SUPPLIER QUALITY STANDARD

For more than 50 years, Physio-Control, maker of the renowned LIFEPAK defibrillators, has been developing technologies and designing devices that are legendary among first response professionals, clinical care providers and citizens everywhere.

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Welcome to the Physio-Control Team

As a supplier to Physio-Control, you become a vital member of our manufacturing team, providing lifesaving tools for lifesaving teams. Together we provide products of the highest quality and reliability which must perform when human life depends on it.

SUPPLIER QUALITY STANDARD

NOTE: Acceptance of a Physio-Control Purchase Order constitutes the Supplier has read, understands, and will comply with the expectations of this standard.

1 Vision of Physio-Control

Our vision is for all Physio-Control suppliers to implement and maintain a quality system that allows them to produce and deliver globally competitive high quality products with zero defects, delivered at the required time and clearly seen by our customers as superior in performance and value. Physio-Control expects our suppliers to conduct business with the highest degree of integrity, and in a socially and environmentally responsible manner.

2 Goal of Physio-Control

The goal of the Physio-Control Supplier Standard is to provide clear and consistent quality expectations for all links in the supply chain. This standard measures supplier performance, rewards improvements, and recognizes suppliers' outstanding continuous improvement efforts. To achieve continuous improvement, Physio-Control expects our suppliers to embrace a robust quality system and to work with us in a spirit of trust, cooperation, and teamwork. The goal of this standard is to establish the expectations for those quality activities.

3 Purpose of Document

This standard identifies the expectations of Physio-Control suppliers and its supply chain's fundamental quality system activities for managing:

- Quality management
- Management responsibilities
- Part realization
- Process control and capability
- Supply chain management
- Acceptance activities and traceability
- Communication and production sustainability
- Ongoing quality control and improvement

This standard is not intended to replace a supplier's existing quality system. Suppliers are requested to perform a self-evaluation to determine where their quality system aligns with this standard; this must include an evaluation of their supply chain. Suppliers are expected to discuss and understand the specific applicability of these requirements with their Physio-Control representatives in order to make informed and effective business decisions.

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

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

1. Any supply/purchase agreement executed by the parties
2. Specification
3. Supplier Standard

4 Supplier Responsibilities

Suppliers are responsible for ensuring that products or services meet established Physio-Control specifications. Audits, approvals or verification by Physio-Control of the supplier's facility, quality system, process controls, acceptance activities, etc., does not absolve the supplier of the responsibility to provide acceptable product, nor will it preclude the subsequent rejection of unacceptable product.

As a Supplier to Physio-Control, you are responsible for managing the quality of items you purchase from your suppliers. Supplier is also responsible for complying with the Bill of Materials (BOM) that is part of the Physio-Control furnished document work package. Supplier must control all items purchased from their sub tier suppliers and incorporated into products manufactured and sold to Physio-Control. Supplier is responsible to ensure that product(s) manufactured utilize only authentic, conforming and specified material requirements as stipulated in the BOM. Prior to implementing material or process changes, Suppliers must notify Physio-Control, using the RDC process (see section 8.3.5). This applies to any changes in material(s) or process(es) requested by Sub-tier suppliers.

5 Quality Management System

Physio-Control encourages our suppliers to comply with the voluntary International Medical Devices – Quality Management Systems-Requirements for regulatory purposes ANSI/AAM/ISO 13485:2003. For suppliers providing finished medical devices, Physio-Control requires adoption of more stringent Regulation, such as 21 CFR Part 820. It is recommended that all suppliers obtain copies of the ISO 13485:2003 and 21 CFR Part 820 Regulation and become familiar with the requirements and terminology used by Physio-Control. Physio-Control continues to move towards the requirements of ISO13485:2003 and will always embrace the philosophies of continuous improvement.

The supplier must keep the Physio-Control Supply Chain Engineer (SCE) informed of the supplier's certification status. Physio-Control requires up-to-date copies of any and all applicable third-party certifications achieved by our suppliers. In the event a supplier's quality system registration or certification status changes or is suspended, the supplier must notify Physio-Control within five (5) business days. In accordance with established agreements, Physio-Control reserves the right to audit the facility in order to insure products continue to meet specified requirements.

