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## **Ballot # 6523**

# **Qualification of Polymeric Seal Manufacturers for Use in the Petroleum and Natural Gas Industries**

API STANDARD 20L  
SECOND EDITION, XXX 201X

BALLOT DRAFT

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## **1 Scope**

### **1.1 Purpose**

This API standard specifies requirements for the qualification of manufacturers of polymeric seals used in the petroleum and natural gas industries.

### **1.2 Applicability**

This standard is applicable to the manufacturers of polymeric seals where API product standards require such services or are otherwise specified as a requirement for compliance. Compliance with this standard is not required to demonstrate compliance with any other API standard or specification. This standard does not consider entities that solely perform assembly of outside manufactured parts as a polymeric seal manufacturer.

**NOTE** This standard does not limit the responsibility of any manufacturer of commercial products utilizing polymeric seals and manufactured to an API standard from its responsibility for compliance with all applicable requirements of that API standard.

## **2 Normative References**

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document applies (including any addenda/errata).

API Standard 20D, *Nondestructive Examination (NDE) Services for Equipment used in the Petroleum and Natural Gas Industry*

API Standard 20N, *Heat Treatment Services - Continuous Furnace for Equipment Used in the Petroleum and Natural Gas Industry*

API Specification Q1, *Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry*

ISO/IEC 17020<sup>1</sup>, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

SAE<sup>2</sup> AMS2817F, *Packaging and Identification, Preformed Packings*

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<sup>1</sup> International Organization for Standardization(www.iso.org), 1, ch. De la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, Switzerland.

<sup>2</sup> SAE International(www.sae.org), 400 Commonwealth Drive, Warrendale, PA 15096.

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## *ASME BPVC<sup>3</sup> Section IX - Welding, Brazing, and Fusing Qualifications*

### **3 Terms, Definitions and Abbreviations**

#### **3.1 Terms and Definitions**

For the purposes of this document, the following terms and definitions apply.

##### **3.1.1**

##### **acceptance criteria**

Defined limits placed on characteristics of materials, products or services.

##### **3.1.2**

##### **calibration**

Comparison and adjustment to a standard of known accuracy.

##### **3.1.3**

##### **chemical analysis**

Determination of the chemical composition of material.

##### **3.1.4**

##### **conformance**

Compliance with specified requirements.

##### **3.1.5**

##### **elastomer**

Amorphous material mechanically mixed with other constituents to form a rubber compound, which is then shaped by flow into articles by means of the manufacturing processes of molding or extrusion, and then (invariably) chemically cured at elevated temperature to form an elastic insoluble material.

##### **3.1.6**

##### **elastomer seal manufacturer**

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<sup>3</sup> ASME (www.asme.org) Two Park Avenue New York, NY 10016-5990

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A commercial entity which converts elastomeric raw material into finished sealing components or systems.

### **3.1.7**

#### **extrusion Intermediate**

An extrusion that is exposed to additional process steps before reaching the final form.

### **3.1.8**

#### **extrusion Final**

An extrusion that is the final product.

### **3.1.9**

#### **insert(s)**

A manufactured metallic or non-metallic component that is subsequently permanently molded or bonded to a seal element to improve the functionality of the final product.

### **3.1.10**

#### **off-site**

A related facility of the organization, operating under the same Quality Management System as the identified polymeric seal manufacturer of the product.

### **3.1.11**

#### **on-site**

The polymeric seal manufacturer's facility.

### **3.1.12**

#### **outsourced**

Any activity performed by a qualified outside organization.

### **3.1.13**

#### **outsource seal-manufacturer**

A seal manufacturer that is a supplier to the Standard 20L polymeric seal manufacturer.

### **3.1.14**

#### **physical testing**

Testing of material to determine properties such as: durometer, color, dimensions, density, tensile strength, modulus, compression set, compressive stress relaxation, flexural strength, abrasion resistance.

NOTE This list is not exhaustive .

### **3.1.15**

#### **polymeric seal manufacturer**

A commercial entity which converts polymeric raw material into finished sealing components or systems.

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### **3.1.16**

#### **processes that require validation**

Processes where resulting output cannot be verified by subsequent monitoring or measurement, such as vulcanization

### **3.1.17**

#### **raw materials**

any material that is used as an input in a transformative manufacturing process.

### **3.1.18**

#### **receiving verification**

The process of ensuring the product received meets purchased requirements.

### **3.1.19**

#### **remote technical assessment**

A technical assessment of capabilities performed using a method other than an on-site audit. This includes, but is not limited to a checklist or a survey.

### **3.1.20**

#### **revolutions per minute**

#### **RPM**

The number of complete rotations about an axis in a given minute

### **3.1.21**

#### **rough machining**

An intermediate machining activity not intended as final dimension.

### **3.1.22**

#### **service suppliers**

Suppliers that perform one or more of the following activities on behalf of the polymeric seal manufacturer:

- machining
- material testing
- heat treatment
- nondestructive examination

### **3.1.23**

#### **thermoplastics**



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Material that is capable of being repeatedly softened by heating and hardened by cooling through a temperature range characteristic of the material and, in the softened state, of being repeatedly shaped by flow into articles by molding, extrusion or forming.

