AEROSPACE MATERIAL SPECIFICATION

AMS7002™	REV. A
Issued 2018-06 Revised 2022-05 Superseding AMS7002	

(R) Process Requirements for Production of Metal Powder Feedstock for Use in Additive Manufacturing of Aerospace Parts

RATIONALE

Correct errors. Align requirements to better align to existing production of aerospace metal powder. Add “other elements” for routine testing.

1. SCOPE

This specification is to prescribe process requirements for production (from raw materials through preparation for shipment, see 8.6) of metal powder feedstock for use in additive manufacturing of aerospace parts.

This specification covers requirements for the production of metal powder for use as feedstock in additive manufacturing. Such powders may be pre-alloyed or commercially pure. This specification is not limited to a specific powder production method. It is intended to define those procedures and requirements necessary to achieve required cleanliness and performance of metal powder feedstock to be used in the manufacture of aerospace parts. This specification is intended to be used in conjunction with AMS powder specifications for additive manufacturing.

1.2 Application

This specification shall be applied to the production of aerospace-quality powder for the additive manufacturing of aerospace parts. A typical application is for powder used in powder bed fusion or directed energy deposition additive manufacturing processes. Powder manufactured in accordance with this specification are typically but not limited to Fe, Ni, Co, Al, Cu, or Ti base alloys or commercially pure metal powder.

1.3 Safety - Hazardous Materials

While the materials, methods, applications, and processes described or referenced in this specification may involve the use of hazardous materials, this specification does not address the hazards that may be involved in such use. It is the sole responsibility of the user to ensure familiarity with the safe and proper use of any hazardous materials and to take necessary precautionary measures to ensure the health and safety of all personnel involved

2. APPLICABLE DOCUMENTS

The issue of the following documents in effect on the date of the purchase order forms a part of this specification to the extent specified herein. The supplier may work to a subsequent revision of a document unless a specific document issue is specified. When the referenced document has been cancelled and no superseding document has been specified, the last published issue of that document shall apply.

TO PLACE A DOCUMENT ORDER: **Tel: 877-606-7323 (inside USA and Canada)**
Tel: +1 724-776-4970 (outside USA)
Fax: 724-776-0790
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SAE WEB ADDRESS: **http://www.sae.org**

For more information on this standard, visit
https://www.sae.org/standards/content/AMS7002A/

2.1 SAE Publications

Available from SAE International, 400 Commonwealth Drive, Warrendale, PA 15096-0001 Tel: 877-606-7323 (inside USA and Canada) or +1 724-776-4970 (outside USA), www.sae.org.

AS7766 Terms Used in Aerospace Metals Specifications

AS9100 Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations

AS9103 Aerospace Series - Quality Management Systems - Variation Management of Key Characteristics

AS9120 Quality Management Systems – Requirements for Aviation, Space, and Defense Distributors

2.2 ASTM Publications

Available from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959, Tel: 610-832-9585, www.astm.org.

ASTM B215 Standard Practices for Sampling Metal Powders

ASTM B243 Standard Terminology of Powder Metallurgy

2.3 ISO Publications

Available from International Organization for Standardization, ISO Central Secretariat, 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, Tel: +41 22 749 01 11, www.iso.org.

ISO 9001 Quality management systems - Requirements

ISO 17025 General requirements for the competence of testing and calibration laboratories

ISO/ASTM 52900 Additive manufacturing - General principles - Terminology

3. TECHNICAL REQUIREMENTS

3.1 Quality System Accreditation

3.1.1 The producer of the powder shall be currently registered and listed in the International Aerospace Quality Group (IAQG) Online Aerospace Supplier Information System (OASIS), to AS/EN/JISQ9100 or, provided the requirements of 4.8 are met, to ISO 9001 when approved by the purchaser.

3.1.1.1 A producer for the purposes of this specification includes both original powder manufacturers and external providers performing any of the following operations that affect critical material attributes (e.g., chemistry, size, moisture, cleanliness):

- Original powder production (e.g., atomization, crushing, milling, chemical processing, in-process sieving/blending, inspection/cerification)

- Secondary powder production (e.g., sieving, blending, packaging or re-packaging, and inspection/certification or re-inspection/re-certification)

A Producer is the entity that takes responsibility for all processing and testing, whichresults in certification to the applicable AMS material specification.