5.1 General Requirements for Suppliers

Suppliers are required to establish, document, implement, maintain, and monitor their quality management system to continually improve its effectiveness in accordance with the requirement of this Physio-Control Supplier Standard. The supplier must:

- Identify the processes needed for the quality management system and its application throughout the organization.
- Determine the sequence and interaction of these processes.

- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective.
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
- Monitor, measure, and analyze processes critical to the quality of Physio-Control Products.
- Implement the actions necessary to achieve planned results in their continuous improvement planning.

When an organization chooses to outsource any process that affects Physio-Control product requirements, the organization must notify Physio-Control via the Request for Design Change (per Section 8.4.3) process and insure control of any process and material that affects Physio-Control product requirements.

5.2 Documentation Requirements

5.2.1 General

The quality management system documentation must include:

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

5.2.2 Control of Documents

A supplier must establish, maintain, and document procedures to control all quality management system documentation and all data generated under the quality management system. The supplier must have current revisions of documents available at all appropriate locations.

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

5.2.3 Control of Records

All quality records must be kept for at least five (5) years unless otherwise agreed to by Physio-Control. These records must be stored in an environment that does not allow document deterioration and are readily accessible upon request by Physio-Control. The supplier will make available any and all quality related records upon demand by Physio-Control or any Regulatory Body such as the FDA or ISO.

6 Management Responsibilities

Top management is required to take an active role in the quality management system. This commitment must address the managerial processes of quality planning, quality control, and quality improvement.

6.1 Management Commitment

A Physio-Control supplier must demonstrate a commitment by top management to continuous improvement. Top management must provide documented evidence of its commitment to the development and improvement of the quality management system by:

- Communicating to the organization the importance of meeting customer as well as regulatory expectations and requirements
- Establishing the quality policy and objectives
- Conducting regularly scheduled management reviews on the effectiveness of the quality system and taking appropriate action when indicators are unfavorable
- Ensuring the availability of necessary resources

6.2 Customer Focus

Top management must ensure that customer needs and expectations are identified, converted into requirements, and fulfilled with the aim of achieving customer satisfaction. Physio-Control requires that suppliers conform to design and performance specifications. Suppliers must meet requirements for reliability, delivery, cost management, and technical support.

6.3 Quality Policy

Top management must endorse a written quality policy that:

- Is appropriate to the purpose of the organization
- Includes a commitment to meeting customer requirements and to continuous improvement
- Provides a framework for establishing and reviewing quality objectives
- Is communicated and understood at all levels in the organization
- Is reviewed for continued appropriateness

6.4 Quality Planning

Top management must ensure that goals and objectives are established for the appropriate functions and levels. The goals and objectives must be measurable and consistent with the supplier's quality policy.

6.5 Responsibility, Authority and Communication

6.5.1 Responsibility and Authority

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

6.5.2 Management Representative

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

6.5.3 Internal Communication

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

6.6 Management Review

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

7 Resource Management

7.1 Environment and Training

Employees must be qualified for the job they perform through education, training, or work experience and be knowledgeable of appropriate quality tools, defect awareness, and processes that affect the quality of products and services provided to Physio-Control. Furthermore, employees must be provided with the equipment, facilities, training, and a work environment conducive to producing high quality products that consistently meet the product specifications of Physio-Control.


LIFEPAK 1000
DEFIBRILLATOR

7.2 Human Resources

A supplier is responsible for providing a system of ongoing monitoring of each employee's education, training, and work experience, and also for providing opportunities for training and continuing education to improve employee's skill level. The training objectives will be to provide employees with an awareness of the relevance and importance of their activities and how they contribute to the achievement of quality objectives.

7.3 Infrastructure

A supplier is responsible for maintaining the facilities, software, equipment, workspace, hardware, and support services to achieve conformity to product specifications and functional requirements.

8 Product Realizations

8.1 Planning of Product Realization

Suppliers, when requested by Physio-Control representative must participate in Design Reviews, and provide prototype builds for the purpose of collaboratively planning for product realization and preventing problems during qualification and production builds.

