



PROGRAM DOCUMENT

PD2001

REV B

161 Thorn Hill Road,
Warrendale, PA 15086-7527

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MANUFACTURER REQUEST FOR PRODUCT APPROVAL AND QUALIFICATION PROCESS

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 Performance Review Institute (PRI) qualification system has been established. The qualification system is based on:

- The qualification of the product according to the procedure defined in this document.
- The approval of the manufacturer's quality system, as defined in AS9100 when applicable, and the fabrication system as defined in applicable product document (i.e., AC7112, AC7115, etc.)

1. SCOPE

This document guides manufacturers to submit application for product qualification approval, submission of data and processes for listing on the PRI-QPL.

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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2. REFERENCES

AC7112	Nadcap Program Requirements for Fluid System Components
AC7115	Nadcap Program Requirements for Elastomer Seals
AC7123	Nadcap Fluid Distribution Systems Audit Criteria for Value Added Hose Assembly Distributors
AS7200/1	Nadcap Audit and Inspection Procedures and Checklists for the Sealant Manufacturers Accreditation Program
AS7202	National Aerospace and Defense Contractors Accreditation Program (Nadcap) Requirements for Accreditation of Value Added Distributors
AS/EN/ JISQ 9100	Quality Systems – Aerospace – Model for Quality Assurance in Design, Development, Production, Installation, and Servicing
EN9133	Aerospace series, Quality management systems, Qualification procedure for aerospace standard parts
ISO 17025	General Requirements for the Competence of Calibration and Testing Laboratories
PRI PD2000	Governance and Administration of an Industry Managed Product Qualification Program

3. DEFINITIONS

3.1 Third Party Verification Testing

The partial or complete qualification testing and inspections by independent ISO 17025 certified laboratories with a relevant scope to verify or conduct a manufacturer's qualification tests.

3.2 Value Added Distributors

Designated and monitored by formal OCM and accredited to AC7123 or AS7202. Authorized by the OCM to place the OCM name and part number on the assembly, with a marking for the distributor. The value added distributor shall have a verified quality system. The fabrication system shall be identical to that of the OCM or shall be approved by the OCM in case of a variation. The fabrication system tooling, tool

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maintenance/control requirements, calibration requirements, and training requirements must all be described in controlled, written documents.

3.3 Acronyms:

GIDEP	Government and Industry Data Exchange Program
OCM	Original Component Manufacturer
OEM	Original Equipment Manufacturer
PD	Program Document
QML	Qualified Manufacturers List
QPG	Qualified Products Group
QPL	Qualified Products List
QPMC	Qualified Product Management Council
SDO	Standard Developing Organization
SPC	Statistic Process Control
VAD	Value Added Distributor