3.1.2 A distributor of powder shall be currently registered to AS9120 or, provided the requirements of 4.9 are met, to ISO 9001 when approved by the purchaser.

3.1.2.1 A Distributor, for the purposes of this specification, is a business that sells material, produced, inspected, and certified by a Producer, without changing the condition or performance of the powder through opening of packaging and introducing additional risk of exposure to moisture, foreign contaminants, or alteration of physical (e.g., rheological, chemical) properties. The same business operates as a Producer when it performs the functions of a Producer in which case it is responsible for fulfilling the requirements of a Producer for the purposes of this standard. A Distributor shall only handle powder in the same un-opened package (e.g., bottle) received from the Producer.

3.1.2.1.1 A distributor may perform splitting a large lot from a producer (e.g., 100 10-pound bottles) into smaller units (e.g., a partial lot of five 10-pound bottles) but shall not open the packaging or transfer powder into another container.

3.1.2.1.2 A distributor shall not perform any other processing (e.g., blending, treatments, sieving).

3.2 Process Control Documentation (PCD)

The process for manufacturing the powder shall be fixed and documented in a revision-controlled process control documentation (PCD).

The PCD shall include a description of the configuration control method that is acceptable to the cognizant engineering organization (CEO). The PCD shall, at a minimum, address key process variables (see 3.2.1), process setup verification (see 3.2.2), process and product cleanliness (see 3.2.3), and the melting process (see 3.3).

3.2.1 Key Process Variables

For each powder producer identification or product number, the producer shall establish parameters for process control factors that will consistently produce powder meeting the requirements of the applicable material specification and this specification. These raw (or charge) materials, controls, processes, and production parameters shall constitute the approved powder production procedure and shall be used for production of subsequent powder and powder samples.

The parameters shall include, but are not limited to, those listed in Appendix A.

Variables and terminology listed in example PCD (Appendix A) may be omitted or modified if approved by the CEO.

Any of the production processes and equipment designs that have controls in the PCD and are considered to be proprietary by the producer, may be assigned a code designation to protect intellectual property. Each variation of these processes or their control shall be assigned a modified code designation.

3.2.2 Process Setup Verification

Requirements (e.g., checklists, secondary steps, additional personal oversight) shall be included in the PCD to facilitate operator selection of the correct machine settings and parameters.

3.2.3 Process and Product Cleanliness

The powder producer shall have a contamination control plan (e.g., process failure modes effect analysis or as otherwise specified by quality system) to document identification of potential sources of contamination for all aspects of the powder production process and to establish substantiated procedures (e.g., standard operating procedures and process control document) to minimize contamination. This control plan shall include but is not limited to:

- Raw materials
- Powder production
- Material (or grade) changes and corresponding inspection of equipment and the first heat of material after a change on primary powder production (e.g., furnace, atomizer, reactors, etc.) or ancillary equipment (e.g., blenders, screeners, hoppers, air classifiers, etc.)
- Powder handling

- Air classification, screening
- Blending, packaging
- Ancillary equipment

The contamination control plan shall be included in the PCD.

3.2.3.1 Powder Handling and Storage

Powder handling and storage methods shall be established to minimize opportunities for moisture pick-up and condensation of ambient humidity on powder surfaces.

3.3 Melting Process

3.3.1 Melting Process Environment

Unless otherwise specified by the applicable powder specification, raw (or charge) material intended for conversion into powder shall be melted in an enclosed vessel under vacuum or inert gas atmosphere.

3.3.1.1 If vacuum melted, an inert gas backfill is permissible.

3.3.1.2 A controlled reactive or reducing gas atmosphere is allowed when specified in the PCD approved by the purchaser (see 8.7) provided the elements of the reactive species are 1) controlled by the applicable powder specification or a CEO approved limit included in the PCD, and 2) defined and measured as either bulk reactive or surface reactive (see 4.4.2).

3.3.2 Input Gas Purity

If gases are specified for use in the melting process, each of the specified gases utilized in the melting process shall be a minimum of 99.9% purity and ordered to an industry standard or internal purchasing specification. The dew point of the gas shall be -60 °F (-51 °C) or lower and either dew point temperature or moisture content shall be specified in the gas certificate. The gas delivery auxiliary equipment, including piping transmitting the gas, shall provide for gas delivery without contamination. The composition of the gas supply shall be certified and recorded in internal documentation (see 8.7).