Key characteristics are features of a part that can cause critical safety, or performance issues if not per specification. Quality planning activities are required for key characteristics identified in Physio-Control specifications. Quality planning activities must be completed before qualification builds, and updated for subsequent builds. Parts must be production-equivalent for qualification builds, and must be produced using production tooling in a production process. If there are process and/or material changes needed after the approval, the supplier must submit a Request for Design Change (RDC) for approval before implementation.

Special processes- As defined in ISO 13485:2003, validation is a requirement of a process where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use. Physio-Control considers such processes as a "Special Process". If a process, rework or repair involves a Special Process, then that process must be validated in accordance with the organization's validation requirements.

8.2 Confidentiality

The supplier and its supply chain must ensure the confidentiality of customer-contracted products, projects under development, and related product information.

8.3 Customer Requirements

8.3.1 Customer-Designated Special Requirements

Key characteristics apply to components and assemblies. The quality control activities for these characteristics must be documented in a control plan. Key characteristics will be identified directly in the specification. Any concerns by a supplier on the ability to meet the requirements must be communicated early in the process to insure adequate time for a solution.

The supplier must demonstrate conformity to customer requirements for designation, documentation and control of processes influencing key characteristics. The supplier must communicate (flow down) key characteristics to their supply chain, when applicable, and require documentation of quality control activities in a control plan.

8.3.2 Review of Requirements Related to the Product

Key characteristics for the product and processes, using information from design reviews, Design FMEAs, and historical information, are confirmed during the Supplier Management Review. The supplier must provide Physio-Control with a Process Failure Modes and Effects Analysis (PFMEA) before the qualification run of product. The supplier's process flows, process capabilities, PFMEA, and its supply chain capabilities and requirements must be reviewed during the process audits.

8.3.3 Audits

A Physio-Control representative may require the supplier to perform specific quality-planning activities. These activities are audited for effectiveness during a System and/or Process type Audit. When directed by Physio-Control, a System and/or Process Audit is conducted to confirm all product expectations. Physio-Control teams initiate this audit as early as possible, preferably during product qualification. Multiple reviews may be required for multiple builds, depending on the magnitude of change or risk from one build to the next.

The System and/or Process Audit's purpose is to:

- Determine the effectiveness of the Supplier's Quality System and quality planning
- Confirm effective control of the process(es) influencing key characteristics
- Discuss applicable Physio-Control requirements
- Review quality process control planning
- Review the supplier's processes and PFMEA to determine the extent of control needed by Physio-Control
- Verify adequate acceptance activities are in place and training is complete
- Review the supplier's supply chain capabilities and acceptance requirements
- Clarify supplier expectations and responsibilities
- Identify and assign preventive action for potential problems in manufacturing or procurement
- Discuss product handling, packaging, and product preservation

Effective audits require supplier participation. It is during the audit that the supplier should ask for clarification on any unclear issue. From this audit the supplier should acquire all of the information required to clearly understand Physio-Control requirements and expectations. It is expected that during these audits the supplier will identify any issues, or question any parameters that could impact the quality of the products provided.

8.3.4 Customer Communications

The supplier must identify and implement with Physio-Control a communication plan. The supplier must also ensure that the personnel involved in the realization of the product or service are made aware of any changes to requirements. Physio-Control points of contact include:

- Commodity Manager. Primary contact for all supplier business-related issues. The commodity manager is responsible for the relationship with the supplier, including but not limited to issues such as contract, quality, cost, delivery, or health of the business.

- Buyer. Primary contact for all purchasing-related issues. The supplier must inform the buyer of any issue that impacts the schedule, or to request any changes.
- Supplier Chain Engineer. Contact for all quality related issues and correspondence. The supplier must inform the Supplier Chain Engineer concerning Supplier Corrective Action Requests (SCARs) and any quality system or product quality issues. The SCE is the primary contact for all design, material, or process changes or issues.

