

▶ *Hanover Risk Solutions*

Component Suppliers

Product manufacturers typically purchase raw materials, parts, assemblies, or other components from external suppliers. As a general rule, the manufacturer or assembler will be liable for injuries or damage proximately caused by the use of defective components. This report provides recommendations for establishing vendor controls and highlights areas to consider when evaluating existing programs. Because of the broad range of purchasing systems and transactions, not all recommendations may be applicable or appropriate for all situations.

Product manufacturers typically purchase raw materials, parts, assemblies, or other components from external suppliers. The manufacturer then transforms or assembles the components into more complicated finished products that are offered for sale.

Components may be “off-the-shelf” items that have been produced according to a standard specification (e.g., bolts made to ASTM E-XXXX) or be custom components produced to the purchaser’s engineering specifications. In addition, component parts may themselves be manufactured from components manufactured by another.

The quality of components can directly influence the quality and reliability of the finished product. One home appliance manufacturer traced 75 percent of all its warranty claims to the poor quality of purchased parts that they used in the product.^[3] The use of poor quality components for safety-critical applications may also lead to product-related injuries and property damage. As a general rule, the manufacturer or assembler will be liable for these losses.

There are two main arguments for holding the finished product manufacturer liable for damages caused by the use of defective components. First, all product manufacturers have a duty to test and inspect their products to determine whether they were produced and assembled correctly and the failure to perform tests, or to test adequately, can indicate that the manufacturer was negligent. Second, a manufacturer is responsible for putting the product on the market and, as a matter of policy, should be held accountable for any harm caused by the product because of product defects.

This report provides recommendations for managing the liability that can be created from the use of components purchased from external suppliers. These recommendations center on instituting an organized system for pre-evaluating supplier capabilities, communicating with suppliers, and verifying that purchased products meet specifications. Because of the broad range of purchasing systems and transactions, not all recommendations may be applicable or appropriate for all situations.

Purchase Control Systems

A purchase control system is an organized set of processes and procedures that a product manufacturer may use for controlling purchases from outside suppliers. The purpose of this system is to ensure that the goods and service acquired are correct and meet the quality and expectations of the manufacturer. Purchase control is not only important for product safety reasons, but for improving the efficiency of the product manufacturing operation itself (e.g., reducing the amount of time spent correcting or responding to problems from incorrect or poor-quality parts).

Basic Elements

Manufacturers use a broad range of purchasing systems. The specific processes that a business should develop to manage these systems will depend upon the management culture of the manufacturer; however, in general, a purchase control system should address three main areas:

- Selection of suppliers.
- Communication with suppliers.
- Verification of supplier performance.

The system should be documented and all persons involved in the purchasing process (e.g., designers, engineers, product safety personnel, and purchasing employees) made familiar with their responsibilities under the system. In addition, the system should be audited on a regular basis to ensure that it is functioning as intended.

Quality Systems

Purchase control is a required element for a quality management system based upon the ISO 9000 series of standards. The ISO requirements are found in paragraph 7.4 of the 2000 edition of ISO 9001. In such cases, the purchase control system should be reviewed to ensure that product safety concerns are explicitly addressed.

Supplier Selection

Manufacturers should establish organized processes to identify potential suppliers and to evaluate their capabilities and reliability. The purpose of this system is to determine whether the chosen supplier has the ability to meet the needs of the manufacturer.

There are numerous methods of evaluating prospective suppliers. These include:

- Reviewing previous experiences with the supplier, if any.
- Checking client references.
- Conducting an on-site assessment of the supplier's manufacturing facility.
- Auditing the supplier's quality management system.
- Obtaining and testing sample products.

The review method chosen will depend upon the scope and complexity of the item being procured, the sales history between the parties, if any, and the criticality of the item. The method should be applied consistently for all suppliers.

The manufacturer should compile a list of rated and approved vendors. The manufacturer's purchasing procedures should prohibit the purchasing department from procuring supplies from vendors not on this list.

Supplier performance should be evaluated after every transaction to identify areas of concern or improvement, and to identify performance trends. Supplier ratings should be adjusted to correspond to the information obtained. Also, supplier performance should be evaluated prior to submission of a purchase order if the supplier has not been used recently or if changes have occurred which might have affected the supplier's ability to maintain its prior performance (e.g., recent management changes or lay-offs).

Supplier Communications

Manufacturers should take steps to ensure the orderly flow of information to and from the supplier. This is important for ensuring that there are no misunderstandings on what is expected from each party and that any problems that occur are handled promptly.

Product Specifications

The manufacturer should develop product specifications for all products that it must purchase. These specifications should include requirements for product performance and product safety. The specific requirements will depend upon the nature of the item being purchased.

The specifications should be written as clear and precise as possible. The specification should contain sufficient information to identify the requirements for the product. Where applicable this may include design drawings, blueprints, or other supplemental material. If a third party standard is being used as the source of a requirement, this standard should be referenced explicitly in the product specification.

Product designers should review the specification for correctness and completeness. Final product specifications should be dated and be maintained under strict document control procedures.

Purchasing Documents

All purchasing documents should include an adequate level of detail concerning the description of the product being ordered (e.g., product specifications and quantity), as well as any other performance requirements that the supplier must meet. Such requirements may include:

- Delivery time and location.
- Acceptance criteria.
- Product inspection criteria.
- Agreed on verification methods.
- Product identification or traceability.
- Responsibilities for correcting nonconforming products.

All purchasing documents should explicitly reference product safety as a purchasing requirement. This should include a requirement that the supplier promptly notify the manufacturer of any identified safety concerns with the product or similarly produced item.