4. QUALIFICATION PROCESS

4.1 General

4.1.1 The qualification process is shown in Figure 1.

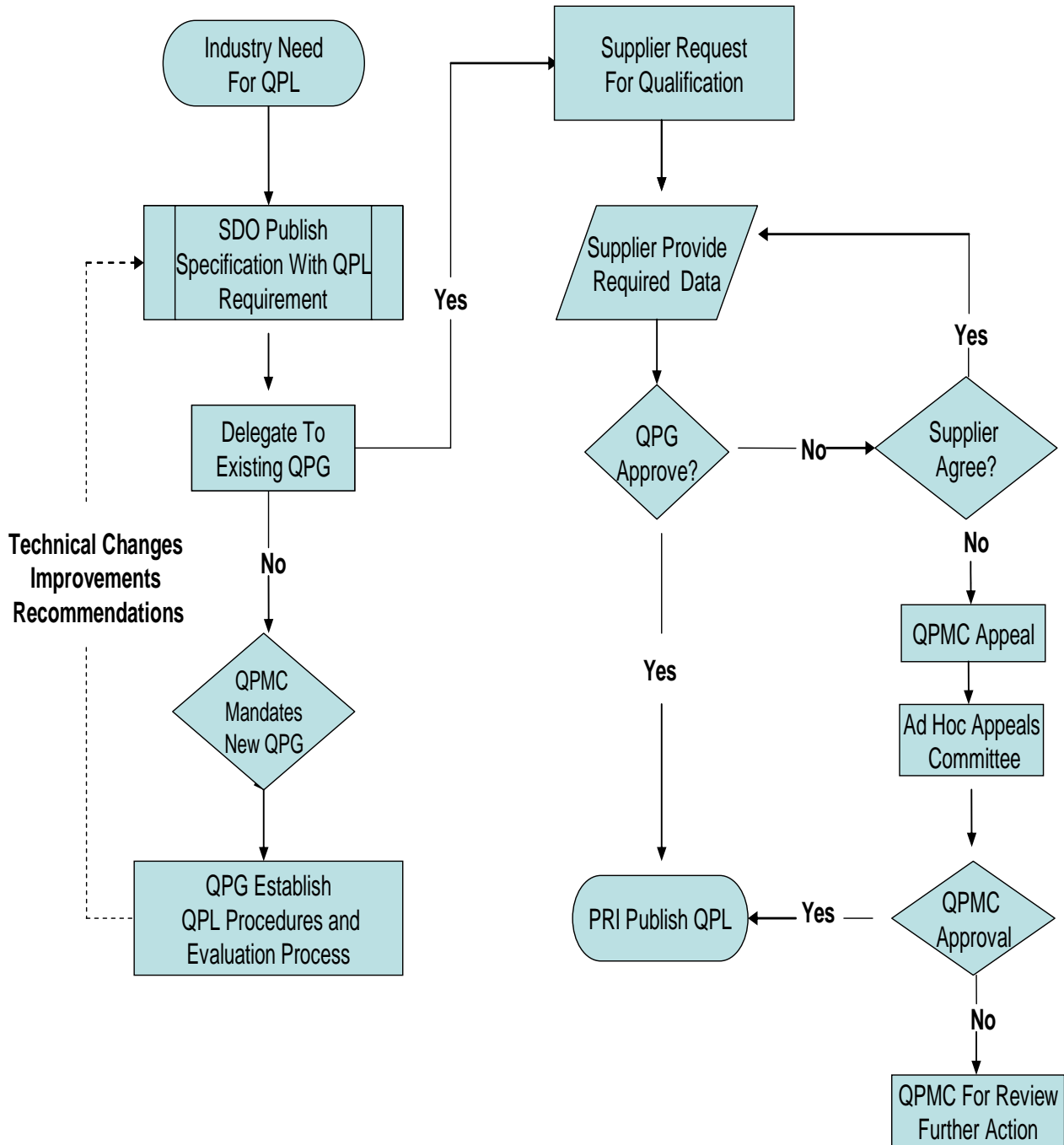
4.1.2 PRI shall administer the QPL Program. Key activities will include, but not be limited to:

- Management of the Manufacturer/Supplier Application process as required to list product on the QPL
- Publication of electronic QPLs
- Provide notification to the QPG and OCM's of revisions to the QPL.
- Development and maintenance of all necessary procedures, forms, records, etc. for program operation

4.1.3 PRI shall also be responsible for managing a QPMC approved Supplier Advisory/Alert system.

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FIGURE 1 -- Flow Chart for the Qualification Process



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4.2 Request for Qualification

4.2.1 Request for Product Approval

The manufacturer seeking product qualification shall send a completed application including a signed supplier agreement and questionnaire for approval to PRI and shall provide the data required by 4.2.2. The Manufacturer shall describe the products to be qualified and specify 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 or approval letters relating to the qualification, a copy of the existing QPL and the associated qualification test reports and product drawings, if available. The QPG may request additional information as required, including the OEM verification of qualification if the QPL document is proprietary to the OEM.

For a *New* qualification, the manufacturer must submit a qualification test plan stating when and where the qualification testing is to be performed including third party testing, if applicable. When test plans are submitted, the manufacturer shall specifically request approval of the qualification test program. The products tested shall be manufactured by the applicant manufacturer according to the manufacturing and inspection requirements applicable for production.

Notes:

- (1) Qualification tests shall be conducted at test laboratories applicable to each individual QPG (refer to applicable QPG Program Document or individual specification);
- (2) If qualification tests are performed at manufacturer's facility, that facility is required to be ISO 17025 approved with a relevant scope, and if not, tests shall be witnessed by a QPG member, designated QPG representative, PRI Auditor or verified by OEM qualification tests.

Applicant shall submit a coherent and appropriate test plan based on associated specifications. The request for product approval shall be directed to:

Performance Review Institute (PRI)
161 Thorn Hill Road
Warrendale, PA 15086

Attention: PRI-QPL Processing Coordinator

- 4.2.2 When required by the governing specification, the request for product approval shall be accompanied by (when they are not already held by PRI):

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- a. Evidence of compliance with AS9100/EN9100/JISQ9100: ISO Registration Certificate with Certificate of Compliance with AS9100/EN9100/JISQ9100 and any other certifications/accreditation required by the QPG;
- b. A general description of the company (organization, products manufactured, number of employees, facilities), the complete street address of the plant at which the product is being manufactured and CAGE code, if available;
- c. The list of approvals or qualifications that have been granted by OEMs or Government Agencies for the product or similar products; or status of evaluation for such approvals if under way, and time to completion.
- d. Evidence of flowdown of the manufacturer's quality requirements when machining, manufacturing, or process operations are subcontracted by the manufacturer. The quality system shall include, as a minimum, material traceability and work instructions, tool certification and calibration if applicable
- e. Qualification data from the manufacturer's laboratory or specified laboratory (as applicable to QPG);
- f. The list of manufacturer's approved distributors with any quality accreditation held by the distributor.

