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# PROGRAM DOCUMENT (PD)

PD2102/Rev C

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## AEROSPACE QUALITY ASSURANCE, PRODUCT STANDARDS, QUALIFICATION PROCEDURE, ELASTOMERIC SEAL

### INTRODUCTION

It is essential that products defined by Industry Standards conform to the requirements of these Standards, and that the quality of the products be consistently maintained. To this effect an Industry consensus-based product qualification system has been established. The qualification system is based on:

- the approval of the manufacturer's quality system, as defined in AS9100;
- listing on the Nadcap QML for AC7115;
- the qualification of the product according to the procedure defined in this standard.

This industry-managed product qualification program is administered by the Performance Review Institute.

### 1. SCOPE

This Program Document (PD) prescribes the qualification procedure supporting aerospace elastomer product standards as adhered to by the SAE Aerospace SAE-AMS-CE Qualified Products Group (QPG).

PRI operating procedures provide that "This report is published by PRI to advance the state of technical, engineering, and quality sciences. The use of this report is entirely voluntary, and its applicability and suitability for any particular use, including any patent infringement arising therefrom, is the sole responsibility of the user."

PRI invites your written comments and suggestions.

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## PRI PD2102 Revision C– DRAFT 3/10/09

### 2. REFERENCES

AS7003	Nadcap Program Operation
AC7115	Nadcap Audit Criteria for the Manufacture of Elastomeric Seals
AS9100	Quality Systems – Aerospace – Model for Quality Assurance in Design, Development, Production, Installation, and Servicing
ISO 9001	Quality systems – Model for quality assurance in design/development, production, installation and servicing
ISO 17025	General Requirements for the Competence of Calibration and Testing Laboratories
PRI PD2000	Procedures for an Industry Managed Product Qualification Process
PRI PD2001	Qualified Product Management Council Procedures for Qualified Product Groups

### 3. DEFINITIONS

#### 3.1 Mandated Body:

A mandated body is one designated by the PRI Qualified Product Management Council (QPMC) in accordance with PRI PD2000. This body is responsible for assessing whether manufacturer's products comply with the relevant standards. The Mandated Body is known as a Qualified Products Group (QPG) and is composed of technically cognizant members from the Original Equipment Manufacturers (OEMs) and Government Agencies. The QPMC has mandated a QPG for Aerospace Elastomeric Seals.

#### 3.2 Material:

An intermediate mixture of a polymer(s) with all the ingredients necessary for the finished product.

#### 3.3 Nadcap Qualified Seals Manufacturer:

A Nadcap qualified seals manufacturer is one who holds a certificate for being certified to AS9100 and is Nadcap accredited to AC7115. Qualified manufacturers are listed in the PRI Qualified Manufacturer List (QML) following the Nadcap Elastomer Seals Task Group review and approval of the audit results.

## PRI PD2102 Revision C– DRAFT 3/10/09

### 3.4 Original Equipment Manufacturer (OEM):

An Original Equipment Manufacturer is a manufacturer of an end item "system" such as airframe or engine.

### 3.5 Product:

Finished articles that are manufactured from a Nadcap approved process.

### 3.6 Product Qualification

#### 3.6.1 Qualified Manufacturers List (QML):

A Qualified Manufacturers List is a document, issued by PRI, which lists manufacturers verified to be certified to AS9100 and Nadcap accredited to AC7115. Current QML information is available in eAuditNet ([www.eAuditNet.com](http://www.eAuditNet.com)). .

#### 3.6.2 Qualified Products List (QPL):

A Qualified Products List is a document, maintained and issued by PRI, which lists products that have passed the test requirements in the applicable procurement standard that requires product qualification. Current QPL information is available in eAuditNet ([www.eAuditNet.com](http://www.eAuditNet.com)). .

The QPG is responsible for approving products to be placed on the Qualified Products List.

### 3.7 Standards Development Organization (SDO):

A Standards Development Organization is an industry committee organization or government agency established to prepare and maintain standards of performance or design.

### 3.8 User:

A user is an organization purchasing a specific product manufactured from an elastomeric material to be utilized within an assembly, part or finished product; a purchaser of an item containing the specific product; or a representative of a government agency.