3.3.2.1 Recycled Gas Purity

Gases from recovery systems shall be monitored and control limits on the moisture and oxygen of recovered gas shall be provided in the PCD.

3.3.3 Process Interruption

Any interruption that requires opening the powder production vessel (i.e., loss of controlled atmosphere) shall be considered the end of the heat. A new heat identifier shall be designated upon subsequently resuming the process. For routine, planned interruptions defined in the PCD, the CEO may waive this requirement if supported by: statistical process control (SPC) and historical data, along with risk analyses, mitigation, and substantiation (i.e., that the controls and resultant variation in powder chemistry uniformity are acceptable).

3.3.4 Input Material Used in Semi-Continuous Powder Production

All input material (e.g., powder, wire, ingot, or bar) used in non-batch production (semi-continuous melting) of powder heats shall conform to the composition requirements listed in the applicable powder specification unless:

- A separate input material composition range is provided in the applicable powder specification (see 8.3), or
- The powder producer has developed and substantiated compositional offsets, specific to the combination of:
    1. Powder production process,
    2. Specified finished powder chemistry and tolerances, and
    3. Specified finished particle size distribution.

3.3.5 Powder Chemistry Uniformity

All heats of material used to make a blend shall meet the chemistry listed, except for “other elements” (see 8.8) or trace elements when listed in the PCD and approved by the purchaser, in the applicable powder specification. The powder lot chemistry shall not be made by blending powder heats of material with any elements out of their specified range. Compositional doping is not permitted. Testing records shall be retained for a period of time agreed upon between the purchaser and supplier at the time of purchase.

3.3.5.1 Trace Element Waiver

If approved by the purchaser, this exception only applies to powder heats made:

- From the same certified raw or revert material lots,
- Under the same fixed conditions,
- During a period of uninterrupted (e.g., not switching between alloys) sequential production on the same dedicated process equipment (see 8.10).

3.3.6 Powder Size Uniformity

Powder shall be of a distribution consistent with the natural output of the fixed practice and not substituted by, nor shifted with powder from other heats with narrower, partial size fractions unless allowed in the producer’s PCD approved by the purchaser. Size deviations are not permitted unless approved by the purchaser (see 8.9).

4. QUALITY ASSURANCE PROVISIONS

4.1 Responsibility for Inspection

The Supplier of the powder shall supply all samples for Supplier’s tests and shall be responsible for the performance of all required tests. Purchaser reserves the right to sample and to perform any confirmatory testing deemed necessary to ensure the powder conforms to specification requirements.

4.2 Approval

The PCD (3.2) shall be established by the producer and approved by the purchaser before powder for production use is supplied. Any changes to the PCD shall be approved by the purchaser prior to implementation.

4.3 Classification of Tests

All technical requirements are acceptance tests. Pre-production tests shall be performed prior to or on the initial shipment of powder to a purchaser, on each lot, when a change in: ingredients, processing, or ingredients and processing requires re-approval as in 4.2, or when purchaser deems confirmatory testing to be required.

4.4 Sampling and Testing

All acceptance tests, except in-process chemical analysis (see 3.3.5, 4.4.2), shall be performed on samples, taken in accordance with ASTM B215, from the blended powder lot at the final particle size distribution. Sufficient powder shall be sampled from each lot to perform all required tests in duplicate.

4.4.1 Powder Specification

The applicable powder specification shall include at a minimum:

- Composition requirements, including the classification of each specified element as: bulk non-reactive, bulk reactive, or surface reactive for testing purposes (see 4.4.2).
- Melting environment and conversion (atomization) gas requirements, including definition of inert gases compatible with the material, if applicable.
- Particle size requirements.
- Test methods for composition, particle size, and any additional powder attributes, if specified.

