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WRITTEN BY: JMC/JS	DATE:	APPROVED BY: JS	DATE:	
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1.0 Purpose

This procedure describes the means by which Product Resources chooses and assesses its suppliers.

2.0 Policy

Product Resources only purchases product destined for manufacturing from suppliers and subcontractors which satisfy Product Resources' Quality and delivery requirements. Product Resources maintains special requirements for suppliers of printed circuit boards, printed circuit board assemblies, cable and wire assemblies, calibration services, and suppliers of critical components of ATEX-Directive-regulated and Medical-Device-Directive-regulated product. Requirements are communicated to suppliers via the Supplier Guidelines Manual.

3.0 Responsibility

The Purchasing Manager has responsibility for Purchasing with the Manufacturing Manager having ultimate responsibility. The Supplier Review Board (SRB) is responsible for the assessment of suppliers.

4.0 Associated Documents

Form 80-1038, Supplier Assessment Questionnaire
 Procedure 43-2184, SRB Report Definition
 Procedure 43-2250, Generating Supplier Report Cards
 Procedure 43-2248, Supplier Guidelines Manual
 Procedure 43-4496, Creating Suppliers in SyteLine

5.0 Supplier Selection/Qualifications and Rating Categories

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

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

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- 5.1 *Evaluate* This category is for new suppliers who manufacture custom products to Product Resources' specifications or whose 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. *Code EVAL*
- 5.2 *General* Suppliers whose materials or services (i.e., office supplies, cleaning supplies, etc.) are not used in the manufacturing process are placed in the General category. *Code GENRL*
- 5.3 *Customer* Customers who supply materials that are used solely in products sold to them are placed in the Customer category. *Code CUST*
- 5.4 *Approved-Custom* Suppliers who manufacture parts to Product Resources' specifications (or whose 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. Form 80-1038 shall be complete and on file before any Evaluate supplier is moved to Approved-Custom. Evidence of having this form on file shall be maintained by having the revision of the questionnaire entered into the Status field in the vendor's record within the manufacturing computer system. *Code A-C*
- 5.5 *Approved-Standard* New suppliers of standard catalog items (parts or services not delivered according to Product Resources' specifications) are started in the Approved-Standard category. Form 80-1038 is not required for these suppliers. *Code A-S*
- 5.6 *Probation* Suppliers who have failed to meet Product Resources' standards for Quality or on-time delivery for two or more consecutive quarters, or as determined by the SRB, are placed 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*
- 5.7 *Unapproved* The SRB determines which suppliers are placed in the Unapproved category. Purchasing is not to use these suppliers. However, 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 must be approved by management on a case by case basis. *Code UNAPP*

6.0 Supplier Review

The SRB meets quarterly to assess the performance of Product Resources' suppliers. The SRB consists of the Quality Assurance

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Manager, the Purchasing Manager, purchasing agents, and any others at the discretion of the QA and Purchasing Managers. All documentation created during the review process is filed per 90-2000-4.2.4, Control of Records. 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:

- 6.1 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.
- 6.2 *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. See 90-2000-7.5.4 for information about customer supplied materials and responsibilities.
- 6.3 *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 supplier shall be reclassified into the Approved, Evaluate, or Probation categories by the SRB based on past performance.
- 6.4 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.
- 6.5 Suppliers are reclassified at the discretion of the SRB.
- 6.6 SRB meeting minutes shall be filed per 90-2000-4.2.4, Control of Records.

7.0 Purchasing Requirements

Data pertaining to the placing of a supplier in the Unapproved category shall be placed in the Notes field of the supplier's record in the Vendor module of the manufacturing computer system.

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Purchasing agents use discretion when placing orders with suppliers in the Probation category.

8.0 Adding Suppliers

- 8.1 Refer to 43-4496, Creating Suppliers in SyteLine, for details and requirements for creating new suppliers in our ERP system.
- 8.2 New suppliers shall be placed in the Evaluate (for suppliers of custom items), General, Customer, or Approved-Standard categories.
- 8.3 When a new supplier is added to the Evaluate category, the supplier shall complete form 80-1038, Supplier Assessment Questionnaire. If the supplier is visited, Product Resources personnel may elect to complete the form instead.
- 8.4 New suppliers are given a copy of the Supplier Guidelines Manual 43-2248 (and this document is referenced on purchase orders).
- 8.5 Suppliers that are ISO 9001 and/or ISO 13485 registered shall be given priority when choosing new suppliers.
- 8.6 Suppliers chosen for ATEX_CRITICAL items must be ISO 9001 registered by a recognized registrar and must provide valid (in-date) certificates.
- 8.7 Suppliers chosen for MD_CRITICAL items must be ISO 9001 registered by a recognized registrar and must provide valid (in-date) certificates.

9.0 Maintenance of Suppliers

- 9.1 All suppliers shall be reviewed quarterly via the Supplier Review Board process. See above for details.
- 9.2 Suppliers from which material has not been received for over one year shall be reassessed per 80-1038 before placing a new order.
- 9.3 Suppliers are updated when new revisions of the Supplier Guidelines Manual are released.
- 9.4 Suppliers of ATEX_CRITICAL items shall be reassessed at least annually 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 items.

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Purchasing conducts the reassessment for such suppliers each January. Product Resources' calendaring system is used to provide an annual reminder to Purchasing and QA.

- 9.5 Suppliers of MD_CRITICAL items shall be reassessed at least annually 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 MD_CRITICAL items.

Purchasing conducts the reassessment for such suppliers each January. Product Resources' calendaring system is used to provide an annual reminder to Purchasing and QA.

- 9.6 Reassessment follows the same process as initial assessment; see Adding Suppliers above.