Review

All purchasing documents should be reviewed for adequacy and correctness prior to transmittal to the product vendor. Documents should be checked for:

- Obvious errors in nomenclature, parts numbers, or product identifiers.
- Omission of necessary drawings or reference specifications.
- Omission of agreed-on quality measures or acceptance criteria.
- Improper delivery times or locations.

In addition, legal departments should review all draft purchasing documents to ensure that appropriate indemnification, hold-harmless agreements, or other contractual risk transfer devices are included.

Modifications

The manufacturer's purchasing procedures should prohibit the modification of purchasing requirements or the acceptance of similar or "substantially equivalent" products without the permission of the design or engineering department and the product safety coordinator. Such products may introduce unanticipated risks over the life cycle of the product.

Other Communications

The manufacturer may want to hold regular meetings, conference calls, or use other methods for maintaining communication with suppliers to keep abreast of product status and to promptly address any concerns that are raised during production. This is especially important when the item being purchased is highly customized or engineered and differences can be made in engineering interpretation.

Product Verification

Manufacturers should establish requirements for systematically verifying that supplied products conform to contract specifications. This typically involves the inspection or testing of products either by the supplier, the manufacturer, or by a designated third party. Product verification methods and procedures should be agreed upon by the manufacturer and supplier and documented in the final purchase order or contract. Important elements to be considered include the product characteristics to be evaluated, the method and extent of verification, criteria for acceptance, and the handling of nonconforming products.

Inspection Criteria

Products often have many specifications and, in many cases, it may be uneconomical or impractical to verify all requirements. The manufacturer should identify key product characteristics that affect product safety, and determine the product parameters that measure these characteristics and methods of measuring these parameters. These criteria should be specified in the purchase order. In addition, the manufacturer should establish acceptable quality levels that should be met.

Verification Methods

There are a variety of methods available for determining vendor compliance. Commonly used verification methods include qualification tests, source inspection, receiving inspection, and vendor inspection.

Qualification Testing

Qualification testing, also called first article inspection or first system testing, involves the intensive evaluation of the very first item produced by the supplier. The purpose of this testing is to determine whether the manufacturing process is capable of producing a product that meets all required specifications before normal production runs are started. The supplier, the manufacturer, or a third party

may perform the testing. The manufacturer should request copies of all test results or other documentation performed by others to verify that testing was performed.

Source Inspection

Source inspection involves the testing of products at the supplier's facility by the purchaser or their agent. Such testing may be desired because adequate inspection at a later time is impracticable or because testing of completed products will not adequately determine the quality of the manufacturing process. The nature and amount of source inspection will depend upon the reliability of the supplier and the criticality of the part.

Vendor Inspection

Vendor inspection involves the inspection of the products at the manufacturing facility by the supplier for compliance with contract specifications. The vendor would then submit test records, process control records, certificates of conformance, or other pertinent documentation to verify the testing was performed.

Receiving Inspection

Receiving inspection involves the evaluation of products by the manufacturer at the time of receipt to verify compliance with product specifications. The type of inspections and procedures used will vary widely. At a minimum, the received materials should be compared with the purchase order for the proper item and count or quantity. The inspection should also look for visible shipping damage. If the product is of the type that cannot be reasonably inspected on the loading dock, the product should be segregated from other approved products until it can be evaluated for conformance.

Training and Equipment

Properly trained and qualified personnel should perform the verification. The test equipment used for the verification should be appropriate for the test method chosen and must be properly calibrated. The testing should be performed according to an organized protocol

and test results be accurately recorded. The results should specify the products covered by the test. The manufacturer should request appropriate documentation from any supplier-performed verification activities.

Non-Conforming Products

Manufacturers should establish procedures for handling supplied products that do not conform to product specifications. If non-conforming products are identified, the supplier should be notified of the non-conformance as soon as possible. The notification should be in writing and include sufficient information to identify the nature and magnitude of the problem. The supplier should be requested to provide corrective actions by a specified date.

Acceptance

Components that have been accepted are usually stored until required for production. The manufacturer should take steps to ensure that the item does not become degraded during storage. Such steps include:

- Storing the product according to supplier's instructions.
- Preventing accidental commingling of products to retain traceability elements.
- Identifying products with limited shelf-life.
- Rotating stock to prevent excessive aging and deterioration.

The storage area should be periodically inspected. The manufacturer should follow good housekeeping procedures.

Record Keeping

The manufacturer should maintain all records relevant to the purchase of goods. Such records include the product specifications, purchasing documents, records of verification

activities, and other supplier correspondence. This can aid in assessing supplier performance and evaluating quality trends. It will also be helpful for identifying the source of complaints or the affected product should corrective action be required.

Program Review

The following questions may be used to help evaluate a manufacturer's purchase control program.

- Does the manufacturer have a policy and procedures for assuring the safety of items procured from suppliers?
- Does the manufacturer have procedures for evaluating supplier abilities, and are these procedures applied consistently?
- Do purchase documents have explicit requirements for product safety?
- Do purchase documents have explicit requirements for product verification, including criteria that must be evaluated and methods to be used?
- Are purchasing documents reviewed before they are sent out to suppliers?
- Does the manufacturer inspect all products they receive? If not, how do they verify conformance?
- Is there evidence that when a product purchased from a supplier is unsatisfactory, the supplier is promptly advised?
- Does the manufacturer have procedures for identifying the product components that were installed in all manufactured product?
- Has the manufacturer taken steps to ensure that accepted products are stored to prevent damage or degradation?

References

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