4.4.2 Sampling for Chemical Analysis

For determination of conformance to Powder Chemistry Uniformity requirements (see 3.3.5), elements shall be tested at the appropriate step of the powder production process (see 8.4):

- Bulk non-reactive elements, defined in the applicable powder specification, whose measured composition are not dependent on time at temperature or by surface area to volume, shall be measured on either:
    1. Melt dip samples from the master heat, or
    2. Powder in loose, consolidated, or re-melted form, or
    3. Certified feedstock used in batch or non-batch production (semi-continuous melting) on dedicated process equipment (see note 8.10).
- Bulk reactive elements, when defined in the applicable powder specification, shall be measured in loose or consolidated powder form.
- Surface reactive elements, when defined in the applicable powder specification, shall be measured at the final particle size distribution.
- “Other elements,” when defined in the applicable powder specification, shall be measured in loose or consolidated powder form to account for potential pickup from downstream processing equipment after testing. Bar feedstock or melt dip sample chemistry may be approved by the purchaser if the production equipment is dedicated and the risk of pickup of other elements downstream of testing is eliminated.

4.4.2.1 Blending of Powder Heats into Powder Lots

When multiple individual powder heats are blended together into a powder lot, each individual powder heat shall be tested for all composition requirements, except “other elements” (see 8.8) or trace elements when listed in the PCD and approved by the purchaser (see 3.3.5), prior to blending. Notwithstanding, “other elements” identified as being of concern (e.g., potential carry-over cross-contaminant from prior work-orders on process equipment) shall still be tested.

If the Producer desires to perform in-process blending prior to removal of fine powder, the surface reactive element requirements shall be met after coarse particle removal (i.e., top cut). If any surface reactive element is above specification maximum limits, the fines shall be removed prior to blending to verify the individual heat meets the compositional requirements of the applicable powder specification. An exception is made for a producer who has developed and substantiated a known offset bias between the in-process and final surface reactive element chemistry. If such an offset is established to conclude to a 99% confidence interval that the material will meet the final chemistry after fine removal, blending may occur prior to fine removal.

If all surface reactive elements are below the specification maximum limit, blending is allowed prior to fine removal.

For heats produced from the same certified lot of input material (3.3.4), the CEO or purchaser and supplier may agree in the approved PCD to replace the individual heat testing requirement with a reduced testing frequency (RTF) requirement. The RTF plan approval shall be based on:

- Specific test frequency (e.g., consideration of beginning/end of campaigns; material changes on process equipment, minimum frequency per reactor/atomizer/process equipment which exposes the product to risks affecting chemistry such as cross-contamination or heat and oxygen/moisture; etc.) and historical data is substantiated to show sufficient capability to predict changes in as-measured composition for the powder production process,

- defined blending limits, procedures, and controls in the PCD, along with

- risk analysis (e.g., risk sources, limits of detection at reduced frequency), mitigation, and substantiation.

Blending of powder from different reactors/atomizers shall be based on above considerations for each individual reactor/atomizer and expressly addressed in the PCD/RTF plan.

The CEO may require confirmatory testing to be performed on samples retained from each in-process batch that is not tested as part of this RTF schedule.

4.4.2.2 Chemistry for Final Lots

Samples for final lot chemistry shall be taken from the final product, at the final size, after blending, prior to packaging.

4.5 Resampling and Retesting

If any specimen used in the acceptance or conformance tests fails to meet the specified requirements, disposition of the powder may be based on the results of testing three additional specimens for each original nonconforming specimen. Failure of any retest specimen to meet the specified requirements shall be cause for rejection of the powder represented. Results of all tests shall be reported. Testing malfunctions not conforming to the analysis method are allowed as a one-to-one replacement test.

4.6 Responsibility for Certification

The producer is the organization responsible for operations performed by the processing and testing entities, but it is not required that all or any processing and testing be performed in house by the producer. The producer takes responsibility that the material meets the specification. Whenever the material owner (e.g., a purchaser who is not the original powder manufacturer who intends to re-sell the powder or a user commissioning additional processing after purchase) authorizes processing to change the certified material size, condition, performance, including any blending or re-packaging, they become the producer and are responsible for the testing and certification to that new size/condition/specification and become responsible for all Producer Requirements.

4.6.1 The requirements of 4.6 apply when any handling involving the opening of containers or exposure of powder to new surfaces or environments is performed. The material owner shall coordinate the processing, generate a new material certification, and take responsibility for compliance.

4.7 Revision of Material Certification

Only the producer that created a material certification document can amend that document (e.g., amend a material certification to an alternate revision).