#### **3.1.24**

##### **thermoplastic seal manufacturer**

Entity that makes thermoplastics through a process involving raw materials and components with different operations divided among different workers.

#### **3.1.25**

##### **thermosets**

Materials that irreversibly cured from a soft solid or viscous liquid pre-polymer or resin.

NOTE The process of curing changes the resin into an infusible, insoluble polymer network, and is induced by the action of heat or suitable radiation often under high pressure, or by mixing with a catalyst.

#### **3.1.26**

##### **thermoset seal manufacturer**

Entity that makes thermoset seals through a process involving raw materials, components, or assemblies with different operations divided among different workers.

#### **3.1.27**

##### **traceability**

The ability to verify the history and delivery location of an item by means of documented record identification.

### **3.2 Abbreviations**

FIFO first in, first out  
MOC management of change  
NDE nondestructive examination  
QMS quality management system  
RPM revolutions per minute  
UV ultraviolet

## **4 Polymeric Seal Manufacturer Qualification**

### **4.1 General**

4.1.1 The polymeric seal manufacturer shall establish, document, implement and maintain, at all times, a Quality Management System (QMS) conforming to API Q1. In addition, the polymeric seal

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manufacturer shall be responsible for conforming to all of the applicable requirements of this standard.

4.1.2 This standard specifies two seal composition classes, elastomers and plastics. The polymeric seal manufacturer may qualify in one or both classes dependent on manufacturing capability.

4.1.3 The following paragraphs describe the conditions which, when met, allow a polymeric seal manufacturer to qualify to the appropriate composition class.

## **4.2 Records of Qualification**

The polymeric seal manufacturer shall maintain evidence of conformity to the qualification requirements of this document.

## **4.3 Responsibilities and Duties**

The polymeric seal manufacturer shall:

- a) perform all functions in accordance with specified standards and applicable quality control criteria;
- b) perform operations only for which it is adequately equipped and has employees who are qualified against defined competencies;
- c) control sub-tier suppliers of products or services in accordance with the requirements of this standard;
- d) use testing, measurement, and monitoring equipment that is calibrated in accordance with the requirement of this standard
- e) utilize personnel that are qualified in accordance with the requirements of the polymeric seal manufacturer's documented procedure;
- f) maintain facility and equipment in accordance with documented procedures.

## **4.4 Processes requiring validation**

The seal manufacturer shall validate the following process where the resulting output can not be verified by subsequent monitoring or measurement.

- a) heat treatment
- b) non destructive examination

## **4.5 Personnel Training and Competency Requirements**

4.5.1 Personnel shall be competent based on the appropriate education, training, skills, and experience needed to meet product and customer requirements.

4.5.2 A documented procedure shall define personnel competency, and identify training and qualification requirements.

5.5.3 The organization shall identify:

- a) methods required for personnel training qualifications;
- b) knowledge and training necessary to address specific customer requirements;

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- c) qualifications required for personnel performing processes that require validation;
- d) method(s) used to verify the competency of personnel.

## **4.6 Measuring and Testing Equipment**

**4.6.1** The polymeric seal manufacturer shall maintain a procedure that testing, measurement, and monitoring equipment is calibrated and maintained and that the equipment is used in a manner that is consistent with monitoring and measurement requirements.

**4.6.2** Calibration shall conform to and be traceable to nationally or internationally recognized standards, as applicable.

**4.6.3** Records of calibration shall be maintained.

## **4.7 Procedure Requirements**

All procedures referenced in this standard shall be documented, fully implemented and maintained to provide control of processes.

## **4.8 Required Maintenance**

**4.8.1** The polymeric seal manufacturer shall have a documented preventative maintenance schedule that includes a list of the basic maintenance tasks to be performed for production equipment (mills, presses, CNC lathes, etc.).

**4.8.2** The equipment will be operated throughout its full range of motions and operational conditions and any identified deficiencies reported and assessed for impact on equipment performance.

**4.8.3** For each piece of equipment, records shall be kept documenting the date of inspection, when maintenance work was performed, what the work entailed, when the next maintenance is due and any deficiencies noted and dispositioned.

## **5 Polymeric Seal Manufacturer Process Control**

### **5.1 General**

This section addresses the required controls for a polymeric seal manufacturer to supply polymeric seals to their customer.

### **5.2 Review of Order Requirements**

**5.2.1** An order review shall be conducted prior to the polymeric seal manufacturer's commitment to deliver product. The polymeric seal manufacturer shall have a documented procedure for the review of order requirements that addresses, as a minimum, that:

- a) purchase order requirements are identified, reviewed and understood;
- b) the polymeric seal manufacturer has the capability to meet the purchase order requirements;
- c) purchase order requirements are acknowledged and documented;
- d) any deviations and/or clarifications accepted by the purchaser shall be documented.

