

Product Life Cycle Management System Requirements for the Petroleum and Natural Gas Industries

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Should: As used in a standard, “should” denotes a recommendation or that which is advised but not required in order to conform to the standard.

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Product Life Cycle Management System Requirements for the Petroleum and Natural Gas Industries

1 Scope

This document defines the requirements of a management system for service providers performing life cycle management of products for organizations in the petroleum and natural gas industry. The document identifies requirements for service providers of life cycle management and the activities required to perform product life cycle management including determination of product life cycle management status, actions required to maintain a status, and development of the life cycle management plan.

Multiple products used together as part of a system application may be included in the scope of this document, but only as individual products.

This document was developed for upstream activities application. This document is intended for pressure-containing and/or pressure-controlling products for wellbore fluids but may also be applied to other equipment that is specified by the product owner or customer. Although this document and/or portions thereof could be applicable to other industry segments, it is recommended that other segments carefully review these requirements in order to determine their applicability and, if necessary, to develop an applicable annex identifying any segment-specific requirements.

This document does not include technical requirements for products and does not include requirements for determination of fitness-for-service for a particular product. In addition, this document does not include requirements for original design and manufacture of product.

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 (including any amendments) applies, except that new editions may be used on issue and shall become mandatory six (6) months from the date of the revision.

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

API Specification Q2, *Specification for Quality Management System Requirements for Service Supply Organizations for the Petroleum and Natural Gas Industry*

3 Terms, Definitions, Acronyms, and Abbreviations

3.1 Terms and Definitions

For the purposes of this document, the terms and definitions given in API Q2 and the following shall apply. When identical terms are defined in API Q2 and this document, the following definitions shall apply.

3.1.1

certification body

An organization independent of the manufacturer that has demonstrated adequate competence, authority, and credibility to perform independent and objective audits of another organization in order to provide verification of the adequate qualification/competency of the audited organization's personnel and evidence that the audited organization's products satisfy applicable requirements.

3.1.2**design validation**

Process of proving a design by testing to demonstrate conformity of the product to design requirements.

3.1.3**design verification**

Process of examining the result of design and development output to determine conformity with specified requirements.

NOTE 1 Design verification activities can include one or more of the following (not an all-inclusive list):

- a) confirming the accuracy of design results through the performance of alternative calculations,
- b) review of design output documents independent of activities of design and development,
- c) comparing new designs to similar proven designs.

NOTE 2 Design verification is addressed in both API Q2 and this document differently. For API Q2, “design and development verification” refers to the design of the service provided by the service provider. For this document, “design verification” occurring under product definition refers to the design of the managed product being controlled by the service provider.

3.1.4**functional specification**

Features, characteristics, process conditions, boundaries, and exclusions that define the performance and use requirements of a managed product, including any customer specific requirements

NOTE See ISO 13879 for additional information on functional specifications.

3.1.5**legal requirement**

An obligation imposed on an organization, including those that are statutory or regulatory.

3.1.6**life cycle management (LCM) status**

One of the designations applied to a product based on availability of or access to records, traceability, usage, repair, and maintenance.

3.1.7**maintenance**

Action(s) taken to minimize the likelihood of causes of equipment failure and unscheduled interruptions.

NOTE This is referred to in API Q2 as “preventive maintenance”.

3.1.8**managed product**

Equipment maintained in accordance with the requirements of this standard.

3.1.9**original equipment manufacturer****OEM**

The organization responsible for the original design and initial manufacture, as well as for ensuring conformance to initial acceptance criteria of the managed product.

3.1.10**owner**

The organization engaging a service provider to perform life cycle management on a managed product.

NOTE The owner may be the equipment manufacturer or a service company for items such as rental tooling and/or equipment. For the purposes of this document, the owner may not necessarily be the legal owner of the equipment.

3.1.11

pressure-containing

Product or part whose failure to function as intended results in a release of retained fluid to the atmosphere.

3.1.12

pressure-controlling

Product or part intended to control or regulate the movement of pressurized fluids.

3.1.13

product specification

Document that identifies the materials, design, testing, and marking requirements of the managed product.

NOTE This is sometimes referred to as a “product standard”.

3.1.14

repair

Action(s) performed on a nonconforming product to make it acceptable for the intended use.

NOTE 1 Repair within the scope of this document includes remanufacture as defined by other API product specifications.

NOTE 2 The distinction between repair and remanufacture may be further specified within API product specifications.

3.1.15

service environment

External or internal conditions to which managed product is subjected throughout its life cycle.

3.1.16

service provider

Organization performing life cycle management in conformance with this document.

NOTE The service provider may be any organization including, but not limited to, original equipment manufacturer, owner, product user, or a third-party entity.

3.1.17

technical specification

Document that describes product capabilities to comply with the functional specification.

NOTE See ISO 13880 for additional information on technical specifications.

3.1.18

traceability

Ability to document the history of an object.

NOTE Traceability can relate to both the origin of materials and finished parts as well as associated processing history.

3.2 Acronyms and Abbreviations

For the purposes of this document, the following acronyms and abbreviations shall apply.

API American Petroleum Institute

ISO International Organization for Standardization

LCM life cycle management

LCMP life cycle management plan

OEM original equipment manufacturer

PD product definition

4 Quality Management System Requirements

The service provider shall establish, implement, and maintain a quality management system conforming to API Q2 without exclusions. Activities that this specification requires to be controlled by the service provider, whether performed internally or outsourced, shall not be excluded from the quality management system.

The service provider shall be responsible for maintaining records required by this document.

5 Life Cycle Management Status

5.1 Responsibility

The service provider shall be responsible for the review, determination, approval, and documentation of the LCM status.

