



A Whitepaper from ReMedPar

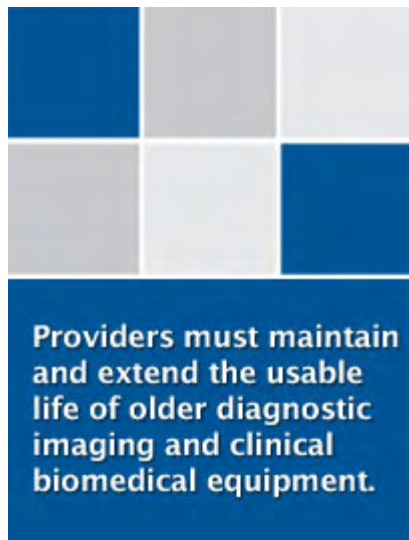
A New Focus on Supplier Quality: Medical Equipment Aftermarket Support

Lynne Wallace
Supply Chain Director
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Introduction

Focus on Supplier Quality has traditionally been concentrated in the Original Equipment Manufacturer (OEM) factory production. In recent years, however, the expectations of Independent Service Organizations (ISOs), Comprehensive Asset Management Providers and Value-Added Third Parties/Sub-Contractors dealing in the aftermarket service and spare parts support for equipment has grown exponentially. This trend is becoming more and more apparent in the medical equipment aftermarket service and support industry.

Current economic conditions coupled with the pressure to reduce healthcare costs and the need to provide affordable medical care for all individuals has resulted in healthcare providers being more vigilant about new equipment purchases. Therefore providers must maintain and extend the usable life of older diagnostic imaging and clinical biomedical equipment. This decision has created the need for an in-hospital repair strategy and the ability to contract with quality-driven, stalwart and cost-effective ISOs. Increasing demand for companies to provide comprehensive asset management of older medical equipment results in the growing market sector referred to as Multi Vendor Services.



Targeting Modalities/Products Helps Focus on Quality

Due to the diversity of medical equipment and medical OEM's technical innovations, the companies that support the service providers usually target particular OEM medical modalities or product models. Few companies are making the commitment and financial investment to support multi-modality medical OEM equipment.

Companies that have targeted specific modalities and equipment to support appear to be actively implementing quantifiable quality systems. The endeavor can be anything from a home-grown set of sustainable policies and procedures modeled after industry recognized quality standards to the commitment to pursue any of a number of agency certifications. Certifications include: FDA current Good Manufacturing Practice (cGMP), FDA 21 CFR Part 11, FDA Quality System Regulation for Devices Part 820, International Organization for Standardization (ISO) ISO 9001 Standard for Quality Management, and the ISO 13485 Medical Device Standard. In addition, there's been an increased interest to participate in the ISO 14001 Environmental Management Systems (EMS) Standard as the Medical OEMs encourage eco-friendly workplaces.



Taking Support to the Next Level

The companies involved in the medical equipment aftermarket range from used equipment dealers to value-added third parties. The differentiator for participants in this expanding market sector is a small, select number of companies that have an appetite to take the support of medical equipment repair to the next level. These companies are strategically investing in used medical systems that are, at the time of acquisition, verified to be in compliance with OEM performance specifications.



The serious competitor in this industry needs not only a sustainable quality system internally but also needs to flow this requirement to their sub-tier supplier base.

The investment does not stop there for the company that leads the way into this new world of quality focused aftermarket equipment servicing. Additional investment is needed for training of staff, reverse engineering, appropriate test equipment, tools and related resources to support a broader range of diagnostic imaging and select clinical biomedical equipment. Included in this expansion of repair capability is the commitment to assure world class quality parts and assemblies at a competitive price. This sophistication can only be achieved by the company embracing the same Supplier Quality criteria and goals as the Medical OEM.

ISO Compatible Quality Systems

Pursuing ISO certification is part of this distinction. ISO 9000 standards do not specify requirements for the goods or services that are to be purchased. It is the responsibility of the company to define and clearly communicate to their suppliers the needs and expectations for the goods and services required. There are 20 elements that comprise an ISO compatible quality system that meets the requirements for agency certification.



Management Responsibility	Quality System	Contract Review	Design Control
Document Control	Purchasing	Handling of Purchaser Supplied Product	Product Identification and Traceability
Process Control	Inspection and Testing	Inspection, Measuring and Test Equipment	Inspection and Test Status
Control of Nonconforming Product	Corrective Action	Handling, Storage, Packaging and Delivery	Quality Records
Internal Quality Audits	Training	Servicing	Statistical Techniques

The serious competitor in this industry needs to not only have a sustainable quality system internally but also needs to flow this requirement to their sub-tier supplier base.