**5.2.2** When contract requirements are changed, the polymeric seal manufacturer shall amend relevant documents and notify relevant personnel of the changed requirements.

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**5.2.3** Records of the results of the review, including resulting actions, shall be maintained for a period of 10 years.

### **5.3 Polymeric Seal Manufacturer Performed Processes**

The polymeric seal manufacturer may perform additional processes on the seal. If the processes listed in Table 1 are performed, the polymeric seal manufacturer shall be in conformance with the listed standards or equivalents.

**Table 1 – Polymeric Seal Manufacturer Performed Processes**

<b>Process</b>	<b>Standard</b>
NDE	Verification of API 20D conformance through an internal on-site process audit
Material Testing	Capabilities and controls of the test facilities shall address the following, as a minimum: a) calibration of equipment b) validation of sample preparation and test methods c) conformance to international standards d) identification and traceability e) qualification of personnel f) record retention g) preservation of product Verification of ISO 17025 conformance is acceptable in lieu of the above activities.
Product Pre-qualification	Applicable API product specification

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## 5.4 Process Class - Elastomers

### 5.4.1 General

In order to conform to this standard, the elastomer seal manufacturer or an external source shall have the following manufacturing equipment, as necessary, at a minimum:

**Table 2 - Process Control Requirements**

Process Control Activity	Comment or explanation	Performed By:	
		Manufacturer	Outsourced
Formulation	Must be controlled and documented	x	x
Compounding	Shall have MTR, with designated quality checks	x	x
Extrusion intermediate		x	x
Extrusion Final		x	Not Permitted
Injection Molding		x	Not Permitted
Curing		x	Not Permitted <sup>1</sup>
Post-curing	Up for debate on final	x	X <sup>2</sup>
Finishing		x	x
Machining		x	x
Inspection		x	Not Permitted
Testing		x	x
Final Release		x	Not Permitted

1 Seal manufacturers shall cure at least 50% plus 1 on a numeric scale of all seals.

2 If the properties of the final product are not degraded due to time between curing and post-curing of parts, this these processes can may be outsourced:

- machining equipment (for machined seals, as applicable);
- molding and curing equipment;
- test and inspection equipment.

### 5.4.2 Process Control - Elastomers

#### 5.4.2.1 Procedure Requirements – General

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The elastomer seal manufacturer shall maintain a documented procedure for each of the processes listed below (in addition to the requirements in API Q1):

- a) calibration of process control equipment;
- b) designated preparation descriptions and weights with tolerances;
- c) process to keep material clean, identified, and free from contamination;
- d) time, temperature, and/or pressure with tolerances and verification method; and
- e) bill of materials with materials to be used, including quantities.

#### **5.4.2.2 Storage of feeder stock and raw materials**

Base polymeric materials and chemical ingredients used in the mixing of an elastomer shall be stored according to the elastomer seal manufacturer and raw material manufacturer.

#### **5.4.2.3 Mixing/Compounding**

**5.4.2.3.1** Mixing equipment shall be calibrated and maintained and comply with the requirements of the compound mixing specified in documented internal standards.

**5.4.2.3.2** The elastomer seal manufacturer shall have storage that is appropriate for the material for in-process, in-transit and un-vulcanized elastomer compounds. Storage requirements shall be in accordance with the elastomer seal manufacturer's documented procedures.

#### **5.4.2.4 Molding and Curing**

The manufacture of elastomers shall have molding and curing capability for the manufacturing processes employed. Molding and curing operations shall be performed in accordance with the elastomer seal manufacturer's documented procedure(s) of the following, as necessary:

- a) compression press loading instructions; (including be not limited to pressure, temperature, and time setting, with tolerances)
- b) transfer press molding instructions; (including be not limited to pressure, temperature, and time setting, with tolerances)
- c) injection press procedure for molding finished parts or components, preheat instructions, if required. Elastomer manufacturer shall have loading instructions for oven(s) or heating device(s) and molding,
- d) post-cure oven instructions for the use and calibration of ovens;
- e) tools used for production realization shall have identification, cleaning and maintenance, operation and set-up instruction.

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#### **5.4.25 Material Preparation for Molding**

The manufacturer of elastomers shall have at a minimum the following equipment and/or documented procedures:

- a) preform extruder instructions;
- b) die control, identification, cleaning, maintenance, operation and set-up of dies;
- c) calendaring procedures that address requirements for finished calendared material including width with tolerances, thickness with tolerances, material to be used, and acceptable finishes;
- d) milling instructions.

#### **5.4.2.5 Bonding**

The elastomer seal manufacturer shall maintain a documented procedure for bonding and surface preparation procedure that addresses:

- a) blast media designation and identification;
- b) anchor pattern requirement;
- c) check of and replacement of spent blast media;
- d) time requirements between blast and adhesive application;
- e) storage of blasted inserts;
- f) degreasing procedure that addresses degreasing method, type of degreaser and cleanliness;
- g) shelf life for adhesives;
- h) designated primer, if required, and top coat adhesive;
- i) dry or wet mil thickness requirements;
- j) viscosity checks;
- k) dilution, if required;
- l) secondary containment of adhesives, including labeling and dating;
- m) method for identifying areas of inserts where adhesive is to be applied;
- n) drying times between coats of adhesive and before molding;
- o) storage of painted inserts and shelf life of painted inserts.

