receiving written authorized approval from SMS.

C. Rework of nonconforming product. Nonconforming product may be reworked provided these operations are carried out according to written procedures and are carried out by personnel having the necessary knowledge and skill sets to perform the rework. Reworked product must be re-inspected and re-tested, and pass all originally specified requirements and quality attributes. The rework operations, including the reinspection and retests, are to be recorded.

D. Product returns. Suppliers must have a procedure for receiving returned product from SMS in the event it is rejected. The supplier's procedure should include verification of the nonconformance. If the nonconformance cannot be verified, for whatever reason, the supplier shall promptly notify SMS and work toward a resolution. When the nonconformance is confirmed by the supplier, appropriate corrective action is to be taken to address and correct the problem. This action may include:

1. Confirming that the correct process inputs were used.
2. Confirming there was an adequate "line clearance" before making the product for SMS.
3. Verifying personnel are adequately trained and have the necessary skill sets.
4. Changing the process plan (i.e., increasing in-process and/or final inspections and tests, moving controls upstream in the process for earlier detection of problems, instituting new inspections or testing, etc.).
5. Modifying the production control plan (i.e., increased in-process monitoring of process parameters).
6. Reworked or returned product subsequently reshipped to SMS is to be clearly labeled or otherwise identified as being reworked or repaired, and packaged in all new materials.

E. Product salvaging. New products may only contain components drawn from used products if expressly approved by SMS.

5. Processing product changes of manufactured product

The supplier shall document all product changes in accordance with its quality management system. This includes, but is not limited to, product changes that could have an effect on product function; design; acceptance; interfaces; transport and storage capabilities; handling; capabilities regarding processing, repairs or maintenance; production processes; recycling or the disposal of products as well as all changes to documents that are distributed with the products (e.g. data sheets, operating manuals or maintenance instructions).

A. Processing product changes initiated by the supplier. All product changes by the supplier are subject to written approval by SMS. For approval, the supplier shall forward to SMS a written change inquiry, which shall address the following points:

- Products and product characteristics affected
- Exact description of required change
- Consequences of product change from the supplier's point of view (including risks)
- Required start of product change (e.g. from serial number, batch number, order or date).
- SMS shall assess the required product change and provide the supplier with written authorization, which may be subject to further requirements.

B. Implementing product changes initiated by the supplier. The supplier shall only implement the changes following the receipt of the written authorization by SMS of the changes and the implementations of any further requirements contained therein, and provide notification of the conclusion of the implemented changes in the form of a written confirmation to SMS.

The supplier shall furthermore provide SMS with prototypes of the changed products free of charge, if this is necessary for further validation at SMS' premises. Following the successful validation of the change, at the supplier's premises or, if necessary at SMS' premises, the delivery of the changed products shall be released in writing by SMS.

The start of the delivery of changed products shall be agreed upon in writing.

C. Processing product changes initiated by SMS. If SMS requests a change in the product, SMS shall forward a written change inquiry to the supplier, which shall address the following points:

- Products and product characteristics affected
- Exact description of required change
- Consequences of product change from SMS point of view (including risks)
- Required start of product change (e.g. from serial number, batch number, order or date).

The 'supplier shall review the degree to which the requested changes can be realized and the consequences, and inform SMS of the outcome of such a review in the form of a written offer.

Following the review of such an offer, SMS shall issue the supplier with a written change order, including the respective validation requirements. Within such a change order the costs and the release regarding the manufacture of an initial batch or a prototype shall be agreed upon.

D. Supplier implementing changes initiated by SMS. The supplier shall implement the product change following the receipt of the written change order and the parameters specified therein by SMS, and provide notification of the conclusion of the implementation of the change in the form of a written change confirmation. The supplier shall furthermore make available to SMS prototypes of the changed products against reimbursement of its costs if this is necessary for further validation at SMS' premises.

Following the successful validation of the product change, at the supplier's premises or, if necessary at SMS' premises, the delivery of the changed products shall be released in writing by SMS.

The start of the delivery of the changed products shall be agreed upon in writing.

Annex III. Specific Requirements for Installation

1. Installation of Siemens Equipment or Accessories to Siemens Equipment

A. Installation instructions. The supplier shall install the product in accordance with the "Installation Instructions" as outlined in Siemens' Factory installation documentation. Any deviation from the "Installation Instructions" must have the prior written authorization from Siemens in order to prevent the adulteration of the finished medical device or creation of non-conformity to the device's performance specifications.

B. Inspection and test. The personnel installing the SMS device shall ensure that the installation, inspection, and any required testing are performed in accordance with SMS instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.

C. Installation records. The supplier is required to complete all of the necessary installation records, including results of inspections and tests, and forward them without undue delay to the appropriate Siemens authority. This includes installation problems incurred, deviations approved by SMS, and parts replaced.