4.8 Additional Quality Requirements for Producers

For producers that are ISO 9001 registered, but not registered to AS9100 (see 3.1.1). The following requirements apply:

4.8.1 Support

4.8.1.1 Resources

4.8.1.1.1 Monitoring and Measuring Resources

4.8.1.1.1.1 Measurement Traceability

The organization shall establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

The organization shall maintain a register of the monitoring and measuring equipment. The register shall include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

NOTE: Monitoring and measuring equipment can include, but are not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.

Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (refer to ISO 9001 or AS9100).

4.8.1.2 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

- Relevant quality management system documented information and changes thereto;
- Their contribution to product or service conformity;
- Their contribution to product safety;
- The importance of ethical behavior.

4.8.1.3 Documented Information

4.8.1.3.1 Control of Documented Information

When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

4.8.1.3.2 For the control of documented information, the organization shall address the following activity, as applicable:

prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

4.8.2 Operation

4.8.2.1 Operational Planning and Control

4.8.2.1.1 Configuration Management

The organization shall plan, implement, and control a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:

- Control product identity and traceability to requirements, including the implementation of identified changes;
- Ensure that the documented information (e.g., requirements, design, verification, validation, and acceptance documentation) is consistent with the actual attributes of the products and services.

4.8.2.2 Control of Externally Provided Processes, Products, and Services

4.8.2.2.1 General

- The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.
- The organization shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.
- The organization shall identify and manage the risks associated with external provision of processes, products, and services, as well as the selection and use of external providers.
- The organization shall require that external providers apply appropriate controls to their direct and sub-tier external providers to ensure that requirements are met.

NOTE: During external provider evaluation and selection, the organization can use quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, external provider approvals from government authorities or customers). Use of such data would only be one element of an organization's external provider control process and the organization remains responsible for verifying that externally provided processes, products, and services meet specified requirements.

4.8.2.2.1.1 The organization shall:

- Define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status.
- Maintain a register of its external providers that includes approval status (e.g., approved conditional, disapproved) and the scope of the approval) (e.g., product type, process family).
- Periodically review external provider performance including process, product and service conformity, and on-time delivery performance.
- Define the necessary actions to take when dealing with external providers that do not meet requirements.
- Define requirements for controlling documented information created by and/or retained by external providers.

4.8.2.2.2 Type and Extent of Control

The organization shall ensure that externally provided processes, products, and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customer by taking into consideration the results of the periodic review of external provider performance (see 4.7.2.2.1.1).

Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by the organization. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit material.

NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.

NOTE 2: Verification activities can include:

- Review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter).
- Inspection and audit at the external provider's premises.
- Review of the required documentation.
- Review of production material approval process data.
- Inspection of products or verification of services upon receipt.
- Review of delegations of product verification to the external provider.

When externally provided product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When the organization delegates verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations shall be maintained. The organization shall periodically monitor the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, the organization shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), the organization shall implement a process to validate the accuracy of test reports.

4.8.2.2.3 Information for External Providers

The organization shall communicate to external providers its requirements for:

- The processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions).
- Design and development control.
- Special requirements, critical items, or key characteristics.
- Test, inspection, and verification (including production process verification).
- The use of statistical techniques for product acceptance and related instructions for acceptance by the organization.
- The need to:

    1. Implement a quality management system;
    2. Use customer-designated or approved external providers, including process sources (e.g., special processes);
    3. Notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;
    4. Prevent the use of counterfeit material;
    5. Notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval;

6. Flow down to external providers applicable requirements including customer requirements;

7. Provide test specimens for design approval, inspection/verification, investigation, or auditing;

8. Retain documented information, including retention periods and disposition requirements.

- The right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain.