#### **5.4.2.6 Mandrel Wrap for Elastomers**

A polymeric seal manufacturer using the mandrel wrap techniques shall have a documented procedure and proper equipment.

NOTE 1 Mandrel wrap and autoclave cure is an accepted technique for the production of inflatable packers, swell packers and other elastomer components.

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NOTE 2 Autoclave curing is also an acceptable technique for curing components such as elastomer stators for down hole motors and pumps.

#### **5.4.2.7 Extrusion of Elastomers**

A polymeric seal manufacturer shall have a documented procedure, in addition to suitable and calibrated equipment for the extrusion process of an elastomer.

NOTE 1 Extrusion is used in wire and cable or control line encapsulation but occasionally for other tools where elastomers are formed by extrusion.

NOTE 2 Extrusion is used in compression molding, injection molding, and other techniques to form preforms, continuous cords, or volume controlled shots, or a combination thereof.

#### **5.4.2.8 Finishing**

When employed, the elastomer manufacturer shall have a documented procedure(s) that addresses the complete process and the appropriate tooling for finishing. If finishing is completed by the elastomer manufacturer, the firm shall have the necessary equipment along with operating procedures for said equipment.

NOTE Most elastomer components are finished, trimmed after vulcanization, or curing. Trimming is typically employed to remove flash but in some applications, it is necessary to finish a part by machining.

### **5.5 Process Class – Thermoplastics and Thermosets**

#### **5.5.1 Facilities and Equipment**

In order to process thermoplastics and thermosets, the thermoplastic and thermoset seal manufacturer shall have at a minimum, inspection and test equipment and adhere to the limitations outlined in Table 2 in section 5.4.1.

#### **5.5.2 Documented Procedures**

The thermoplastic and thermoset seal manufacturer shall maintain a documented procedure for each of the processes listed below and shall verify that process sheets for the work being performed contain the correct manufacturing process procedures as applicable:

- a) calibration of temperature controllers, pressure gauges, balances, quality and inspection tools, and revolutions per minute (RPM) gages;
- b) designated preparation descriptions with tolerances;
- c) process to keep material clean, identified, and free from contamination;
- d) maintenance procedures for equipment;
- e) time, temperature, humidity, and/or pressure as required with tolerances and verification method; Bill of materials with a list of all items and quantities. Standard operating procedures for equipment and tools along with safety procedures and verification method including but not limited to the below:



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- 1) injection molding procedure including start up, shut down, and clean out procedures;
- 2) extrusion procedure including start up, shut down and clean out procedures;
- 3) casting or molding procedure;
- 4) molding procedure including start up, shut down, and clean out procedures;
- 5) welding procedure;
- 6) heat treating procedure.

#### **5.5.4 Material Receipt**

**5.5.4.1** Materials received from a supplier shall be provided with a certificate of conformance that contains material properties tested per batch. This certificate shall be traceable to the purchase order.

**5.5.4.2** The thermoplastic and thermoset seal manufacturer shall check the certificate against internal and customer requirements to confirm compliance.

#### **5.5.5 Mixing**

**5.5.5.1** A documented recipe and mix procedure that is revision controlled shall be available.

**5.5.5.2** Defined storage control requirements shall be available for both the polymer and additives and their inventory shall be verified per the manufacturers' recommendations.

**5.5.5.3** The thermoplastic and thermoset seal manufacturer shall test each compound batch against their internal specification to verify conformance. Each batch of compound shall have a unique number assigned to it.

#### **5.5.6 Pre-conversion Drying**

**5.5.6.1** The thermoplastic and thermoset seal manufacturer shall have a documented procedure based on the recommendations of the polymer manufacturer in determining the drying conditions.

**5.5.6.2** The settings specified shall be verified by moisture testing of the compound. The measurement should have a listed tolerance and resolution of the equipment.

**5.5.6.3** When an oven is used to perform drying, the oven shall have calibrated temperature controls. When the thermoplastic and thermoset seal manufacturer uses a desiccant dryer, a gauge repeatability and reproducibility system shall be put in place.

#### **5.5.7 Injection Molding**

**5.5.7.1** When the thermoplastic or thermoset seal manufacturer employs an injection molding process they shall have an injection molding procedure in place that is based on the recommendations of the resin manufacturers, as well as the result of an internal process development, that defines the processing temperature, mold temperature and mold fill time.

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**5.5.7.2** The injection molding procedure shall, if applicable, define the barrel temperature, injection pressure, pack pressure, hold pressure, back pressure, injection speed, screw RPM and cycle time, including the time in mold.

**5.5.7.3** The thermoplastic and thermoset seal manufacturer shall perform verification of the injection molding output at a specified frequency. This verification shall include destructive or nondestructive inspections, such as radiography, weighing, ultrasonic, visual, dimensional, rheological and mechanical property measurements.