D. Training. The supplier is responsible for ensuring that its personnel and any agents it uses to install/de-install product for SMS are competent and fully qualified and are appropriately licensed under all federal, state and local laws, rules and regulations. During training, trainees must demonstrate their ability to perform required tasks in a safe, correct, and efficient manner, under the guidance and supervision of another qualified person who will evaluate their work. The training is to be provided by SMS or the curriculum is to be based on Siemens training programs.

[Also see "Personnel Training" in Article III. Records of all training must be maintained by the supplier to document that personnel have been trained in accordance with the established training plan and these records are to be made available to SMS upon request.]

E. Personnel competency. The supplier is to maintain records (list) of the equipment and the SMS product(s) their personnel are qualified to install. A copy of this list is to be provided to SMS upon request.

F. Equipment storage. The supplier is required to use only a Siemens approved facility for the storage of Siemens owned equipment.

G. De-installations. For de-installations and relocations of product, the supplier is to confirm and communicate to SMS if the product was removed from service or the new location of the product so that the Siemens database can be updated accordingly.

2. Installing non-Siemens Equipment for Siemens

A. Installation instructions. The supplier shall install the product in accordance with the "Installation Instructions" as provided by the equipment manufacturer. Any deviation from the "Installation Instructions" must have the prior written authorization from Siemens or the equipment manufacturer in order to prevent the adulteration of the finished medical device or creation of non-conformity to the devices performance specifications.

B. Inspection and test. The personnel installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.

C. Installation records. The supplier is required to complete all of the necessary installation records, including results of inspections and tests, and forward them, without undue delay, to the appropriate Siemens authority. This includes installation problems incurred, deviations approved by the equipment manufacturer or SMS, and parts replaced.

D. Training. The supplier is responsible for ensuring that its personnel and any agents it uses to install/de-install product for SMS are competent and fully qualified and are appropriately licensed under all federal, state and local laws, rules and regulations. During training, trainees must demonstrate their ability to perform required tasks in a safe, correct, and efficient manner, under the guidance and supervision of another qualified person who will evaluate their work.

[Also see "Personnel Training" in Article III. Records of all training must be maintained by the supplier to document that personnel have been trained in accordance with the established training plan and these records are to be made available to SMS upon request.]

E. Personnel competency. The supplier is to maintain records (list) of the equipment and the product(s) their personnel are qualified to install. A copy of this list is to be provided to SMS upon request.

Annex IV. Specific Requirements for Service

1. Servicing Siemens equipment or Accessories to Siemens equipment

A. Service calls. The supplier is required to understand and follow the SMS service call process.

B. Service records. The supplier shall maintain records of each service call. A copy of the service record is to be left at customer location and a copy of the service record is to accompany the invoice when submitted to Siemens. The record must include:

1. The name of the equipment serviced;
2. Any device identification(s) and control number(s) used;
3. The date of service;
4. The individual(s) servicing the equipment;
5. The service performed, including parts used; and
6. The test and inspection data.

C. Training. Personnel must receive SMS technical training and be certified by SMS to work on specific SMS equipment prior to being authorized to perform maintenance or service on SMS equipment.

[Also see "Personnel Training in Article III. Records of all training must be maintained by the supplier to document that personnel have been trained in accordance with the established training plan and these records are to be made available to SMS upon request.]

D. Spare parts. Only Siemens certified spare parts are to be used during maintenance and repairs.

E. Data collection and analysis. Upon request, the supplier shall collect, analyze, and report to SMS data for:

1. Part usage
2. Service call history
3. Equipment uptime
4. Service call response time
5. Preventive maintenance completion
6. Product modification completion

F. Field corrections, modifications, updates. The supplier shall have a process to act, without undue delay, on a field correction, product modification or update initialed by SMS.

2. Servicing non-Siemens Equipment for Siemens

A. Service records. The supplier shall maintain records of each service call. A copy of the service record is to be left at customer location and a copy of the service record is to accompany the invoice when submitted to Siemens. The record must include:

1. The name of the equipment serviced;
2. The Siemens Notification Number or Reference Number
3. Any device identification(s) and control number(s) used;
4. The date of service;
5. The individual(s) servicing the equipment;
6. The service performed, including parts used; and
7. The test and inspection data.

B. Training. The supplier is responsible for ensuring personnel servicing and/or maintaining the equipment are competent on the basis of their education, training, skills, and experience. The

supplier is to establish a certification program that ensures that personnel are qualified before being allowed to service or maintain that equipment. Personnel qualification shall include one or more of the following: (1) have taken and passed the original equipment manufacturer's (OEM) technical training course(s), (2) successfully attended an industry recognized technical training program, (3) successfully completed a formal, predetermined and documented in-house training program that is essentially equivalent if given by the OEM. This training program provides, in detail, the curriculum or contents of the training to be given and the qualifications the trainer must have.