We encourage our suppliers to visit our supplier website to receive the latest information on such things as upcoming events, forms and communications (go to: www.physio-control.com/suppliers.aspx)

8.3.5 Customer Change Notification

The Physio-Control Request for Design Change (RDC) process must be used to request any proposed change in process, materials, or design. You will be notified of RDC approval or denial via a signed and returned RDC form. Implementation of changes approved by Physio-Control to materials, parts and assemblies is communicated to suppliers only through released drawings. The RDC process must be completed and updated documentation must be released, before any changes are implemented. RDC's are submitted to Supplier Management via your Physio-Control Commodity Manager or Supply Chain Engineer.

The use of the RDC process is an essential, fundamental, and a mandatory requirement of doing business with Physio-Control. Adherence to the RDC process means that Physio-Control must receive proper and prompt notification of any change, especially RoHS related changes.

A supplier must use a Request for Design Change (RDC) form to request approval from Physio-Control. Physio-Control may subsequently elect to require a submission for qualification before approval depending on the potential impact to form, fit or function. The supplier must review and update, as necessary, all applicable items in the PFMEA/PCP to reflect the actual production process before the RDC is implemented.

8.4 Design and Development

8.4.1 Design and Development Planning

Physio-Control typically discusses with the supplier designs, workmanship standards, manufacturing processes, assembly techniques, and personnel hazards. Suppliers must provide technical leadership for their product, assist in the identification of potential problems, and work with Physio-Control in correcting problems. When the supplier is responsible for the product design control, it must conduct the reviews stated previously and include representation from their supply chain and Physio-Control, as appropriate.

8.4.2 Design and Development Inputs

Physio-Control develops the design verification and validation test plan at the system level. When requested, the supplier must participate in design verification and validation reviews involving their products. The supplier must help define a test plan and may be asked to assist in conducting the test either at Physio-Control or by the supplier.

8.4.3 Control of Design and Development Changes

The supplier and its supply chain must identify, document, communicate, and control all design changes using the Request for Design Change (RDC) process form. The supplier must evaluate the effect of any proposed changes to all products and inform Physio-Control of the results.

8.5 Purchasing

8.5.1 Purchasing Process

As a primary supplier to Physio-Control, the supplier must be responsible for the quality of the products and services provided by **their** supply chain.

The requirements of this document must include the supplier's supply chain. A supplier must have a documented system to properly select and monitor suppliers. A supplier must communicate the specifications to their supply chain and continually verify the product meets specifications.

When providing custom parts and assemblies to Physio-Control, the supplier is responsible to control each element or sub-tier supplier. Changes to material or processes must use the RDC process to communicate to Physio-Control and to gain Physio-Control approval prior to implementing any of the changes. Suppliers are responsible to enforce this requirement at all levels of the supply chain (see section 8.3.5)

As a supplier to Physio-Control, the supplier is responsible for managing the quality of items purchased from your suppliers. Therefore:

- The suppliers are responsible for complying with the BOM that is part of the Physio-Control furnished document work package.
- Suppliers control all items you purchase from your suppliers and incorporate into products manufactured and sold to Physio-Control.
- Suppliers are responsible to ensure that your product is manufactured with authentic, conforming and specified material requirements stipulated in the BOM.

8.5.2 Purchasing Information

In its purchasing documents, the supplier must describe the requirements for approval of the product and the qualification of the procedures, processes, specifications, equipment, and personnel necessary to produce the product.

8.5.3 Verification of Purchased Product

Physio-Control must verify the purchased product using a verifiable and validated test method. The primary supplier to Physio-Control is fully responsible for the quality of the products and services they provide, including that of the supplier's supply chain.

8.6 Production and Service Provision

8.6.1 Control of Production and Service Provision

Suppliers must incorporate and document process controls as needed to ensure stable conditions for the manufacturing process. Process control documents include but are not limited to process

sheets, inspection and test instructions, test procedures, standard operating procedures, preventive maintenance instructions, and process control plans.

The supplier must have readily available process control documents in place before part qualification. In the process control documents, the supplier must identify processing parameters and product characteristics identified during design reviews, PFMEAs, and process audits. The supplier must make the documents available for Physio-Control to review them. There will be no changes to the Process Control Plans without agreement from both parties.

