Carestream

Supplier Manual

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1. Introduction

The purpose of this manual is to define the requirements for doing business with Carestream Health Inc. (Carestream Health Inc. and its affiliates shall be referred to herein as “Carestream”), and to outline processes used to ensure our supply base is continually improving to provide Carestream the lowest cost, top level service, highest quality products and exceptional delivery performance.

Implementation of the processes outlined in this manual will not only reduce risk of supply chain disruptions but will also help Carestream and its suppliers to increase our competitive industry position and ensure our continued success.

2. Scope

This manual applies to all Suppliers of materials and services to Carestream on a worldwide basis. Any questions regarding the applicability of the requirements contained in this manual should be directed to your Carestream Commodity Manager.

3. Guiding Principles

A. Carestream Quality Policy

Carestream Health is committed to providing quality products, services and solutions that satisfy customer, statutory and regulatory requirements for medical, dental, and non-destructive testing film and imaging systems, and contract manufacturing. This is accomplished by managing risk to continually improve the safety and quality of our products, and the effectiveness of the quality management system.

B. Carestream Purchasing Policy

The policy of Carestream Health, Inc. is to obtain the best value for the materials, goods, and services that it purchases, and to maintain the highest ethical standards in dealing with its suppliers. Value includes price, quality, and service. Purchasing Departments are the sole authorized agencies of Carestream Health and its subsidiaries for the procurement of materials, goods, and services. All buying, including commitments to buy and related activities, will be handled by the Purchasing Departments. More information can be found at:

Carestream Purchasing Policy

4. Supplier Selection and Approval

Carestream will select suppliers that are capable of meeting Carestream requirements for quality, delivery, and cost effectiveness. During the selection process, Carestream will require information as described below and potentially additional information depending on the material or service provided.

- Supplier Profile (name, address, etc...)
- Pricing Quotation (various quotation processes such as reverse auctions may apply)
- Quality System Assessment (may be on-site or survey depending on risk category)
- Capability qualifications regarding the materials or services to be provided
- Financial Assessment

The decision to select a supplier may include many cross-functional team members. Final selection is based on the results of the aforementioned processes. Some suppliers will be accepted with conditions

that must be addressed before awarding of business. Upon approval, suppliers will be added to the Approved Supplier List (ASL).

5. eCommerce

Carestream embraces the use of technology to streamline and add efficiencies to the procurement process.

Our portal used for placing orders, order acknowledgement and invoicing is called EZCollab. Please contact your local Commodity Manager to find out how to switch over to EZCollab.

Carestream conducts e-auctions from time to time and as a Carestream Vendor, your organization may be called upon to participate in an online event.

6. Sub-Tier Suppliers

Supplier may not engage any subcontractor without the prior written authorization of Carestream. It is the responsibility of the supplier to manage the quality of all sub-contractor operations. All quality requirements described in this manual are also to be applied for sub-contractors. All documents, registers and audit reports must be kept available by the supplier and/or submitted for Carestream evaluation when required.

When changes are communicated to Carestream suppliers from their direct suppliers (i.e., sub-tier suppliers) which have potential impact to the material of construction, design, form, fit or function or have potential impact on safety, quality, identity, potency, or purity of the products supplied to Carestream, it is the obligation of the Carestream supplier to notify Carestream of such changes. Carestream suppliers should have an appropriate system in place to ensure that they will be informed by their suppliers of any changes that may potentially impact the Carestream approved part, design, and/or quality requirements.

7. Quality System Requirements

To become an approved supplier, the supplier must first exhibit proof of an acceptable Quality Management System (QMS) that gives the assurance of a commitment to quality and to continuous improvement. This is accomplished by completing a Quality System Assessment either on-site or by a survey. Other evaluation methods may be utilized for unique services such as individual consultants, service providers working within the Carestream QMS, and other unique service suppliers.

A. Supplier Quality Assessments: Carestream suppliers must allow Carestream personnel or designee access to supplier manufacturing and/or testing facilities and manufacturing, testing, and quality documentation, as deemed appropriate, for the purposes of desk audits and/or on-site audits to verify the existence of a sound quality system. The Carestream Supplier Quality Assessment worksheet and survey is the primary tool used to assess the quality management system of Carestream suppliers.

B. Quality System Registrations: Carestream encourages suppliers to maintain registrations to quality system standards such as ISO 9001-2015, ISO 13485:2016, ISO/IEC 17025:2017, etc. Registration to such standards may reduce the scope of Carestream on-site or “virtual” assessments and in some cases eliminate the need for an assessment depending on the materials or services provided by the supplier.

8. Corrective Actions

When process or product non-conformances are identified to have occurred or have the potential to occur, Carestream suppliers must maintain and apply an effective closed loop corrective and preventative action system.