[Also see "Personnel Training" in Article III. Records of all training must be maintained by the supplier to document that personnel have been trained in accordance with the established training plan and these records are to be made available to SMS upon request.]

C. Spare parts. Only certified spare parts are to be used during maintenance and repairs. These are parts manufactured by the OEM, for the OEM, or aftermarket parts specifically manufactured for the equipment being serviced or maintained.

D. Data collection and analysis. Upon request, the supplier shall collect, analyze, and report back to SMS data for:
1. Part usage
2. Service call history
3. Equipment uptime
4. Service call response time
5. Preventive maintenance completion
6. Product modification completion

E. Service manuals. The supplier is required to maintain and keep up-to-date all OEM manuals and related technical literature for the equipment.

Annex V. Specific Requirements for Warehousing/Distributing Product for Siemens

A. Handling. The supplier shall have controlled processes to ensure that only product authorized by Siemens is received, stored and distributed. The process is to include a method that prevents mix-ups, damage, deterioration, contamination, or other adverse effects from occurring to product during handling. Records of receipts, including the date and name of person accepting the receipt, shall be maintained.

B. Storage. The supplier shall have processes that ensure control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

C. Product packaging. The supplier is responsible for and shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

D. Distribution. The supplier shall control the distribution of product to ensure that only product approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before products are released for distribution. Where a product's fitness for use or quality deteriorates over time, the controls shall ensure that expired products are not distributed.

E. Distribution records. The supplier shall maintain distribution records and make them available to SMS upon request. Records are to include:
1. The name and address of the initial consignee;
2. The identification and quantity of devices shipped;
3. The date shipped; and any control number(s) used.

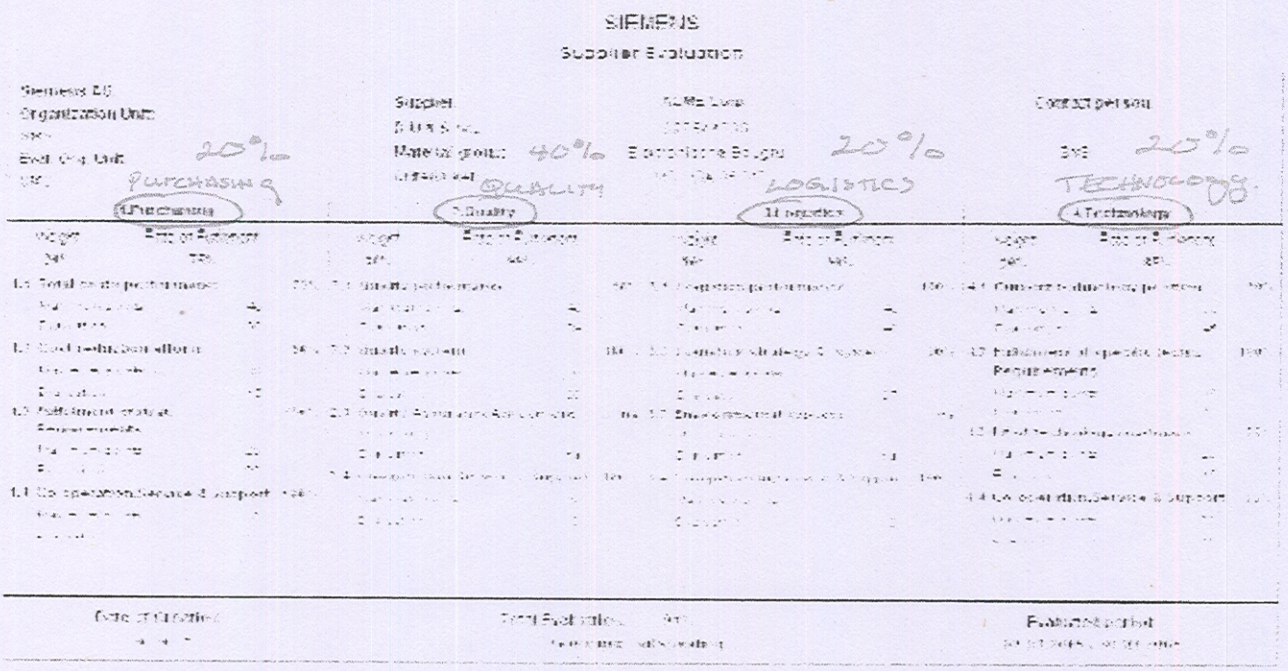
F. Product recall, field corrections, modifications, updates. When the supplier distributes product directly to the SMS customer, the supplier shall have a written procedure to support, without undue delay, a product recall or product correction and update initiated by SMS or the original product manufacturer.