## PRI PD2102 Revision C– DRAFT 3/10/09

### 3.9 Acronyms:

OEM	Original Equipment Manufacturer
PD	Program Document
QML	Qualified Manufacturers List
QPL	Qualified Products List
QPMC	PRI Qualified Product Management Council
QPG	Qualified Products Group
SDO	Standard Developing Organization

## 4. PROCEDURES

### 4.1 Compliance with PRI PD2000

The procedure of the QPMC Qualified Products Group (QPG) shall be in compliance with PRI PD2000.

### 4.2 Manufacturer Request to be Included on a PRI-QPL

#### 4.2.1 Request for Product Approval

The manufacturer seeking product qualification shall send a request for approval to PRI (see below). The manufacturer shall describe the products to be qualified and identify the type of qualification, *New* or *Grandfathered*.

For a *Grandfathered* qualification in which the product is adopted from an existing OEM, government or military QPL, the manufacturer must submit official correspondence relating to the qualification, a copy of the existing QPL and the associated qualification test report, if available. If the original qualification test report is not available, then the manufacturer shall supply a current test report verifying conformance to the most recent revision of the applicable specification.

For a *New* qualification, the manufacturer must submit a qualification test report showing that the manufacturer's materials fully meet the requirements of the applicable specification. The materials tested shall be molded into test specimens by the applicant manufacturer according to the manufacturing and inspection requirements applicable for production of these materials.

## PRI PD2102 Revision C– DRAFT 3/10/09

The request for product approval shall be directed to:

Performance Review Institute (PRI)  
161 Thorn Hill Road  
Warrendale, PA 15086  
Attention: PRI-QPL Program

### 4.2.2 Requirements for Product Approval

The request for product approval shall be accompanied by:

- a. a Nadcap QML Certificate for compliance with AC7115;
- b. original manufacturer: certificate showing certification to AS9100;
- c. complete street address and cage code of the plant at which products are being manufactured (molded);
- d. subcontractor: certificate showing current AS9100 or ISO9001 certification by an IAQG approved registrar for subcontractors if significant elastomeric manufacturing and/or processing operations are subcontracted (such as, but not limited to custom mixing operations). Quality System accreditation shall be required within 2 years from the issuance of PD2102C. In the interim, compliance to ISO9001 shall be verified by the finished part manufacturer.

Subcontractors shall be audited to applicable sections of the AC7115 checklist by the finished part manufacturer. Record of this audit shall be maintained by the finished part manufacturer.

- e. Test report containing a full qualification and verification data as described in 4.5.1.
- f. Evidence that material qualification testing has been performed by a laboratory meeting the requirements of section 4.5.1.1.

### 4.3 PRI Preliminary Review of Product Approval Request and Test Report

Upon receipt of the data required by 4.2.2, including the qualification test data, PRI shall forward the request to the Mandated Body, the QPG.

## PRI PD2102 Revision C– DRAFT 3/10/09

### 4.4 Mandated Body, QPG Review

#### 4.4.1 Review of Request for Product Approval and Test Report

The manufacturer's request for product approval shall be evaluated and replied to by the QPG within thirty working days. If approval cannot be granted, the reply shall clearly and specifically identify the basis for the disapproval including any deficiencies in documentation, qualification/verification test data, and/or identified manufacturing and process controls. The reply may request that corrective actions be taken in the event the submitted test data does not comply with the requirements of the applicable standard(s).

#### 4.4.2 Grandfathering of Previous Military or OEM QPL Approvals

For grandfathering of military QPLs or OEM-user QPLs, the supplier must provide evidence of the QPL listing. The QPG shall determine the adequacy of any second or third party accreditation and may request additional testing where necessary to meet the intent of this standard. The supplier shall provide test data to support the specification requirements that are less than two years old and they have a year to submit new test data and achieve Nadcap accreditation. If the supplier fails the Nadcap audit, they will be immediately removed from the QPL. Grandfathering of Military and OEM-user QPLs will continue for a particular standard until it is converted to an SAE equivalent and revised to include the requirement for a QPL.