A. Methodology When supplier non-conformances are identified by a Carestream Manufacturing Site or Business Unit, a supplier corrective action request may be initiated. Determination of when a corrective action will be issued is the responsibility of the Carestream Manufacturing Site or Business Unit. Feedback
from the supplier shall be within the Carestream provided format. It is expected that the supplier be responsive to status and information requests. The Carestream Corrective Action Request process is as follows

- Nonconformance identified by Carestream or a customer of Carestream.
- The Carestream receiving location will issue a request for corrective action to the supplier.
- Supplier will provide a containment response to Carestream within 24 hours.
- Supplier will provide a root cause and corrective action plan response within the timeframe described on the Corrective Action Request form, or a short-term correction if a root cause is not requested.
- Supplier will provide evidence of effectiveness of corrective actions within the timeframe described on the corrective action form

B. Chargeback Non-conformances on product supplied to Carestream can have a large effect on deliveries, product performance, and ultimate Carestream customer satisfaction. In the case of a nonconformance, it is the responsibility of the Supplier to insure adequate conforming product, parts, materials or services are delivered in time to prevent any line stoppage situations. This can be accomplished in the following ways:

- Expedite shipping of conforming and certified parts so they arrive before line stoppages occur; or
- Provide sorting, repair, or rework resources to the appropriate Carestream facility in a timely fashion to prevent any line shortages.
- Carestream reserves the right to sort, repair, or rework the non-conforming material at Supplier's expense as required to ensure acceptable parts or materials are utilized and production requirements are met. All sorting will be coordinated with the Carestream production facilities by the appropriate plant personnel.

In the event that non-conforming product, parts, materials, or services result in costs to Carestream (including, but are not limited to, charges related to sort, rework, repair, product scrap, production downtime, customer-imposed charges, warranty or recall costs, shipping, Engineering effort, etc.), Carestream reserves the right to charge the supplier costs associated with the non-conformance.

9. Change Management

Managing all changes correctly is critical and must be done in a manner that minimizes potential adverse effects. Carestream requires suppliers to inform us of all supplier-related changes and in many cases get prior approval from Carestream to proceed with a change. Changes to products or services rendered which have potential impact to material of composition, design, form, fit or function or have potential impact on safety, quality, identity, potency, or purity require formal documented notification to Carestream. Notification of changes must be with a timeline appropriate for the product's supply chain lead time, but

notification must always be received by Carestream prior to shipment of the goods by the Supplier to the Carestream facility.

Unapproved changes or changes made by Suppliers without written notification to Carestream are subject to chargebacks on costs incurred related to the change.

Suppliers must have an established change control system in place to ensure appropriate timing for the change request notification for the change, traceability of the implemented change, and testing or qualification to ensure there are no negative impacts to the supplied product's quality or other performance metric due to the change in the product or service being delivered to Carestream.

Some examples of changes that may affect the quality of the product or service include the following:

- Manufacturing facility location change
- On-site relocation of established manufacturing processes
- Sub-tier supplier source/process change
- Raw material change
- Manufacturing method/process change
- Changes to machine, tool, die, molds etc.
- Inspection method change
- Major Facility/Equipment change
- Rework or sorting

Please contact your Carestream Commodity Manager if you have questions regarding a change.

10. Supplier Development

A. Performance Measurement

Carestream continuously monitors the performance of key suppliers. For quality performance Carestream sites generally will use DPPM, or DPU depending on the commodity purchased. Other KPI's (Key Performance Indicators) may be used for service suppliers. In addition to quality performance, other factors such as delivery, l1ead-time, productivity, etc. may be rolled up into a balanced scorecard.

B. Productivity

Carestream expects suppliers to work with us and independently to reduce the total cost of goods and services to Carestream on a year over year basis. Carestream expects that suppliers will have a productivity strategy they can share with Carestream that supports Carestream's productivity goals.

C. Quality Improvement

Carestream expects suppliers to have a robust continuous improvement process for material and service quality as part of their Quality Management System. Based on performance and the criticality of the material or service provided to Carestream we may require specific improvement plans for some suppliers and may partner in those plans

D. Delivery

Carestream expects suppliers to achieve 100% on-time delivery defined as 0 Days Late and 0 Days Early unless a different delivery time window has been agreed upon with the Carestream site or business unit.

11. Logistics Requirements

A. Supply Chain Integrity - This section applies to all Carestream suppliers shipping materials into the US from other international locations.

All Carestream suppliers will maintain membership in or security measures consistent with the requirements of supply chain security programs such as but not limited to Customs-Trade Partnership Against Terrorism (C-TPAT), Partners In Protection (PIP), or Authorized Economic Operator (AEO). Supplier shall use its best efforts to produce, store, handle, and ship products in a safe and secure manner, and to avoid any unauthorized access to the products which are being stored or transported on behalf of Carestream. If Supplier engages any sub-contractor, Supplier shall be responsible for ensuring that such sub-contractor complies with the same requirements to protect and secure the products and the integrity of the supply chain. Carestream and its nominated representatives shall, subject to the reasonable business security requirements of Suppliers, have the right to audit Suppliers' compliance with all of its obligations to comply. If Supplier has obtained certification for a supply chain security program administered by any Customs Administrations, Supplier will provide Carestream with proof of participation. Proof of participation should be sent to the Carestream US Import/Export department. Contact your Commodity Manager for more information.