**5.5.7.4** Preventive maintenance shall include screw / barrel wear check rings and checking tooling for evidence of corrosion and wear.

### **5.5.8 Iso-Static / Cold Compression Molding and Sintering**

**5.5.8.1** When the thermoplastic or thermoset seal manufacturer employs a hot compression molding process they shall have a documented molding and/or sintering procedure in place that is based on the recommendations of the resin manufacturers, as well as the result of an internal process development that defines the pressure profile, dwell time, outgassing time, sintering profile and the compound weight.

**5.5.8.2** The thermoplastic and thermoset seal manufacturer shall have their ovens surveyed for internal temperature profile on a specified frequency, as well as have mold clean up procedures.

NOTE: For uniformity oven survey refer to API 20H & API 20N for guidelines.

**5.5.8.3** The thermoplastic and thermoset seal manufacturer shall perform verification of the molding and/or sintering output at a specified frequency. This shall include physical testing as well as the review of time and temperature charts.

**5.5.8.4** Preventive maintenance shall include inspection of molds for wear and dimensional conformity.

### **5.5.9 Hot Compression Molding**

**5.5.9.1** When the thermoplastic or thermoset seal manufacturer employs a hot compression molding process they shall have a molding procedure in place that is based on the recommendations of the resin manufacturers, as well as the result of an internal process development that defines the pressure and temperature profile, as well as the dwell time. The molding procedure shall also define the compound weight.

**5.5.9.2** The thermoplastic and thermoset seal manufacturer shall have mold clean up procedures, and shall perform verification of the molded output at a specified frequency. This shall include physical testing and the review of time and temperature charts.

**5.5.9.3** Preventive maintenance shall include inspection of molds for wear and dimensional conformity.

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## **5.5.10 Extrusion**

**5.5.10.1** When the thermoplastic or thermoset seal manufacturer employs an extrusion process they shall have an extrusion procedure in place that is based on the recommendations of the resin manufacturers, as well as the result of an internal process development. This procedure shall define the barrel temperature, process temperature, die pressure, back pressure, screw RPM, cycle time, and whether a forming tube is necessary.

**5.5.10.2** The thermoplastic and thermoset seal manufacturer shall perform verification of the extrusion output at a specified frequency. This verification shall include destructive or nondestructive inspections, such as x-ray, ultrasonic, visual, rheological and mechanical property measurement.

**5.5.10.3** Preventive maintenance shall include checking the screw and barrel for wear.

## **5.5.11 Spin Casting or Rotational Molding**

**5.5.11.1** When the thermoplastic or thermoset seal manufacturer employs a spin casting or rotational molding process they shall have a casting or rotational molding procedure in place that is based on the recommendations of the resin manufacturers, as well as the result of an internal process development. This procedure shall define the time under temperature and rotational velocity.

**5.5.11.2** The thermoplastic and thermoset seal manufacturer shall perform verification of the casting or molding output at a specified frequency. This verification shall include destructive or nondestructive inspections, such as radiography, ultrasonic, visual, weight, rheological and mechanical property measurements.

## **5.5.12 Transfer Molding**

**5.5.12.1** When the thermoplastic or thermoset seal manufacturer employs transfer molding process they shall have a transfer molding procedure in place that is based on the recommendations of the resin manufacturers, as well as the result of an internal process development. This procedure shall define the barrel temperature, process temperature, die pressure, back pressure, screw RPM (if applicable), mold and cycle time. Gauges for measuring the above parameters shall be calibrated.

**5.5.12.2** The thermoplastic and thermoset seal manufacturer shall perform verification of the molding output at a specified frequency. This verification shall include destructive or nondestructive inspections, such as radiography, ultrasonic, visual, rheological and mechanical property measurements.

**5.5.12.3** Preventive maintenance shall include checking the screw (if applicable), barrel and mold for wear.

## **5.5.13 Welding**

**5.5.13.1** The thermoplastic and thermoset seal manufacturer who perform welding applications shall have a welding procedure in place that is based on the recommendations of the resin manufacturers, as well as the result of an internal process development. This procedure shall

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define the essential variables required to produce a conforming product. Procedures and personnel shall be qualified in accordance with ASME BPVC Section 9.

**5.5.13.2** The thermoplastic and thermoset seal manufacturer shall perform verification of the welding output at predetermined intervals. This verification shall include destructive or nondestructive inspections, such as x-ray, dye penetrant, ultrasonic, calorimetry and visual inspections.

#### **5.5.14 Heat Treatment**

**5.5.14.1** When the thermoplastic or thermoset seal manufacturer employs a heat treating process they shall have a procedure in place that is based on the recommendations of the resin manufacturers, as well as the result of an internal process development.

**5.5.14.2** This procedure shall define the temperature, ramp rate, hold time, cool down, and oven type. Gauges for measuring the above parameters shall be calibrated and the ovens shall be surveyed on a specified frequency.

NOTE 1: For uniformity oven survey refer to API 20H & API 20N for guidelines.

