

DOCUMENT NUMBER 91-3001	REVISION C	TITLE Supplier Management	REV DATE 10/2021	Page 1 of 4
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1.0 Purpose of Procedure

This document describes Product Resources' supplier management process. It provides for a procedure and assigns responsibilities.

2.0 Scope of Process

The process includes suppliers of both material for product as well as suppliers of services which impact the QMS.

3.0 Process Owner(s)

- 3.1 Manufacturing Manager
- 3.2 Purchasing Manager
- 3.3 Supplier Review Board (SRB)

4.0 Procedure

4.1 Supplier Selection, Qualifications, and Rating Categories

Suppliers are selected on the four requisites of Quality, delivery, price, and service.

Supplier qualifications and rating categories are maintained by Purchasing within the Vendor module of the manufacturing computer system. Every supplier shall have a category stored in the Vendor Type field of the supplier's record. Seven rating categories are currently used:

- 4.1.1 Evaluate: This category is for new suppliers who manufacture custom products to Product Resources' specifications or whose materials-related services are used in the manufacturing process. These suppliers are placed in the Evaluate category for at least one complete quarter or until the SRB has sufficient delivery and quality data on which to base a reclassification. Such suppliers who have been inactive for some time or undergo significant organizational change may also be returned to Evaluate as effectively new suppliers. Code EVAL
- 4.1.2 General: Suppliers whose materials or services (i.e., office supplies, cleaning supplies, etc.) are not used in the manufacturing process and which do not fit the below service provider definition are placed in the General category. Code GENRL
- 4.1.3 Customer: Customers who supply materials that are used solely in products sold to them (customer supplied material, or CSM) are placed in the Customer category. Code CUST
- 4.1.4 Approved-Custom: Suppliers who manufacture parts to Product Resources' specifications (or whose materials-related services are used in the manufacturing process) and who have met Product Resources' standards for Quality and on-time delivery (as determined by the SRB) are placed in the Approved-Custom category. A Supplier Assessment Questionnaire (implemented within Product Resources' QMS software) shall be complete and on file before any Evaluate supplier is moved to Approved-Custom. Code A-C

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- 4.1.5 Approved-Standard: New suppliers of standard catalog items (parts or services not delivered according to Product Resources' specifications, many of which are distributors) are initially placed and are maintained in the Approved-Standard category. The Supplier Assessment Questionnaire is not required for these suppliers. Code A-S
- 4.1.6 Probation: Suppliers who have failed to meet Product Resources' standards for Quality or on-time delivery for two or more consecutive quarters and at the SRB's discretion, are placed in the Probation category. Purchasing uses discretion when placing orders with suppliers in the probation category. Code P-Q for quality, Code P-D for delivery, Code P-D/Q or P-Q/D for both quality and delivery
- 4.1.7 Unapproved: The SRB determines which suppliers are placed in the Unapproved category. This is normally due to a history of non-performance, unsuitable business practices or, in the case of custom materials, the supplier has not been used for several years. Purchasing is not to purchase from these suppliers. Any supplier placed in this category will be treated as a 'new' supplier if reclassified. Code UNAPP

There are occasionally extenuating circumstances when an Unapproved supplier must be used – the supplier has the only available inventory, the supplier is the sole source of a part, etc. The use of an Unapproved supplier, when necessary, must be approved by management on a case by case basis.
- 4.1.8 Service Providers: This category is for companies that provide a service to Product Resources that impacts Product Resources' execution of the QMS, such as calibration providers, design services, software, certification, etc. Service providers are not evaluated through the Supplier Review Board. Code SERPRO

4.2 Supplier Review

The SRB (Supplier Review Board) meets quarterly to assess the performance of Product Resources' suppliers. The SRB consists of the Quality Assurance Manager, the Purchasing Manager, purchasing agents, and any others at the discretion of the QA and Purchasing Managers. The SRB shall apply the following standard: Product Resources' goal is to have all suppliers achieve an on-time delivery rate of 95% or better and a product acceptance rate of 98% or better. Delivery criteria shall be -14, +0 days. All suppliers used in a given quarter shall be mailed a report card and shall be examined by the SRB. An electronic copy of the report card shall be stored on the company file server. Reference procedure 43-2250 for instructions on generating report cards.

The SRB applies the following guidelines:

- 4.2.1 Suppliers in the Evaluate, Approved, or Probation categories with unacceptable delivery or Quality performance for that quarter shall be notified at the discretion of the SRB.
- 4.2.2 Customer Suppliers Performance data shall be forwarded to Sales for any supplier in the Customer category with unacceptable delivery or Quality performance for that quarter. Purchasing shall directly handle the account if Purchasing is communicating directly with the customer.
- 4.2.3 General Suppliers If it becomes necessary to purchase materials or services for use in the manufacturing process from a supplier in the General category, the

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supplier shall be reclassified into the Approved, Evaluate, or Probation categories by the SRB based on past performance.

4.2.4 Evaluate suppliers may be reclassified into either the Approved or Probation categories by the SRB based on the past performance of at least one quarter. If the SRB lacks sufficient performance data, the supplier may be kept in the Evaluate category.

4.2.5 Suppliers are reclassified at the discretion of the SRB.

4.3 Adding Suppliers

Refer to 43-4496, Creating Suppliers in SyteLine, for details and requirements for creating new suppliers in the manufacturing computer system. New suppliers are placed in either the Evaluate, General, Customer, Approved-Standard, or Service Provider categories; see their definitions above. When a new supplier is added to the Evaluate category, the supplier shall complete a Supplier Assessment Questionnaire implemented via the QMS software. Purchasing is responsible. If the supplier is visited, Product Resources personnel may elect to complete the Supplier Assessment Questionnaire instead. New suppliers are given a copy of the Supplier Guidelines Manual 43-2248 (and this document is referenced on purchase orders).

When a supplier is added to the Service Provider category, the Product Resources party making or responsible for the supplier selection shall complete the Service Provider Questionnaire (80-3010) and is responsible. New service providers do not use the Supplier Assessment Questionnaire and are instead initiated with this special-purpose questionnaire that is primarily concerned with the suitability of the supplier to perform the outsourced service. Completed Service Provider Questionnaires are routed to Purchasing for archiving. They are stored on the Purchasing drive in the Service Provider Questionnaires area.

Suppliers that are ISO 9001 and/or ISO 13485 registered shall be given priority when choosing new suppliers. Suppliers chosen for part numbers suffixed with ATEX_Critical and MD_Critical shall be ISO 9001 or ISO 13485 registered by a recognized registrar and must provide valid (in-date) certificates.

4.4 Maintenance of Suppliers

All suppliers shall be reviewed quarterly via the Supplier Review Board process. Suppliers with vendor code A-C from which material has not been received for over three years shall be moved to vendor code UNAPP and treated as a new supplier. Any suppliers that have not been used for a period of ten years or more may be purged from Product Resources ERP system. Suppliers are updated when new revisions of the Supplier Guidelines Manual are released.

Suppliers of ATEX_Critical and MD_Critical items shall be reassessed at least annually, even if continuously active, to verify that those suppliers continue to meet the requirements for providing such product. See the Supplier Guidelines Manual for a description of additional requirements for suppliers of ATEX_Critical and MD_Critical items.

Purchasing conducts the reassessment for ATEX_Critical and MD_Critical suppliers each January. Reassessment requires that a new supplier questionnaire be completed as well as a review that the supplier ISO quality certification is current. Product Resources' calendaring system is used to provide an annual reminder to Purchasing and Quality. Reassessment follows the same process as initial assessment; see Supplier Selection and Adding Suppliers above.

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5.0 Control of Records

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.