Grandfathered suppliers shall have one year from their QPG QPL approval to become a Nadcap qualified seals manufacturer.

### 4.5 QPL Qualification Requirements

#### 4.5.1 Initial Qualification Process

- Qualification test data for an elastomer product/material specification shall consist of a complete set of test data according to the specification and verification test data.
  - Verification test data shall be listed in the applicable specification; if not listed, at a minimum, the acceptance tests per specification
- The test report shall include the name and address of all test labs used, date of test, specification number and revision, compound identification, batch number, cure date, and lot number, as applicable.
- The specification number and revision, compound identification, batch number, cure date, and lot number shall be the same for qualification and verification test data. (See Figure 1)

##### 4.5.1.1 Test Laboratory Requirements:

1. If the manufacturer (Nadcap Seals QML, only) provides a full set of test data from their lab, then the data shall be verified by verification test data produced by an independent ISO 17025 certified lab.

## PRI PD2102 Revision C– DRAFT 3/10/09

2. If the manufacturer chooses to have an independent ISO 17025 certified lab produce a full set of test data, then the qualification data shall be verified by verification test data produced by a second lab not affiliated with the lab used for qualification. The verification lab can be the manufacturer's lab or an independent ISO 17025 certified lab.
3. If an external lab is used for generation of data, then a copy of the external lab report shall be submitted.

Note: If discrepancies are noted in the qualification and verification data, the QPG will review the data (ASTM Precision and Bias information for the particular test will be used as a guide) and decide if a referee test program is required to confirm the correct data.

### 4.5.2 Recertification/Requalification Process

Recertification/Requalification testing is required every three years (or as required by specification) to remain on a QPL for a given specification. Recertification/Requalification tests are typically defined in the product/material specification. When recertification/requalification tests are not defined in a specification, the QPG shall determine the required tests:

Current Test Plan Matrices available at <http://www.pri-network.org> / Qualified Products.

Questions regarding the necessary testing should be addressed to the QPG. Recertification/Requalification test data shall be produced by the manufacturer's lab or an independent ISO17025 certified lab. One set of data is acceptable. No verification testing is necessary. The test report shall include name and address of test lab used, date of test, specification number and revision, compound identification, batch number, cure date, and lot number, as applicable. See Figure 2.

### 4.5.3 Removal of a QPL Listing

A supplier's QPL listing may be removed for one or more of the following reasons:

1. failure to maintain Nadcap QML accreditation status;
2. Nadcap Audit Failure;
3. failure to submit recertification/requalification data for renewal prior to the expiration date;
4. failure to notify the PRI/QPG of material/manufacturing changes;
5. if a Nadcap or QPG Supplier Advisory is issued.

Actions by PRI:

1. Notify the QPG of the infraction from the above list and obtain the requirements for reinstatement from the QPG
2. Notify the applicable supplier with the detailed requirements for reinstatement
3. Notify QPG members of the QPL removal
4. "Expire" the applicable QPL Listing

Supplier information is added to the applicable QPG meeting agenda to define actions required for reinstatement. (See Figure 3)

## PRI PD2102 Revision C– DRAFT 3/10/09

### 4.5.4 Reinstatement to QPL Listing Following Removal

A Supplier may be reinstated on the PRI-QPL by:

1. completing the applicable Nadcap audit and receive accreditation
  - a. Supplier notifies PRI QPL Administrator when accreditation is received or;
2. submitting the applicable qualification data for renewal or;
3. submitting material/manufacturing changes or;
4. closing the Nadcap or QPG Supplier Advisory;
5. completing any additional actions identified by the QPG.

NOTE: Reinstatement can be implemented for the remaining approval period (qualification).

Actions by PRI:

1. Notify QPG of the status of the reinstatement

Actions by QPG:

1. Review data submitted within seven (7) days to identify any additional reinstatement requirements or approve reinstatement

Actions by PRI:

1. Applicable supplier is notified of the reinstatement or of any additional actions required
2. If approved, applicable QPL Listing is posted (See Figure 3)

### 4.5.5 Submittal of Test Reports

For Initial Qualification or recertification/requalification test data, submit a report (as defined in 4.5.1 and 4.5.2) to the PRI Office for review and approval by the QPG. The QPG shall review, disposition and communicate the results of the review of the test report to PRI and the manufacturer within 30 working days. Corrective actions may be requested where data submitted is incomplete or otherwise deficient.