- Ensuring that persons are aware of:

  1. Their contribution to product or service conformity;

  2. Their contribution to product safety;

  3. The importance of ethical behavior.

4.8.2.3 Production and Service Provision

4.8.2.3.1 Control of Production and Service Provision

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; ensuring that documented information for monitoring and measurement activity for product acceptance includes:

  1. Criteria for acceptance and rejection;

  2. Where in the sequence verification operations are to be performed;

  3. Measurement results to be retained (at a minimum an indication of acceptance or rejection);

  4. Any specific monitoring and measurement equipment required and instructions associated with their use.

- The accountability for all products during production (e.g., material quantities, split orders, nonconforming product);

- The control and monitoring of identified critical items, including key characteristics, in accordance with established processes;

- The identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;

- The availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;

- The provision for the prevention, detection, and removal of foreign objects;

- The control and monitoring of utilities and supplies (e.g., water, compressed gas, electricity, raw materials) to the extent they affect conformity to product requirements

- The identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

4.8.2.3.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production and shall be maintained.

Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

4.8.2.3.2 Identification and Traceability

The organization shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

NOTE: Traceability requirements can include:

- The identification to be maintained throughout the product life;
- The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch to the destination (e.g., delivery, scrap);
- For a powder blend of two or more heats or lots, the ability to trace those heats or lots to the powder blend and then to the next highest configuration (e.g., either a heat(s)/batch(es) of raw materials or powder heats/lots).
- For a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.

4.8.2.3.3 Control of Changes

Persons authorized to approve production or service provision changes shall be identified.

NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.

4.8.2.3.4 Control of Nonconforming Outputs

NOTE: The term “nonconforming outputs” includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.

The organization’s nonconformity control process shall be maintained as documented information including the provisions for:

- Defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- Taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
- Timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- Defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts.

NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.

4.8.2.3.4.1 Dispositions of use-as-is for the acceptance of nonconforming products shall only be implemented:

- After approval by an authorized representative of the organization responsible for design (i.e., CEO) or by persons having delegated authority from the design organization;
- After authorization by the customer, if the nonconformity results in a departure from the contract requirements.

4.8.2.3.4.2 Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable. Counterfeit, or suspect counterfeit, material shall be controlled to prevent reentry into the supply chain.

4.9 Additional Quality Requirements for Distributors

NOTE: Some of the requirements in this section, which are based on AS9120, have had variants of the word “Production” changed to variants of “Operation” to distinguish Production activities by the producer (as defined in 3.1.1.1) from Operations performed by the distributor.

For distributors that are ISO 9001 registered, but not registered to AS9120 (see 3.1.2). The following requirements apply:

4.9.1 Support

4.9.1.1 Documented Information

4.9.1.1.1 Control of Documented Information

When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

Documented information that provides evidence of product origin, conformity, and shipment shall be retained.

NOTE: Examples of documented information that is retained may include, but is not limited to:

- Manufacturer or distributor test and inspection reports;
- Purchase orders/contracts;
- Certificates of conformity (manufacturer, sub-tier distributor), copies of authorized release certificates;
- Nonconformance, concession, and corrective actions;
- Documented information of lot or batch traceability;
- Documented information of storage, preservation, or shelf-life condition (e.g., time, temperature, humidity).

4.9.1.1.1.1 For the control of documented information, the organization shall address the following activity, as applicable:

Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

4.9.2 Operation

4.9.2.1 Operational Planning and Control

4.9.2.1.1 Configuration Management

The organization shall plan, implement, and control a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:

- Control product identity and traceability to requirements, including the implementation of identified changes;
- Ensure that the documented information (e.g., requirements, design, verification, validation, and acceptance documentation) is consistent with the actual attributes of the products and services.

4.9.2.1.2 Prevention of Suspected Unapproved Material

The organization shall plan, implement, and control a process appropriate to the organization and the product that identifies and prevents the release of unapproved or suspected unapproved material.

NOTE: Suspected unapproved material prevention processes should consider:

- Training of appropriate persons in the awareness and identification of suspected unapproved material;
- Requirements for assuring traceability of material to an authorized source;
- Inspection processes to detect suspected unapproved material;
- Monitoring of suspected unapproved material reporting from external sources;
- Quarantine and reporting of suspected unapproved material in accordance with applicable requirements from the competent authority or customers, as required.

4.9.2.2 Control of Externally Provided Processes, Products, and Services

4.9.2.2.1 General

- The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.
- The organization shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.
- The organization shall identify and manage the risks associated with external provision of processes, products and services, as well as the selection and use of external providers.
- The organization shall require that external providers apply appropriate controls to their external providers to ensure that requirements are met.