5.0 PRI AND MANDATED QPG REVIEW PROCESS AND SCOPE PRIOR TO QUALIFICATION TESTS

5.1 PRI Review

PRI shall review all submitted documentation (as defined in 4.2.2) for completeness. After this verification, PRI shall forward the request to the applicable QPG

5.2 QPG Review and Response

5.2.1 Review of Request for Product Approval and Test Plan

The manufacturer's request for product approval shall be evaluated and a response submitted by PRI within forty-five (45) working days from receipt at PRI. The reply shall include a statement in the event that manufacturing and process controls are found not to meet program and/or specification requirements.

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5.2.2 Review of Requests with Test Reports and Previous Military or OEM Approvals

For grandfathering of military QPLs or OEM-user QPLs the QPG shall determine adequacy of second or third party accreditation and request additional testing, if required. Grandfathering shall be limited to a specific period of time, for example twenty four (24) months, as defined by the QPG. After this initial specified time, the QPG shall decide if the data is sufficient to continue with QPL listing. In all cases, any periodic testing necessitated by the governing specification as part of the re-certification shall be completed prior to grandfathering approval.

6.0 MANUFACTURER SUPPORT OF QPG EVALUATION

6.1 Access to Background Material

The QPG shall have access to the manufacturing and inspection requirements and records of the product submitted for evaluation, per applicable QPG.

6.2 Test Verification

The QPG reserves the right to request specimens and to perform verification tests or partial qualification tests.

6.3 Qualification Test Report

At the end of the qualification test program, the manufacturer shall prepare a detailed report. The report shall include the obtained results and verification data such as inspection records and the manufacturer's drawing package defining the configuration of the qualified product. This report shall be submitted to the PRI office for review and approval by the QPG.

NOTE: The manufacturer shall identify drawings, bill of materials, operations, and process controls in the fabrication of specimens that were qualification tested. These controls shall not be modified in later production without prior QPG approval.

7.0 QPG AND QPMC APPROVAL AFTER QUALIFICATION TESTS

7.1 QPG Response

After submission of the test report the QPG shall write a disposition within 45 working days from date of receipt at PRI, and forward it to PRI. This disposition shall include a statement as to whether the results are acceptable. Corrective actions may be requested where necessary.

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7.2 Notification of PRI-QPG Decision

PRI shall notify the manufacturer of successful completion of the approval process and update the QPL within five (5) working days of notification of successful qualification by the QPG. PRI shall send an approval letter to the manufacturer.

7.3 QPMC Approval

When necessary, the QPMC shall review the QPG report and recommendation. In the absence of a request by the Council 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 Council. When granted, approval shall be forwarded to the manufacturer by PRI. It shall contain the following information:

- a. Reference to the SDO standards defining the products;
- b. Reference of the part standards, if applicable;
- c. Name of manufacturer and place of manufacture;
- d. Product designation;
- e. Date of the approval;
- f. Type, class and other specification classifications, as applicable.

NOTES:

a. Manufacturer Responsibility

Inclusion of a product on the QPL does not relieve the manufacturer of its contractual obligations to deliver products that comply with all specification requirements.

b. Responsibility for Quality Assurance

Inclusion of a product 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 regulatory obligation to ensure that the delivered products comply with the specification requirements.

7.4 In-Service and Fabrication Problem Reporting

Manufacturers and distributors of products shall report all sampling and periodic test failures and escapement of non-conforming products in writing to PRI within 24 hours/ next business day or as defined by the QPG.

PRI shall notify the QPG within twenty-four (24) hours of receiving notice of such failures or problems.

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The QPG shall determine within twenty-four (24) hours of notification by PRI on additional actions that are required.

In case a failure or nonconformity report is originated by a User, the User and manufacturer may discuss whether the problem is an actual manufacturing/performance issue and whether PRI should be notified. The manufacturer would then notify PRI if necessary. The User may decide to contact PRI instead, who would then intercede with the manufacturer in determining if a Supplier Advisory Notice is required.

The manufacturer shall be required to respond in writing to the notification within five (5) working days of receipt of the PRI Supplier Advisory Notification, per Appendix A, describing the source of the problem and the corrective action.