## PRI PD2102 Revision C– DRAFT 3/10/09

### 4.6. QPMC Approval

When necessary, the QPMC shall review the QPG report and recommendation. A manufacturer can request a QPMC review if the manufacturer does not agree with the QPG report and recommendation. In the absence of a request by the QPMC for review of the QPG report, the QPG report shall be final, and PRI shall grant the approval for the products concerned on behalf of the QPMC. This Qualification Approval shall contain the following information:

- a. Reference to the SDO standards defining the products;
- b. Type and/or class of the material, if any;
- c. Name of manufacturer and place of manufacture;
- d. Compound designation;
- e. Approval Letter Number and issue date;
- f. Expiration date of the qualification.

Notes:

- a. Supplier Responsibility

Inclusion of a compound on the QPL does not relieve the supplier of its contractual obligations to deliver products molded from the compound that complies with all specification requirements.

- b. Responsibility for Quality Assurance

Inclusion of a compound on the QPL does not constitute a waiver of any requirement for inspection, for process control, or for maintenance of quality control procedures during production. It also does not in any way relieve the OEM-user of its contractual obligation to ensure that the delivered products comply with the specification requirements.

### 4.7 Validity Period of Qualification Certificate

The Product Qualification Certificate shall be valid for a maximum of three years. Six months before a qualification certificate expires, PRI shall notify the manufacturer of the QPL expiration date and inform the manufacturer of which recertification/requalification tests will be required as listed in the specific product/material specification.

(<http://www.pri-network.org/PRI/Test-Plan-Matrices.id.735.htm>) Verification of AS9100 certification shall be submitted with the recertification/requalification test report to PRI.

## PRI PD2102 Revision C– DRAFT 3/10/09

### 4.8 Non-Conformance Reporting

Users of products manufactured from the materials should report discrepancies, which cannot be resolved with the manufacturer to PRI. PRI shall notify the QPG and the manufacturer of the problem. The manufacturer shall be required to respond to the notification in a written reply describing the source of the problem. The QPG shall review the information and if necessary, recommend a course of action to resolve the problem. In the case of repetitive complaints from the users to PRI on product discrepancies, the QPG shall request corrective action from the manufacturer and proof that the corrective action resolved the discrepancies. Corrective action may include a PRI audit at the place of manufacture. After consideration of the corrective action and the audit report, if required by the QPG, PRI shall notify the manufacturer of any further necessary action.