NOTE: During external provider evaluation and selection, the organization can use quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, external provider approvals from government authorities or customers). Use of such data would only be one element of an organization's external provider control process and the organization remains responsible for verifying that externally provided processes, products, and services meet specified requirements.

4.9.2.2.1.1 The organization shall:

- Define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status.
- Maintain a register of its external providers that includes approval status (e.g., approved conditional, disapproved) and the scope of the approval) (e.g., product type, process family, authorized approval to distribute).
- Periodically review external provider performance including process, product and service conformity, and on-time delivery performance.
- Define the necessary actions to take when dealing with external providers that do not meet requirements.
- Define requirements for controlling documented information created by and/or retained by external providers.

4.9.2.2.2 Type and Extent of Control

The organization shall ensure that externally provided processes, products, and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customer by taking into consideration the results of the periodic review of external provider performance (see 4.8.2.2.1.1 c).

Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by the organization. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit material.

NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.

NOTE 2: Verification activities can include:

- Review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter).
- Inspection and audit at the external provider's premises.
- Review of the required documentation.
- Review of production material approval process data.
- Inspection of products or verification of services upon receipt.

When external provider test reports are utilized to verify externally provided products, the organization shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant risk, the organization shall implement a process to validate the accuracy of test reports.

4.9.2.2.3 Information for External Providers

The organization shall communicate to external providers its requirements for:

- The processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions).
- Test, inspection, and verification.

- The use of statistical techniques for product acceptance and related instructions for acceptance by the organization.
- The need to:
    1. Implement a quality management system;
    2. Use customer-designated or approved external providers, including process sources (e.g., special processes);
    3. Notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;
    4. Prevent the use of suspected unapproved, unapproved, and counterfeit material (see 4.8.2.1.2);
    5. Notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval;
    6. Flow down to external providers applicable requirements including customer requirements;
    7. Provide a certificate of conformity, test reports, or authorized release certificate, as applicable;
    8. Retain documented information, including retention periods and disposition requirements.
- The right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain.
- Ensuring that persons are aware of:
    1. Their contribution to product or service conformity;
    2. Their contribution to product safety;
    3. The importance of ethical behavior.

4.9.2.3 Operation and Service Provision

4.9.2.3.1 Control of Operation and Service Provision

The organization shall implement operation and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; ensuring that documented information for monitoring and measurement activity for product acceptance includes:
    1. Criteria for acceptance and rejection;
    2. Where in the sequence verification operations are to be performed;
    3. Measurement results to be retained (at a minimum an indication of acceptance or rejection);
    4. Any specific monitoring and measurement equipment required and instructions associated with their use.
- The accountability for all products during operations (e.g., material quantities, split orders, nonconforming product);
- The availability of evidence that all operations and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;

- The provision for the prevention, detection, and removal of foreign objects;
- The control and monitoring of utilities and supplies (e.g., water, compressed gas, electricity, raw materials) to the extent they affect conformity to product requirements.

4.9.2.3.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure operational processes shall be validated prior to final release for operation and shall be maintained.

Storage requirements shall be defined for operations equipment or tooling in storage including any necessary periodic preservation or condition checks.

4.9.2.3.2 Identification and Traceability

The organization shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

Unserviceable product shall be controlled and physically segregated from serviceable product.

NOTE: Traceability requirements can include:

- The identification to be maintained throughout the product life;
- The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch to the destination (e.g., delivery, scrap);
- For a powder blend of two or more heats or lots, the ability to trace those heats or lots to the powder blend and then to the next highest configuration (e.g., either a heat(s)/batch(es) of raw materials or powder heats/lots).
- For a product, a sequential record of its production and operations (manufacture, assembly, inspection/verification) to be retrievable.

The organization shall maintain product identification and traceability by suitable means (e.g., labels, bar codes) from receipt; during splitting, storage, packing, and preservation operations and until delivery. This includes handling or packing operations outsourced to external providers.

When delivering split product, the following information shall be retained:

- Amount delivered relative to amount received from external provider,
- Purchase order number(s),
- Customer's name(s).

4.9.2.3.3 Control of Changes

Persons authorized to approve operations or service provision changes shall be identified.

NOTE: Operations or service provision changes can include the changes affecting processes, operations equipment, tools, or software programs.