While the manufacturer is evaluating a failure analysis and corrective action(s), the manufacturer must submit a written update at least once every two weeks informing PRI of the status of the investigation.

In case of complaints from Users to PRI on the performance of a qualified product, the QPG may request an audit at the place of manufacture. After consideration of the corrective actions and any audit report results, PRI shall notify the manufacturer of the QPG decision.

PRI reserves the right to issue Supplier Advisory Notifications, per Appendix A, and/or immediately remove the manufacturer or value added distributors from the applicable QPL when a product failure is reported. PRI also reserves the same rights and actions if it is discovered that a manufacturer or value-added distributor has not reported failures to PRI within the twenty-four (24) hour requirement or the next business day.

PRI shall notify manufacturers within five (5) working days of direction by the QPG if the manufacturer will be removed from the QPL and the QPL will be updated in the same time frame. The notice will be mailed to the manufacturer with a delivery receipt.

7.5 Manufacturer Process Changes to be reported to PRI

The manufacturer shall:

- a. Inform PRI in writing of any proposed change in its quality system which might affect the granted approval;
- b. Inform PRI in writing of any changes in the company situation (change of address, merger, take-over, change in operations, place change, strike, plant closure, natural disaster, etc.) which might affect the product. In such an event, the manufacturer must submit status reports at least every two weeks until all open actions associated with the event have been resolved;

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- c. Request approval from PRI in writing for any proposed modification in product design, equipment, tooling, materials, processing, and manufacturing. All changes that would have an impact on the following should be reported: form, fit, function, reliability, weight, structural strength, or the ability of the product to meet any requirements of the standard. Details, including pre- and post-change engineering and manufacturing documents shall be provided to PRI with the change proposal. Changes require QPG approval prior to implementation based on applicable QPG documents. PRI shall respond to a request for a change within thirty (30) calendar days.
- d. PRI must be advised in writing of the intended date of the change and the manufacturer must submit written updates of the status of the change until the change is fully implemented. PRI approval of proposed changes after qualification does not relieve the manufacturer of responsibility associated with the product(s). Proposed changes shall be brought to the attention of PRI at least thirty (30) working days prior to the proposed change implementation date.
Note: Changes shall not be implemented until approval is received from PRI.
- e. PRI reserves the right to require Supplier Advisory Notifications and/or immediately remove the manufacturer from the applicable QPL if it is discovered that a manufacturer has not reported changes and has not had the changes approved per 7.5.c above. PRI will notify the manufacturer within five (5) working days of direction by the QPG if the manufacturer will be removed from the QPL and the QPL will be updated in the same time frame. The notice shall be mailed to the manufacturer with a delivery receipt.

7.6 PRI Confidentiality Requirement

- 7.6.1 All information provided to PRI shall be treated in accordance with the confidentiality requirements of PRI. Operating procedures are in place within PRI to handle and protect all proprietary and company confidential information that is furnished by all manufacturing sources, or potential sources, for a QPL. This includes all second party or other persons acting for PRI.
- 7.6.2 Examples of proprietary data include raw qualification data, formulations, cost and yield information, procedures, PRI audit results, design techniques and guidelines, etc. Examples of non-proprietary information include QMLs and QPLs.
- 7.6.3 All QPL test data released outside PRI shall be identified as "Proprietary" before being released to QPG members. A record shall be kept indicating the material sent, date sent, why it was sent, and to whom it was sent.

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7.6.4 QPG members receiving such proprietary information shall sign a PRI-QPL Confidentiality Agreement that they shall not use such proprietary information, except in connection with PRI or QPG related transactions with the party disclosing such proprietary information. QPG members shall handle this proprietary information in accordance with PRI operating procedures.

Note: US Government employees are covered by the Trade Secrets Act, 18 U.S.C Section 1905. Signature of acknowledgement shall be provided to PRI.

8.0 REQUALIFICATION

The requalification can be renewed for an additional period. The product qualification period shall be automatically extended until the review is complete. The review period should not exceed forty-five days (45) calendar days. Disagreements and appeals shall be conducted in accordance with PRI PD2000.

9.0 APPENDICES

9.1 Appendix A – Supplier Advisory Process

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APPENDIX A – Supplier Advisory Process

1.0 SCOPE

The purpose of this process is to provide a means for advising QPMC and QPG members about the state of conformance of products listed on the PRI-QPL.

2.0 DEFINITIONS

2.1 Level #1 Advisory: Preliminary Information: This advisory is used to report a possible significant nonconformance which is being investigated. This advisory is initiated prior to receipt of manufacturer's comments.