8.6.2 Validation of Processes for Production and Service Provision

The Supplier must validate any processes for production and service processes where the resulting output cannot be verified by subsequent monitoring or measurement, or as directed by Physio-Control. This includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered. Validation must demonstrate the ability of the processes to achieve planned results. In the case where the organization has no validation requirements, reference the Global Harmonization Task Force Guidance on Process Validation (GHTF.SG3.N99-10, June 29, 1999). The documented validation must be made available upon request.

8.6.3 Identification and Traceability

The supplier must provide product Traceability as required by Physio-Control, so that if Physio-Control finds a discrepancy in the product, it can be contained. Traceability allows for parts to be matched to process, product and system and root cause to allow for suspect population to be identified and quarantined.

The supplier must provide Physio-Control with Certificates of Conformity (C of C) when designated in the specification. The basic information requirements on the C of C include:

- Physio-Control part number (including dash number)
- Revision of Physio-Control specification implemented at the time of manufacturing
- Lot/date code for traceability
- Quantity shipped per lot/date code

A supplier must establish and maintain documented procedures for product identification during all stages of production.

Physio-Control utilizes the supplier's lot/date code or serial number to track material installed into our products. To trace the part's history when determining the root cause and bounding of an issue, the manufacturer must use the lot/date code or serial number to identify records of raw materials, processes, operators, acceptance, test and process controls.

8.6.4 Customer Property

The supplier must exercise care with all Physio-Control property (i.e. test equipment, tooling, fixtures, etc.), including intellectual property while the supplier is controlling or using it. The supplier must identify, verify, protect, and maintain property Physio-Control provided for use or incorporation into product. The supplier must make available to Physio-Control evidence or historic records concerning Physio-Control equipment maintenance. If the supplier loses, damages, or makes Physio-Control property unsuitable for use, it must report the issue to Physio-Control. The supplier must have written consent from Physio-Control to sell or consign any tooling to another entity and must contact Physio-Control regarding potential re-qualification.

8.6.5 Preservation of Product

The supplier must preserve conformity of product during internal processing and delivery to the destination. This must include identification, handling, packaging, storage, and protection. The supplier must ensure their products are packaged and transported in a manner that prevents damage or deterioration. Suppliers must maintain documentation detailing proper packaging, cleanliness, storage, and shipping instructions on its products.

8.7 Control of Monitoring and Measuring Devices

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

9 Measurement, Analysis and Improvement

9.1 General

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

9.2 Monitoring and Measurement

9.2.1 Customer Satisfaction

A supplier must include a customer satisfaction metric when reviewing its quality management system, which is then included in the management review process. The supplier must review trends in customer satisfaction and improve its activities based on the results using a structured process improvement technique. Suppliers must use this data to drive improvements in Physio-Control's satisfaction metrics.