NOTE 2: Heat treating covers processes commonly known as annealing, curing, and post-curing.

**5.5.14.2** The thermoplastic and thermoset seal manufacturer shall perform verification of the output at a specified frequency. This verification shall include destructive or nondestructive inspections, such as visual, rheological, calorimetric or mechanical property measurements.

#### **5.5.15 Finished Part Processing**

**5.5.15.1** This processing step shall include but not limited to the following operations as applicable:

- a) milling;
- b) turning;
- c) stamping;
- d) grinding;
- e) thermoforming.

**5.5.15.2** The thermoplastic and thermoset seal manufacturer shall have documented procedures for controlling operations that allow conformance to manufacturer and/or customer requirements.

**5.5.15.3** Verification of the process output shall be performed and checked for conformance to requirements. The process output verification shall include dimensions, physical characteristics, packaging, and labeling.

## **6 Control of Outsourced Processes and Material**

### **6.1 General**

**6.1.1** A polymeric seal manufacturer shall maintain a documented procedure(s) for outsourced processes and material that contains specified requirements.

**6.1.2** The procedure(s) shall conform to the purchasing requirements in API Q1.

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**6.1.3** The polymeric seal manufacturer shall maintain a list of approved suppliers by location and scope of supply.

## **6.2 Control of Raw Material and Outsourced Processes**

### **6.2.1 Initial Approval**

A polymeric seal manufacturer shall perform initial approval of suppliers through:

- a) Verification of a QMS and
- b) Performing an assessment of the raw material supplier's capabilities and controls through either:
  - 1) an on-site technical audit or;
  - 2) a technical questionnaire, which shall be reviewed by competent personnel. If the response does not meet the polymeric seal manufacturer requirements, then an on-site technical audit shall be performed. The technical questionnaire shall include, as applicable to the scope of supply:
    - i. scope of capabilities (product, grades, sizes, form);
    - ii. testing capability and equipment;
    - iii. calibration of measuring and testing equipment;
    - iv. outsourced activities;
    - v. certifications / records;
    - vi. industry licenses or accreditation;
    - vii. process monitoring and controls.
  - 3) performing inspection, testing, or verification of relevant characteristics of a received product.

### **6.2.2 Records**

Records of the results of the supplier's approval, including resulting actions, shall be maintained.

## **6.3 Control of Outsource Polymeric Seal Manufacturer and Service Suppliers**

### **6.3.1 Initial Approval of Outsource Polymeric Seal Manufacturers**

Polymeric seal manufacturers may procure materials from other polymeric seal manufacturers. The polymeric seal manufacturer shall qualify the outsource polymeric seal manufacturer through one of the below methods:

- a) The outsource polymeric seal manufacturer maintains an API Standard 20L license or
- b) a QMS that is in compliance with a national or international standard and meets the below requirements of the Polymeric Seal Manufacturer:
  - 1) verification that the suppliers QMS conforms to the quality systems requirements specified for suppliers by the polymeric seal manufacturer; and

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- 2) the polymeric seal manufacturer shall test and qualify the order against the requirements of Section 7.2

### 6.3.2 Records

Records of the results of the sub-polymeric seal manufacturer's approval, including resulting actions, shall be maintained.

## 6.4 Control of Service Suppliers

### 6.4.1 Initial Approval

A polymeric seal manufacturer shall approve service suppliers as specified in Table 3. If the processes listed in Table 3 are performed, the polymeric seal manufacturer shall be in conformance with the listed standards or equivalents.

### 6.4.2 Records

Records of the results of the service supplier approval, including resulting actions, shall be maintained.

**Table 3 – Service Supplier Qualification Requirements**

Service	Qualification Requirements
Machining	Verification of capabilities and controls through an on-site audit or a remote technical assessment that addresses the following, as a minimum: <ol style="list-style-type: none"> <li>a) calibration</li> <li>b) identification and traceability</li> <li>c) qualification of personnel</li> <li>d) controls in place for services being provided</li> <li>e) preservation of product</li> <li>f) inspection</li> <li>g) For suppliers performing machining, evidence of conformance to API 20M MQL or greater</li> </ol>
Material Testing	The test facility shall be qualified through verification of capabilities and controls via an on-site audit or remote technical assessment that addresses the following, as a minimum: <ol style="list-style-type: none"> <li>a. calibration of equipment</li> <li>b. validation of sample preparation and test methods</li> <li>c. conformance to international standards</li> <li>d. identification and traceability</li> <li>e. qualification of personnel</li> <li>f. record retention</li> <li>g. preservation of product</li> <li>h. Evidence of conformance to ISO 17025 for the required service</li> </ol>

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Continuous Heat Treatment	Evidence of conformance to API 20N or AMS 2750
Batch Heat Treatment	Evidence of conformance to API 20N or AMS 2750
Nondestructive Examination	Evidence of conformance to API 20D, ISO 17025, or ISO 17020 for the required service

## **6.5 Control of Outsourced Compound Mixing**

### **6.5.1 General**

A supplier for mixed compound shall have the capability to mix the compound and meet the requirements of this standard and the polymeric seal manufacturer's specification. The supplier shall follow a documented quality control program for the mixing operation that addresses the following:

- a. Raw material certificates shall be verified to be compliant with the raw material manufacturer's specification.
- b. At a minimum, a rheometer test shall be required as part of the mixer's quality program.
- c. For mixed production compound, all lots or batches of compound shall be tested by the compound mixer and meet the specified physical properties before being shipped. The physical property testing frequency shall be at least one sample from every 10 batches mixed throughout the run.