2.2 Level #2 Advisory: Potential Product Impact: An advisory used to report a product, process or quality system discrepancy which potentially impacts the performance of the product. The advisory includes either the manufacturer's concurrence or statement of rebuttal, and any supplementary information the manufacturer wishes to add.

2.3 Level #3 Advisory: Product Performance/Safety Alert: A product alert, used to report a discrepancy which impacts delivered product function or safety. It may be reported and verified by a User, reported by the manufacturer or value added distributor, or observed by the auditor. The advisory includes either the manufacturer's concurrence or his statement of rebuttal, and any supplementary information the manufacturer or value added distributor wishes to add.

3.0 RESPONSIBILITIES

3.1 Email shall be the primary mechanism for disseminating the notification of a Supplier Advisory or as directed by the applicable QPG. All QPMC and QPG Users will be sent a notification of an issuance of a Supplier Advisory.

3.2 QPMC and QPG Users shall communicate in writing to PRI information on any manufacturers' discrepancies which the User deems sufficiently important to warrant notification of other Users.

3.3 PRI auditors and source inspectors are responsible for documenting observed conditions involving any nonconformance to aerospace standards/specifications, product/service nonconformance, or conditions in the manufacturer's facility which could put the product/service quality at risk. If any potential/product impacting condition is identified, the auditor must immediately notify PRI, who will be responsible for initiating the notification within 24 hours or the next business day to all Users.

3.4 Manufacturers shall promptly investigate reports of nonconformance(s) received from Users, Manufacturers and suspected nonconformances identified by auditors, and initiate corrective action as appropriate. Manufacturers are encouraged to provide their own comments to be incorporated as part of the advisory (within five working days). If a

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serious nonconformance (potential product impact and/or product impacting) of delivered product/service is uncovered, the manufacturer shall directly notify customers and the affected aerospace primes of the pertinent facts, preliminary analysis of hardware impact and recommended actions within five working days.

- 3.5 The PRI Staff shall, upon receipt of information from users, auditors or manufacturers, consult with technical experts to determine the importance of the information, and post appropriate messages. This review may result in suspension, withdrawal or cancellation of QPL listing at the discretion of the applicable QPG following receipt/review of manufacturer response.
- 3.6 Evidence of notification of Customers is required for closure of Supplier Advisory, if necessary. This does not require evidence of receipt or action taken by the customer. This form is available at www.pri-network.org/reference documents.
- 4.0 PROCEDURE
- 4.1 Discovery identified and documented in writing to PRI Staff (from Manufacturer, User, Auditor through audit results).
- 4.2 PRI Staff shall investigate and validate all potential advisories, with concurrence from the QPG Chairperson or designee to determine if an advisory is warranted.
- 4.3 PRI Staff shall complete Supplier Advisory by identifying: Supplier Advisory Number, Advisory Date, Supplier, Subject of Advisory, Level of Advisory, Current QPL Status, Source of Information, Advisory Description (including scope of effectivity- part numbers, date codes, etc), and identification of QPG.
- 4.3.1 Supplier advisories shall be designated as Level #1 Preliminary at first, unless product impact is clearly communicated from the manufacturer.
- 4.3.2 PRI Staff to forward notification of the Supplier Advisory to the QPMC and QPG Users.
- 4.4 PRI shall forward the applicable advisory to the Manufacturer via e-mail or as directed by the applicable QPG and by overnight certified mail. PRI shall wait a maximum of five working days, from receipt date of certified mail, for comments, before upgrading any advisory to Level #2 or Level #3, unless product impact is clearly communicated from the manufacturer.
- 4.5 Manufacturer shall address and document root cause and corrective action for any Preliminary Advisory.
- 4.5.1 Upon review of the manufacturer's response, the applicable QPG shall be responsible for determining the appropriate Level of the advisory. Consideration shall be given for subsequent upgrading or downgrading of the level of advisory during the course of the investigation. Documentation for all QPG decisions shall be maintained.

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- 4.6 PRI Staff shall update advisories as new information is acquired. PRI Staff shall notify all QPMC and QPG Users of any updates.
- 4.7 The Supplier Advisory shall be noted as closed by the applicable QPG following closure or resolution as determined by the QPG with concurrence by the QPG Chairperson. For the purposes of this document, closure or resolution of the Advisory shall occur with closure of the associated nonconformance(s), if applicable, or when the Advisory is deemed resolved by the QPG. (Note: If applicable, evidence of customer/aerospace prime notification is required)
- 4.8 Supplier Advisories (and updates) shall be filed in a central location at PRI and maintained by the QPL Secretariat or designee for a minimum of ten (10) years after closure.