9.2.2 Physio-Control Supplier Audits

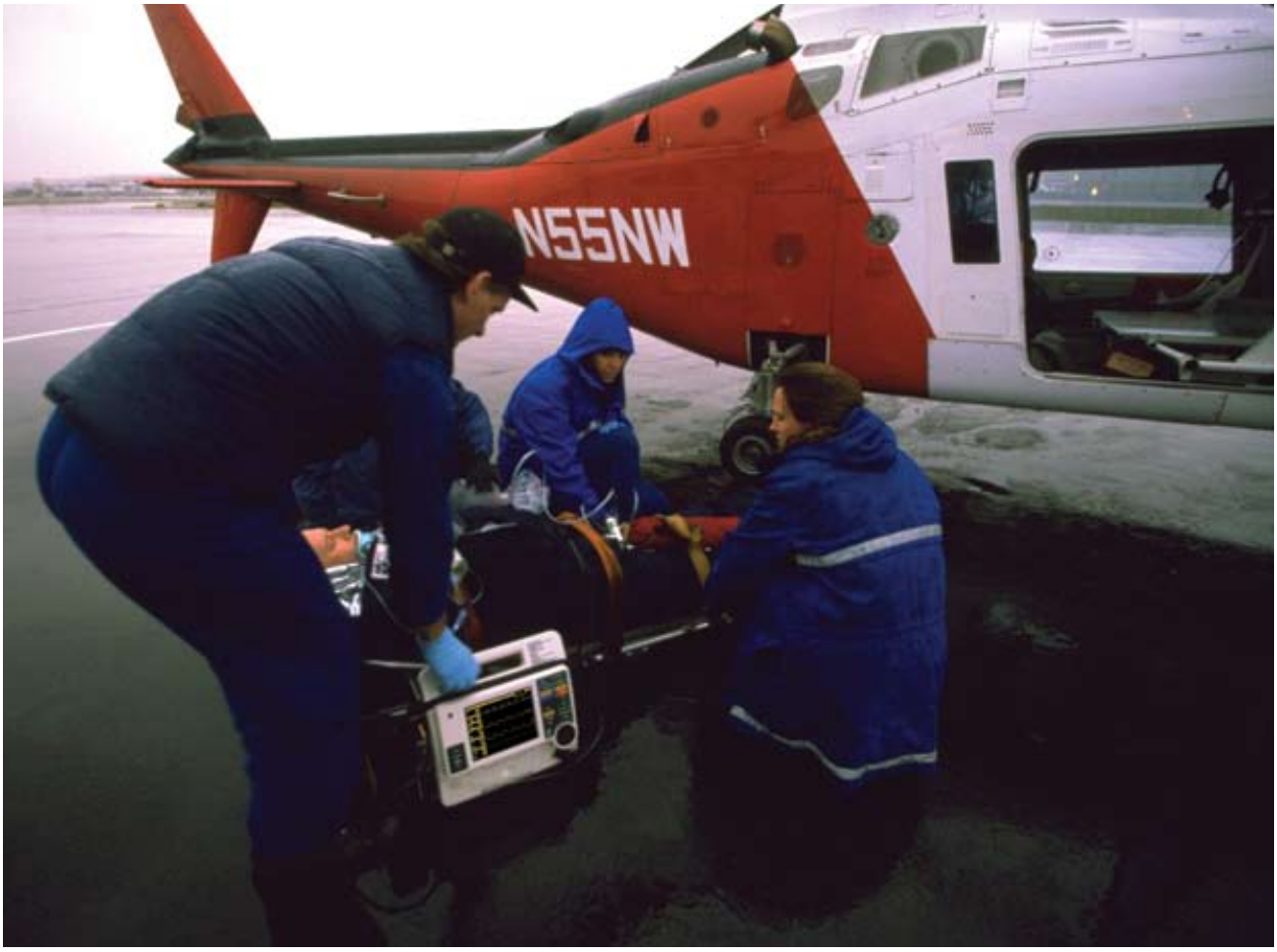
Physio-Control reserves the right to perform on-site audits of the supplier's or supply chain's facility. The supplier's personnel, processes and facilities must be made available as required during the audit. When performing an audit, Physio-Control must have access to a supplier's personnel, processes, documentation, and facilities. At the end of the audit, Physio-Control will share findings with the supplier or supply chain supplier in a closing meeting and issue them a report summarizing the results. The report will clearly note any items requiring corrective action. The supplier must then submit to Physio-Control a corrective action plan to address these issues within the agreed-upon time.

9.2.3 Monitoring and Measurement of Processes

A supplier must determine and implement measurements necessary to monitor processes critical to product quality. Mistake-proofing activities will be considered a method of control. If mistake proofing is not feasible, statistical techniques must be used to monitor the process. The charting of the monitored variables must be completed by the person(s) able to take action on the process. A written procedure describing actions to take when out-of-control conditions exist must be present. Documentation must show evidence that proper techniques were followed by the owner of the process. Review of process monitoring techniques must be made available to Physio-Control personnel upon request.

9.2.4 Monitoring and Measurement of Product

A supplier must integrate product measurements and monitoring as required to confirm the products are produced properly and remain stable over time. The supplier must conduct capability studies on all key characteristics as well as on other characteristics identified by Physio-Control during such processes as design reviews, PFMEA, and process audits.



For First Articles, suppliers must use a minimum of 22 samples to establish a 90/90 confidence interval, unless Physio-Control specifies otherwise. The supplier must perform the following activities to assure Physio-Control that the product being supplied is to specification:

- Submit an initial First Article Inspection Report verifying all features are within specification or as otherwise designated by Physio-Control.
- Provide capability studies on all key characteristics as well as other characteristics identified by Physio-Control, whether produced internally or by the supply chain.
- Verify products comply to the Control Plan unless otherwise directed by Physio-Control.
- Track the material and processes for Physio-Control part numbers.