### 4.9 Notification of Material/Manufacturing Changes

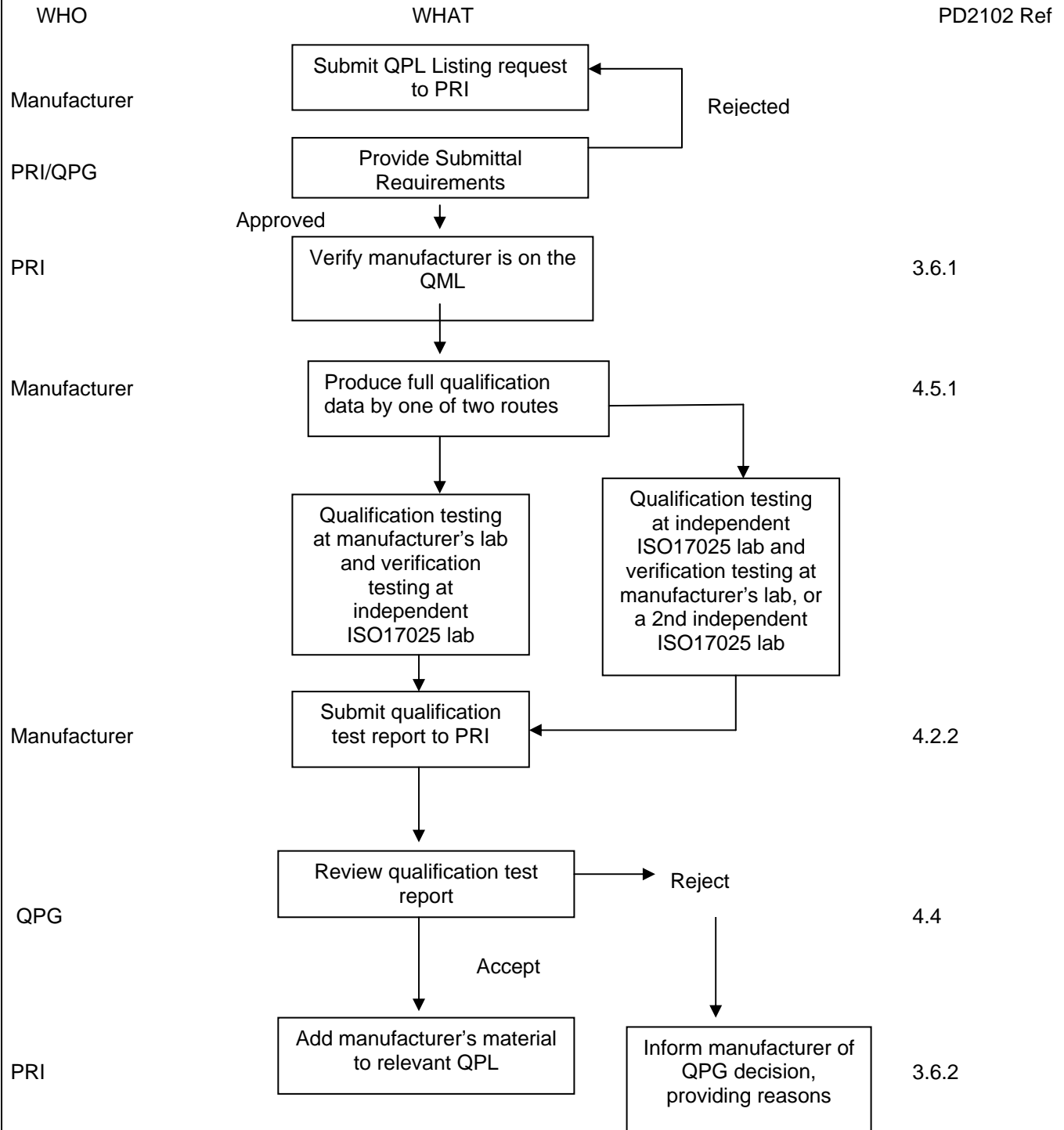
- 4.9.1 The manufacturer shall follow the requirements for material and process changes in accordance with AS9100 and the QPG shall be notified and approve the change.
- 4.9.2 The manufacturer shall inform PRI of any proposed changes to the following and the date to be accomplished:
- a. Change in formulation, including changes in raw material suppliers.
  - b. Manufacturing equipment and machinery. This does not include normal replacement of wear items or addition of new machines of brand, type and model already in use at the approved facility.
  - c. Movement of manufacturing facilities, machinery, processes and personnel to a new location. This does not include minor operations and machinery within a building.
  - d. Business changes such as mergers, acquisitions by other companies, plant closings, and discontinuation of products.
- 4.9.3 Any production product made by any of the revised changes as listed above which require approval from PRI, shall not be shipped without written approval from PRI approving the changes.
- 4.9.4 PRI reserves the right to approve the changes upon written notification only, additional testing and/or partial to full plant audit.

#### 4.10 PRI Confidentiality and Conflict of Interest Requirement

All information provided to PRI shall be treated with appropriate confidentiality. Confidentiality and conflict of interest requirements for all programs under the direction of the QPMC are defined in PD2000. All participants in the PRI QPL program shall comply with these requirements.