G. Environmental controls. Where environmental conditions (temperature, humidity, ESD, etc.) could reasonably be expected to have an adverse effect on quality, the supplier shall establish and maintain procedures to adequately control these environmental conditions. Maintenance schedules and activities must be documented.

Annex VI. How SMS Evaluates It's Suppliers

A. Introduction. Those suppliers identified based on annual spend or those suppliers whose products and/or services are critical to the safety, efficacy, and reliability of the medical devices SMS manufactures, will be deemed "Class A" suppliers, and will be evaluated by SMS using the following structured system utilized by all of our business units. The system is based on objective metrics that are focused on the major controlling points of the products and/or services being provided, and further strives to fairly and comprehensively evaluate suppliers based on four major categories, which are represented in TABLE A, below, the details of which may be found by reviewing the remainder of this document. This information is being provided so that suppliers will understand the basic requirements and the basis of the system whenever they receive an evaluation from SMS. The minimum requirements for all suppliers are quality and delivery performance, which are elements within the quality and logistics categories of the evaluation system.

Table A. Overview of SMS Evaluation System (Example)



B. Supplier Evaluation Classifications. After a supplier has been evaluated, the numerical value of that evaluation automatically classifies the supplier as:

- **Outstanding:** A Supplier with a Total Supplier Evaluation Score of 90% or above.
- **Good:** A Supplier with a Total Supplier Evaluation between 70% and 89%.
- **Insufficient:** A Supplier with a Total Supplier Evaluation between 50% and 69%.
- **Poor:** A Supplier with a Total Supplier Evaluation less than 50%.

Suppliers will be evaluated by using the Med Standardized Criteria Set. If your business has more than one location, you may receive an evaluation for each location.
Suppliers that maintain an evaluation rating of Outstanding are typically recognized by SMS and its businesses in some of the following ways:

- Invitation to an SMS Supplier Day, where they will receive appropriate recognition for their excellent performance.
- Inclusion on the SMS "Outstanding Suppliers" plaque, which is prominently displayed in the lobby of the appropriate BU.
- Permission from SMS to use "Siemens Outstanding Supplier Status" as a customer reference in their marketing literature.

C. Details of the SMS Evaluation System.

1. **Purchasing**
   - a. **Total Cost Performance**
     - i. Are supplier's prices competitive?
     - ii. Payment terms
     - iii. Additional procurement costs
   - b. **Cost Reduction Efforts**
     - i. Cost reduction efforts
   - c. **Fulfillment of Strategic Requirements**
     - i. The market strategy of the supplier
     - ii. How is the supplier's economic situation?
     - iii. How is the conduct during contract negotiations?
     - iv. Supplier is registered in Click4Suppliers (c4s)
     - v. Does the supplier offer an Open Book Policy?
   - d. **Co-Operation, Service, & Support**
     - i. Cooperation, Service, & Support
2. **Quality** 70%+
   - a. **Quality Performance**
     - i. Product Acceptance Quality Performance (includes Receiving, In Process, Service, Reporting and Documentation, Packing, etc.)
     - ii. Field Quality Performance After Delivery (or similar measure; e.g. Open MPSR ratio)
   - b. **Quality System**
     - i. Does the supplier have a Quality Management System (QMS) which meets the requirements of Siemens or the business unit?
     - ii. Quality Management System, audit findings
     - iii. Number of corrective and preventative action (CAPA) or supplier development plans
   - c. **Quality Assurance Agreements (QAA)**
     - i. QAA in place or part of the frame contract, as appropriate
   - d. **Co-Operation, Service, & Support**
     - i. Cooperation, Service, & Support
3. **Logistics**
   - a. **Logistics Performance**
     - i. Does the supplier meet targeted delivery/milestone dates?
     - ii. How good is the response time to delivery problems
     - iii. Delivery flexibility
   - b. **Logistics Strategy and System**
     - i. Does the supplier offer logistics models which meet the needs and requirements of the business unit?
     - ii. Interface connection
   - c. **Environmental Aspects**
     - i. Does the supplier have an EMS which systematically advances the improvement of environmental protection and keeps Siemens informed about current actions for environmental protection?
     - ii. Does the supplier meet the requirements of the ecological product/service design, packing, and logistics?

iii. Documentation of hazardous materials

d. Co-Operation, Service, & Support

i. Cooperation, Service, & Support

4. Technology

a. Current technology position

i. Product technology ("Product" also means Service and Software)
ii. Engineering capability and competence
iii. Engineering documentation
iv. Technical equipment and facilities

b. Fulfillment of specific technical requirements

i. Prototypes and engineering samples
ii. Supplier communication and support of changes

c. Fit of technology roadmaps

i. The supplier's technology roadmap includes research, design, manufacturing processes, environmental health and safety characteristics

d. Co-Operation, Service, & Support

i. Cooperation, Service, & Support
ii. Support of manufacturing and/or sustained engineering