Because of the unique nature of the Medical Multi Vendor Services market, the supply chain's respective business models can vary based on capital and resource investment. Although portions of the ISO elements can be imposed on the supplier, the actual adherence to the ISO quality system requires the company to assess potential suppliers and classify the respective supplier based on their business model.

To try and qualify potential suppliers using all of the 20 elements identified above would result in the inability to have a sufficient supply base to meet the customer needs. Dealing with older and end-of-life medical equipment by various OEMs in multiple modalities is cost prohibitive to the typical supplier entering into this industry.



Supplier Quality and Part Class Distinction

Suppliers that support the Medical Multi Vendor Services market usually fall into the following **Supplier Part Classes**:

- ▶ **0 – USED** – Untested, no reconditioning, used as is, no or minimal warranty (possible recourse only if supplier provided incorrect or different part than ordered).

- ▶ **1 - USED / TESTED** - Tested, known good working part at time of de-installation at system's end-user facility (hospital, medical clinic, doctor's office, etc.), no reconditioning, no traceability. Industry norm is one turn/sale of component/assembly.

- ▶ **2 - USED / TESTED / TRACEABILITY** - Tested, known good working part at time of de-installation at system's end-user facility (hospital, medical clinic, doctor's office, etc.), no reconditioning, documented procedure and traceability to system by serialization with a documented process to track the verification of system readiness and a basic documentation trail that is completed and signed by the de-install crew and controlled by the supplier. Industry norm is one turn/sale of component/assembly.

- ▶ **3 - USED / TESTED WITH QA** - Tested, known good working part at time of de-installation at system's end-user facility (hospital, medical clinic, doctor's office, etc.), no recondition, documented procedure and traceability to system by serialization (per 1a class above), re-tested on supplier-owned test system and/or qualified test equipment prior to inventory storage and/or shipment to customer. Industry norm is one turn/sale of component/assembly.

- ▶ **4 - RECONDITIONED WITH QA** - Known good working part at de-install, reconditioned at supplier facility, tested on supplier-owned system and/or qualified test equipment, ESD protected throughout complete recondition process into

inventory and out for shipment to customer. Class 3 is preferred as this covers reconditioned equipment to OEM standard.

- ▶ **5 – NEW** – Not reconditioned/used. Tools, Test Equipment, Consumables, Accessories, Distributor Parts, Manufactured Parts, Original Design Manufacturer (ODM) Parts and Medical Original Equipment Manufacturer (OEM) with verification "new part" at time of order placement.



This class distinction drives the level of expectations for a supplier’s quality system. To effectively develop a Supplier Quality program, the company must be able to identify and assess the supplier’s business model. An assessment that results in the supplier’s part class to be a 1 or 2 category does not indicate a sub-standard supplier. If the supplier documents policies and processes, exhibits management and employee involvement and actively pursues a sustainable quality program, then the part class level and associated risks is minimized. The propagation of suppliers in the Part Class 1 and 2 levels reflects the most common business model.

Few suppliers invest in equipment to use as test beds to allow the final performance verification prior to shipment to their customer (Part Class 3). The advertised statement that the parts are “tested” at the supplier is more often than not based on the part being harvested from a known working system without follow-on testing. The handling of the part, ESD protection, packaging, storage and shipment methods to prevent damage and preserve the integrity of the part become the primary focus for a sustainable quality system.

Conclusion



As the Medical Multi Vendor Services business becomes a financially attractive option to the end customers, the awareness of the need to establish a quality-driven supply chain is becoming more evident. There are a few companies that have the level of expertise and infrastructure to verify the performance integrity for reconditioned parts (Part Class 4). By establishing a sustainable quality management system and obtaining the ISO certification that complements their business model, these companies have positioned themselves to become the industry leaders in the dynamic Medical Multi Vendor Services marketplace.



About ReMedPar

Founded in 1987, ReMedPar is the leading third-party medical parts provider for aftermarket diagnostic imaging and biomedical engineering equipment. For over 20 years ReMedPar has delivered on its mission to provide high quality and cost effective parts to keep critical equipment running. ReMedPar is unique in that we are not merely a part sourcing organization but a business with a long heritage in technical capabilities, extensive investment in quality assurance, and an expansive tested inventory line up. Our commitment to technical expertise is manifested in the many aspects of our business from parts identification, on time delivery of quality parts to in-depth technical training classes and unparalleled technical support. This results in quality parts that you can count on at the most cost effective price. For more information, visit www.remedpar.com or call us at **1-800-624-3994**.



ReMedPar
101 Old Stone Bridge
Goodlettsville, TN 37072

www.remedpar.com
1-800-624-3994

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