# PRI PD2102 Revision C– DRAFT 3/10/09

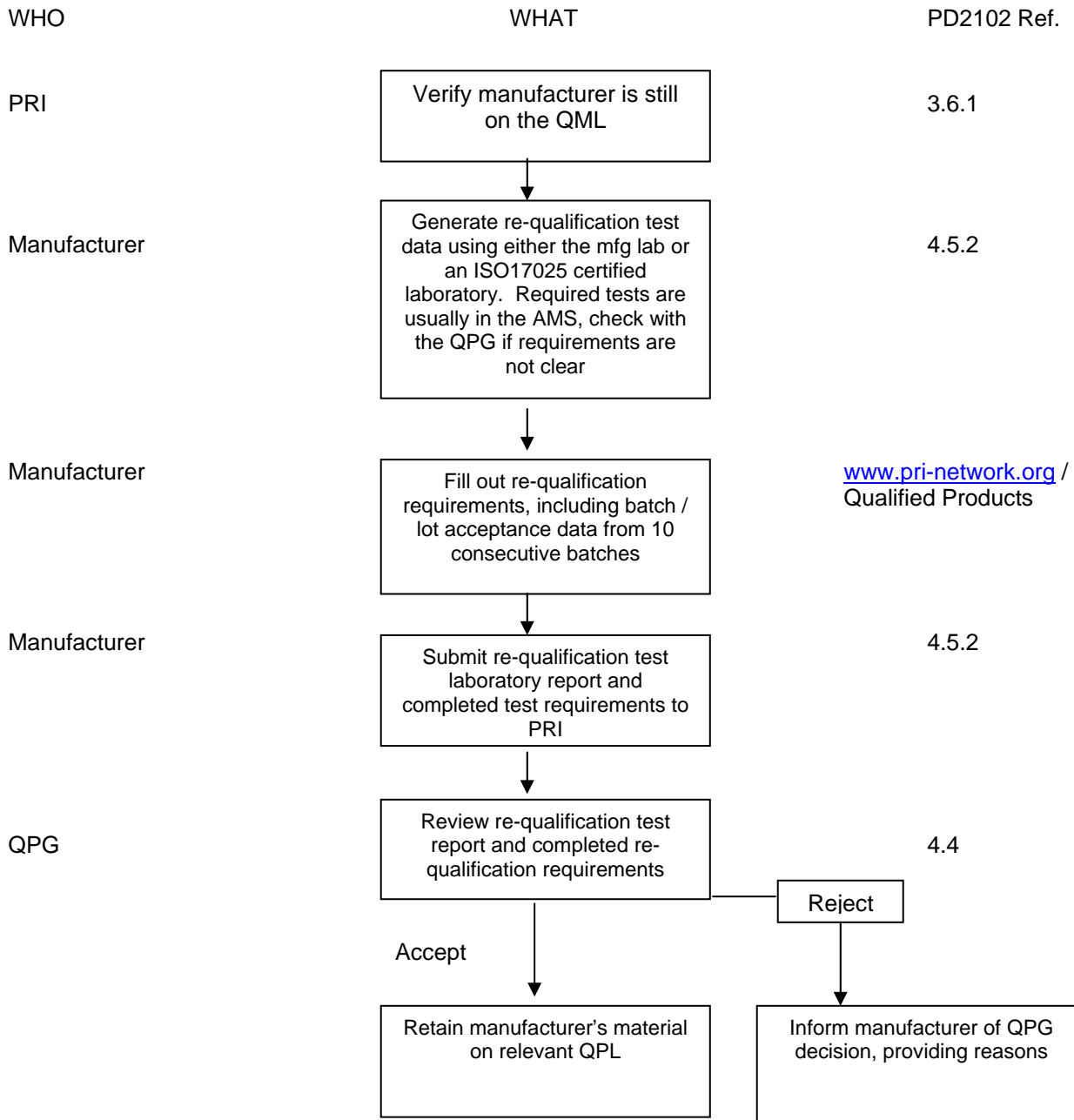
Initial Qualification of Elastomeric Seal Materials  
Figure 1



# PRI PD2102 Revision C– DRAFT 3/10/09

## Re-Qualification of Elastomeric Seal Materials

Figure 2



# PRI PD2102 Revision C– DRAFT 3/10/09

## Removal and Reinstatement of Elastomeric Seal Products

Figure 3