NOTE: See section 8 for traceability and shelf life requirements.

### **6.5.2 Control of Outsourced Testing**

The compounder shall either have the capabilities of testing or outsource testing to approved laboratory that meet the requirements of this standard and comply with the polymeric seal manufacturer's testing requirements. The organization performing the testing shall have the following equipment, as required:

- a) rheometer;
- b) mooney viscometer ;
- c) durometer;
- d) universal load frame;
- e) impact, abrasion, etc.;
- f) ovens.

## **7 Inspection Requirements**

### **7.1 General**

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**7.1.1** The polymeric seal manufacturer shall have a documented procedure that defines the inspection process and acceptance criteria.

**7.1.2** The procedure shall include the following requirements:

- a) receiving inspection;
- b) in process inspection;
- c) final inspection;
- d) Identification and traceability of product, (See Section 8).

**7.1.3** Where sampling is used, the sampling plan shall be based on evaluation of the risk and shall be documented. The sampling plan shall be in conformance with a nationally or internationally recognized standard for sampling (eg ANSI Z1.4,...)

## **7.2 Receiving Inspection**

The polymeric seal manufacturer shall verify that product or service received meets stated purchase order requirements and associated acceptance criteria.

## **7.3 In Process and Final Inspection**

**7.3.1** In Process inspection shall inspect, test, and/or verify product at planned stages as required by the quality plan, process control documents, and/or documented procedures.

**7.3.2** Inspection of finished product shall include at a minimum:

- a) a durometer hardness measurement;
- b) a visual inspection for defects and;
- c) a dimensional check of at least the critical dimensions.

Note: In Process and Final inspection can be performed as one or more activities. Some product characteristics can require final inspection/verification during manufacturing.

## **7.4 Records**

Records of inspection shall be maintained

## **8 Identification and Traceability**

**8.1** The polymeric seal manufacturer shall have documented procedures for control of identification and traceability from the raw material to the final product. The procedure shall include, as a minimum:

- a) method of identifying the product;
- b) method of identification that allows traceability to all records associated with the product;
  - 1) traceability of product back to received raw material;
  - 2) product traceability during storage;
  - 3) tracking shelf life of raw, intermediate, and final materials;



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- 4) method of traceability for product during outsourced processes;
- 5) method for verifying traceability upon material receipt.

c) method for maintenance or replacement of identification and/or traceability marks;

## **9 Nonconforming Product**

The polymeric seal manufacturer shall maintain a procedure to control nonconforming products that is in accordance with API Q1.

Records of disposition of nonconforming products shall be maintained.

## **10 Externally Controlled Property**

**10.1** The polymeric seal manufacture shall maintain a documented procedure for the identification, verification, safeguarding, preservation, maintenance, and control of externally controlled property, including intellectual property and data, in conformance with the requirements of API Q1.

**10.2** Records for the control and disposition of externally controlled property shall be maintained

## **11 Packaging, Storage and Handling**

### **11.1 General**

**11.1.1** Elastomer components are age sensitive and shall be stored in accordance with the polymeric seal manufacturer's documented procedure.

**11.1.2** Packaging shall be heat sealed, as practical, of sufficiently low permeability to protect the compound from oxidation and designed to prevent physical and environmental damage.

**11.1.3** Where heat sealed bags are impractical as determined by the purchaser, other means of protection from the environment, storage, handling, and a new shelf life shall be specified by the purchaser.

**11.1.4** Labeling shall provide legible identification to assure traceability.

### **11.2 Packing Requirement**

**11.2.1** Elastomer seals and O-rings shall be packaged and labeled in dark bags, certified UV resistant materials or non-transparent boxes and stored to ensure optimum storage life. Every package shall be labeled with the following information:

- a) customer's part number;
- b) quantity in package;
- c) product description;
- d) cure date;

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- e) shelf life (expiration date or number of years);
- f) material classification;
- g) manufacturer's identification;
- h) manufacturer's batch number;
- i) any additional information required by the purchase agreement.

**11.2.2** All packaging materials shall be free of deleterious materials such as copper naphthenates, creosote preservatives, and plasticizers. Suitable materials include plastic lined paper bags and polyethylene bags more than 0.075 mm thick and UV resistant. Opaque packaging is preferred but certified UV resistant materials can be used if available. Metal foil bags may be used provided they are salt free.

**11.2.3** All materials covered under this specification shall be packaged to prevent damage during transportation and storage.