9.3 Control of Nonconforming Product

The supplier must establish and maintain documented procedures to ensure that proven or suspected non-conforming products and material are prevented from unintended use or installation. This control must identify, document, evaluate, isolate, document disposition of non-conforming products, and define the notification of the departments concerned (both internal and external).

If Physio-Control finds non-conforming parts, either through incoming inspection, use, consumption, assembly, or warranty claims; the supplier must provide the resources necessary to evaluate, contain, sort, rework, and/or scrap the nonconforming product. This may involve sending a representative to the Physio-Control site at the supplier's expense. The supplier must provide a representative to help establish containment of the material at the Physio-Control factory, warehouse, in transit, and at the supplier within 24 hours. Physio-Control may require a quicker response based on the severity of the situation.

If non-conforming products become incorporated into Physio-Control products or become a warranty problem, the supplier must assist Physio-Control in evaluating and correcting the problem.

9.3.1 Customer Information

The supplier must notify Physio-Control immediately if a non-conforming product has been shipped. Even if the supplier is not certain if the product has shipped, Physio-Control must be notified immediately.

9.4 Data Analysis

Physio-Control requires our suppliers to obtain appropriate data and apply statistical and problem-solving techniques to solve problems and to drive continuous improvement activities. During this process, the supplier must analyze the following:

- Results achieved
- Internal and external product failures (including warranty)
- Unfavorable process or product quality trends
- Supply chain (including sub-tier supply chain) quality performance

The supplier must make a summary of its quality performance available to all of their employees, and quality performance data to Physio-Control upon request.

9.5 Improvement

9.5.1 Continual Improvement

The supplier must use evidence to demonstrate how data, past experience, and lessons learned show continuous improvement of its quality management system.

9.5.2 Corrective Action

Suppliers must take corrective action to eliminate non-conformities. When the non-conforming part adversely affects the form, fit or function of our devices or demonstrates an unfavorable trend, Physio-Control issues a supplier corrective action request (SCAR). To fulfill the SCAR, the supplier must:

- Acknowledge receipt of a SCAR within 24-48 hours and describe containment actions
- Provide situation updates within an agreed-upon time defined at the supplier's first response
- Complete a root-cause analysis within three business days from the date of notification, and have a plan to create an effective and robust corrective and preventive action

9.5.3 Preventive Action

Suppliers receiving a SCAR must establish a preventive action process that eliminates the cause(s) of potential nonconformities and focuses on building good quality into the product and processes to ensure that any further non-conforming products never reach the customer.

10 Restriction of Hazardous Substances (RoHS)

Physio-Control is responding to the European Union's RoHS directive and is concerned about the effects of RoHS on medical device performance and reliability. Currently, medical devices are exempt from RoHS requirements. However, representations are sometimes made by component manufacturers and material suppliers that RoHS and non-RoHS items are interchangeable.

As a supplier to Physio-Control you must assume that RoHS and non-RoHS parts are not interchangeable. Physio-Control has changed some designs to allow the selective use of RoHS parts, materials, and assemblies; however, the vast majority of our designs require the continued use of non-RoHS items.

The authority to determine the interchangeability of RoHS and non-RoHS items in our products rests solely with Physio-Control. This authority has not been delegated to any supplier.

If your organization desires to change a part, material, or assembly to meet RoHS requirements, you must submit an RDC to Physio-Control per section 8.3.5.

Appendix A

Document Distribution, Control, and Usage

Purpose

This document provides assistance to Physio-Control suppliers in fulfilling the Documentation Requirements section of the Physio-Control Supplier Quality Standard.

Scope

This document is an informal summary and provides suggestions. In all cases, the Purchase Order and the Master Purchase Agreement are the governing documents. Questions and ambiguities should be resolved with the Physio-Control Buyer or Supplier Quality Engineer.