B. Shipping Requirements

Shipping requirements from Carestream can be found on this link:

Shipping Requirements

12. Labeling, Identification and Traceability

A. Barcoding Shipping Document Requirements

To help reduce receiving errors and improve timely payments, Carestream requires all suppliers, who ship material into our receiving locations, to provide bar-coded shipping labels for each shipment that reflect the shipping content and Purchase Order detail.

Barcoding

B. UDI (Unique Device Identifier) - This section applies only to Carestream OEM and Contract Manufacturer suppliers that provide medical devices or device accessories.

The Food and Drug Administration requires that medical devices distributed in the US carry a Unique Device Identifier (UDI). The UDI is a unique numeric or alpha numeric code that consists of two parts:

i. A device identifier that identifies labeler and specific version or model
ii. A production identifier, a variable portion of the UDI that identifies one or more of lot/batch, serial #, and expiration date.

In order to be compliant, a medical device labeler must:

i. Create a Unique Device Identification code, in alignment with an overseeing Standards body
ii. Place the UDI in both human and AutoID form on the device, its label or both
iii. Provide the FDA with UDI data for inclusion in the Global Unique Device Identification Database (GUDID) for all products, maintain that record, and add new product IDs as new products are introduced.

Please contact your Carestream Commodity Manager if you have questions regarding more specifics or the applicability of UDI requirements.

C. Traceability Suppliers of product materials are required to establish a traceability system that tracks raw material lot / batch numbers to the finished product lot / batch numbers including traceability to inspection records.

D. Country of Origin It is the responsibility of suppliers to Carestream to make the determination of Country of Origin for product sold to Carestream. The Supplier is also responsible for marking the product and/or packaging with the appropriate Country of Origin marking. This should be stated as "Country of Origin _____", or "Made in_____".

13. Standard Terms & Conditions

Terms and Conditions may vary from country to country, based on local trade laws.

A. Payment Methods: Information regarding the Payment Methods available from Carestream can be found through this link:

Payment Methods

B. Invoicing: The process and requirements for Invoicing Carestream can be found through this link:

Invoicing

14. Supplier Code of Conduct

Suppliers play a vital role in Carestream's success and sustainability. The selection of raw materials, the mixing of chemical solutions, the fabrication of components, the assembly of finished goods, and the packaging prior to delivery are all examples of supplier activities that support material flowing to Carestream. It is important that these upstream activities are conducted in a manner that protects the environment, preserves human rights, and is consistent with ethical business practices. Carestream and its customers expect nothing less. Refer to these links to review the details of the Carestream Supplier Code of Conduct.

Supplier Code of Conduct (includes Conflict Mineral Reporting)

Business Conduct

15. Environmental, Health & Safety (EHS) Expectations

As defined in the Supplier Code of Conduct, Carestream Health expects that its suppliers will conduct their business in compliance with their local environmental, health, and safety regulations.

Components, materials, and finished goods are used to create products and systems for Carestream customers. These supplied items are to be compliant with national and international regulations. In order for Carestream to demonstrate compliance to restricted materials regulations, Suppliers are required to maintain documentation (testing and/or supplier documentation) regarding compliance with materials restriction requirements and respond to Carestream restricted material declaration requests. Declaration request will be made using Gensuite, a web-based platform designed to enable suppliers to provide declarations for REACH, RoHS and other restricted substances legislation.

Additional specifications for the supply of equipment, packaging, batteries, and chemicals to Carestream can be found at

EHS Supplier Expectations

16. Contingency/Business Resumption Plans

Some Carestream suppliers are required to have business interruption contingency planning. This plan should address items such as, but not limited to, natural disasters (e.g. hurricanes, tornadoes, flooding, etc.), facility downtime (e.g. due to union strike, fire damage, computer system failure, etc.), sub-tier supplier interruptions and logistics failures. Suppliers where Contingency or Business Resumption Plans are required will be contacted by their Carestream Commodity Manager.

17. Data Privacy and Information Security

Carestream and its Suppliers should respect the privacy rights of everyone you do business with, including your suppliers, customers, consumers, and employees. You are responsible for complying with all relevant data privacy and information security laws and regulatory requirements when handling (collecting, storing, processing, transmitting, or sharing) the personal data of others, including patient information or other customer confidential information when performing services for Carestream.

18. Supplier Diversity

We at Carestream Health, Inc. consider it vitally important to enhance our diverse supplier base. Compliance to US government mandate is important, but first and foremost is our obligation to the communities that include our customers. Carestream Health is committed to being a leader in promoting supplier diversity. Engaging diverse suppliers gives Carestream Health the advantage of tapping the best, most agile and innovative companies.

Supplier Diversity

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