### **11.3 Temperature and Humidity Control**

The storage temperature shall be below 120°F (49°C). The relative humidity shall be controlled to prevent condensation. If the elastomers are not stored in sealed moisture proof bags, the relative humidity of the atmosphere in storage shall be defined.

### **11.4 Storage Contacting Media**

#### **11.4.1 Oxidation, Ozone and Radiation Contact**

Exclude or minimize air flow to prevent oxidation. Precautions shall be taken to protect stored products from sources of ionizing radiation. Storage rooms shall not contain equipment that is capable of generating ozone in excess of manufacturers documented limits.

NOTE: Examples are mercury vapor lamps and high-voltage electrical equipment giving rise to electric sparks or silent electrical discharges. Combustion gases and organic vapors should be excluded from storage rooms, as they may give rise to ozone via photochemical processes.

#### **11.4.2 Oil, water or excessive dust contact**

Seals shall not come into contact with liquid or semi-liquid materials (for example, petrol, greases, acids, disinfectants, cleaning fluids) or their vapors during storage. If used, powder shall be free from constituents having a deleterious effect on the rubber.

#### **11.4.3 Metal or alloy contact**

For seal products with rubber-to-metal bonds, the metal part of rubber-to-metal bonded products shall not come into contact with the rubber of other products.

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## **11.5 Avoid Deformation**

Elastomers shall be stored free from superimposed tensions and compressive stresses or other causes of deformation.

Seals are allowed to be folded during storage according to AMS 2817F.

Long seals may be stored either vertically or horizontally as is appropriate for their length.

## **11.6 Recording data during storage**

The seal manufacturer shall perform a periodic stock check as defined by the manufacturers documented procedures to include as a minimum shelf life and proper storage.

## **11.7 Storage rotation**

Elastomeric seal stock should be rotated on the first in, first out (FIFO) principle. In some instances contractual requirements may preclude FIFO.

## **11.8 Shelf Life of Elastomer Seal**

Elastomer components are age sensitive and shall be stored in accordance with the polymeric seal manufacturer's documented procedure. Elastomeric seals shall not be shipped after the expiration date without the approval of the purchase agreement.

NOTE: 1 ISO 2230 and SAE ARP5316 may be used for guidance.

## **12 Management of Change (MOC)**

### **12.1 General**

The polymeric seal manufacturer shall maintain a documented procedure for MOC conforming to API Q1.

### **12.2 MOC Evaluation Criteria**

**12.1.1** Minimum criteria to include in the MOC evaluation are:

- a) nature of the change;
- b) location where the change is occurring;
- c) personnel affecting product conformance;
- d) identification and assessment of risk due to the change;
- e) actions taken to address risk due to the change;
- f) impact of the change on the product or service.

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**12.1.2** A process change is anything that can affect the form, fit and function of the finished product outside of reasonable tolerance ranges.

EXAMPLES Materials of construction, mechanical properties (tensile, elongation, compression set, hardness, friction and wear characteristics, etc. that effect performance) along with dimensional changes.

**12.1.3** Basic process steps such as preform type, mold design, pressing tonnage (force to hold the mold closed), time, temperature, post cure, etc., and sequences which affect the components form, fit and function shall remain consistent throughout the components manufacturing life.

Any changes in the basic process steps and sequence can warrant the requirement for a new first article inspection or component qualification. Gross changes in process such as altering material, preform type, change in tool design, pressing tonnage, injection pressure, time, temperature, post cure, etc. would be considered process changes as they can alter the final components properties.

EXAMPLES Substituting compression molding for injection molding or changing the preform from an extruded shape to die cut rings.

**12.1.4** When manufacturing components in reworked tools or new tools of the same design as the existing tooling for the first time, a dimensional only First Article is required.

**12.1.5** Minor changes in process and sequence may be acceptable as long as they will not affect form, fit and function.

EXAMPLE Manufacturing the component(s) on a second machine of similar capability to the originally approved and qualified first article inspection component.

NOTE When processing plastics and elastomers, some processing parameters or steps may require adjustment to meet the form and fit guideline while maintaining component integrity. These "processing window" adjustments do not constitute a process change. Typical adjustments will include minor temperature and time adjustments to prevent defects such as backrind. Re-cutting or replacing worn tools to reinstate initial dimensions considered an adjustment.

## **12.3 Customer Notification**

The polymeric seal manufacturer shall notify the customer when required by contract, of the changes and any residual or new risk due to the change.

## **13 Records and Document Control**

### **13.1 Record Control Procedure**

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**13.1.1** The polymeric seal manufacturer shall maintain a documented procedure to identify the controls and responsibilities needed for the identification, collection, storage, protection, retrieval, retention and disposition of records required in this standard.

**13.1.2** Actual numerical results of the physical property tests for the batch of elastomeric seal elements shall be maintained by the seal manufacturer.

## **13.2 Record Retention**

Records shall remain legible, identifiable, and retrievable. Records shall be retained for a minimum of ten (10) years after date of shipment or as required by customer, legal, and other applicable requirements, whichever is longer.

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