Document Distribution

Documents are typically sent to the supplier by Physio-Control Purchasing or Physio-Control Configuration Management departments. Upon receipt of the documents, the supplier should first inspect the document package and make note of its release status.

Each document should be accompanied by its own Document Approval/Status Page. The Lifecycle Status section indicates the document's release status. Only documents with the Lifecycle Status of "Released" can be use for production. Suppliers should then place the documents into their own document control system.

Document Control

Suppliers should have a document control system that is capable of assuring positive control of documents and their usage. Those people using documents under the supplier's direction should have ready access to the correct documents to perform their tasks. Suppliers should assure that their sub-tier suppliers and contractors have documents that are necessary and sufficient to perform their tasks.

Configuration Management

Document revisions should be controlled by the supplier's configuration management system to assure that Physio-Control Purchase Orders are entered, planned, built, tested, and inspected to the correct documentation.

Document Interpretation

Physio-Control documents are intended to be complete and self-explanatory. Questions and clarifications regarding document content, change effectivity, etc. should be directed to the Physio-Control Buyer.

Change Requests

Documents that the supplier believes needs to be revised should be discussed with the Buyer and if appropriate, the supplier should submit a Request for Design Change (RDC) form to Physio-Control.

Appendix B

PCBA Process Requirements

Purpose

The objective of this Appendix is to clearly define Physio-Control process requirements in regards to prevention of ionic contamination on Physio-Control Printed Circuit Board Assemblies (PCBAs) and Physio-Control requirements for control of PCBA rework and Special processes.

Scope

The requirements defined in this document apply to all PCBAs designed by Physio-Control. Any modification to process or change in material requires an approved Request for Design Change (RDC) prior to implementation.

Background

Physio-Control products are affected by contamination and therefore Physio-Control must dictate requirements to control their source.

Physio-Control recognizes that rework and repair processes present a higher risk to product reliability than do standard assembly processes. These processes require exceptional attention. The most common cause of out-of-control use of chemistries is during rework or repair. All solder chemistries used for rework or repair must be controlled and documented as defined herein, with particular attention on the use of liquid flux.

Requirements

Process Chemistry Requirements

It is of utmost importance to control the chemistries used to assemble Physio-Control PCBAs, since certain residues have the potential to become ionic. Therefore, Physio-Control must review and approve all solder, fluxes, chemistries, processes and associated operations that have the potential of leaving residues on the surface of Physio-Control products. These include but are not limited to solder paste, solder fluxes, cored wire solder, solvents, cleaners and assembly or rework aids. Whenever possible hand soldering should be avoided and the use of cored wire solder is preferred.

No additional liquid flux, clean or no-clean from squeeze bottles is allowed in any soldering operation (i.e. component side of wave soldering, hand soldering or SMT reflow). There will be no cleaning of no-clean flux. Any exceptions must be approved in writing by Physio-Control. Requests must be submitted via the RDC process. Only flux applied to the bottom side by normal spray or foam machine application may be used for wave soldering of Physio-Control boards. Selective pallets shall not be used in conjunction with a no-clean wave solder process.

Chemistries must be properly marked and clearly distinguishable. All operators and support personnel that work on Physio-Control products must be trained in the differences between flux chemistries and the results of an incorrect application of flux. This training must be documented. Work instructions must clearly define the chemistries to be used throughout all operations. Deviations from any of the requirements stated herein must be approved by Physio-Control prior to implementation.

Operators must wear clean gloves or finger cots and must handle PCBAs by the edges whenever possible. Process monitoring of cleaning and soldering operations must be defined, approved by Physio-Control and strictly enforced as part of an overall control plan.

Rework/Special Process Requirements

All rework processes, be it standard (resolving in-line defects) or non-standard (i.e. engineering fixes, substantial rework or upgrades), requires a risk analysis (e.g. Failure Modes Effects Analysis (PFMEA)) and associated process control plan (PCP). Non-standard rework or repair requires approval from Physio-Control prior to implementation. Operators performing rework or repair must receive explicit training on the rework and the effectiveness of their training must be documented. Line clearances must also be an integral part of the process to insure no mixing of material or chemistries.

We envision a society in which no person dies suddenly as a result of a cardiorespiratory event.

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