Managed products shall meet requirements of one of the defined LCM status. Products that do not satisfy one of the defined LCM statuses shall be deemed outside the scope of this document. The service provider shall determine and document the existing identification, marking, and traceability of managed product.

5.2 Determination of Life Cycle Management Status

NOTE 1 This document provides requirements for three life cycle management statuses: LCM-1, LCM-2, and LCM-3.

The following shall be used as a basis for determining the life cycle management status:

- product identification,
- product definition,
- manufacturing records,
- traceability,
- usage history,
- repair and maintenance history,
- product conformance (for LCM-3 only).

Records of the life cycle management status shall be maintained. If the owner is different from the service provider, the service provider shall communicate the life cycle management status and changes to the owner. The service provider shall maintain records of such communication. Life cycle management status records shall be maintained on the managed product from the time the product is originally placed in the life cycle management program until the product is decommissioned in accordance with the LCMP (see 7.10).

NOTE 2 Life cycle management status changes may be driven by changes in product condition or performance capabilities, gap in maintenance or usage history, and/or owner requests.

NOTE 3 Annex A provides a summary of life cycle management status requirements.

5.3 Life Cycle Management Status Requirements

5.3.1 LCM-1

5.3.1.1 Product Identification

The managed product shall be legibly and permanently identified to allow traceability to the original equipment manufacturer and the date of manufacture.

5.3.1.2 Product Definition

The product definition shall be established and documented by the service provider.

The product definition for LCM-1 shall include the following:

- a) technical specification (including changes since the original manufacture of the managed product);
- b) design verification using one or more of the following:
 - review of design output documents to determine conformity to specified requirements,
 - calculations supporting technical specifications and managed product characteristics,
 - comparing new designs to similar proven designs;
- c) design validation using one or more of the following:
 - prototype tests,
 - functional or operational tests,
 - tests specified by industry standards/specifications or regulatory requirements,
 - review of field performance history of managed product;
- d) verifiable characteristics of managed product required to maintain conformance to the technical specification, as applicable including:
 - dimensional limits including tolerances,
 - surface treatments and finishes,
 - materials;

NOTE Materials may include requirements for integrity (free from cracks, inclusions, etc.) and details such as mechanical properties, hardness, heat treat condition, or chemical composition.

- e) constituent components and associated requirements,
- f) product verification methods and techniques including acceptance criteria;
- g) testing requirements including:
 - testing of managed product required to meet functional, technical, or industry requirements,
 - testing after repairs;
- h) maintenance requirements for continued managed product conformance to the technical specification.

5.3.1.3 Manufacturing Records

Manufacturing records for the managed product and current constituent components shall be in accordance with the records required to be supplied to customer by the industry product specification used to manufacture-managed product. Additional manufacturing records required by contract shall be maintained by the service provider. When an industry product specification does not exist, records shall be in accordance with requirements specified by the product owner.

Required manufacturing records shall be maintained on the managed product from the time the product is originally placed in the life cycle management program until the product is decommissioned in accordance with the LCMP (see 7.10).

5.3.1.4 Traceability

The managed product and any current constituent components shall be traceable in accordance with the industry product specification or the product definition developed for the managed product.

5.3.1.5 Usage History

Usage history (see 7.8) after the managed product is placed into life cycle management shall be maintained in accordance with the LCMP (see Section 7). Required usage history shall be maintained on the managed product until the product is decommissioned in accordance with the LCMP (see 7.10).

5.3.1.6 Repair and Maintenance History

Repair and maintenance history after the managed product is placed into life cycle management shall be maintained in accordance with the LCMP (see Section 7). Required repair and maintenance records shall be maintained until the product is decommissioned in accordance with the LCMP (see 7.10).

5.3.2 LCM-2

5.3.2.1 Product Identification

The product identification shall be the same as defined in LCM-1 (see 5.3.1.1).

5.3.2.2 Product Definition

The product definition shall be the same as defined in LCM-1 (see 5.3.1.2).

5.3.2.3 Manufacturing Records

Manufacturing records shall be the same as defined in LCM-1 (see 5.3.1.3).

5.3.2.4 Traceability

The managed product and any constituent components shall be traceable in accordance with the industry product specification or product definition to which the product was originally manufactured.

5.3.2.5 Usage History

Usage history (see 7.8) shall be maintained on the managed product from the time product is originally placed in service until the product is decommissioned in accordance with the LCMP (see 7.10).

5.3.2.6 Repair and Maintenance History

Record of repair and maintenance history shall be maintained on the managed product from the time the product is originally placed in service until the product is decommissioned in accordance with the LCMP (see 7.10).

5.3.3 LCM-3

5.3.3.1 Product Identification

The managed product shall be legibly and permanently identified to allow determination of the original equipment manufacturer, conformance to the API product specification, date of manufacture, and conformance of the original equipment manufacturer's quality management system to API Q1 at the date of manufacture (see 5.3.3.7 for product conformance requirements).

NOTE A managed product marked with the API Monogram by an organization licensed by API in conformance with the API Monogram Program requirements satisfies 5.3.3.1.

5.3.3.2 Product Definition

The product definition shall be established and documented by the service provider. The product definition shall include the following, as a minimum:

- a) the original technical specification and any changes since original manufacture;
- b) design verification and design validation in conformance with API Q1 and applicable API product specification to which the managed product was originally manufactured;
- c) verifiable characteristics of the managed product required to maintain conformance to the technical specification and API product specification, as applicable including:
 - dimensional limits including tolerances,
 - surface treatments and finishes,
 - materials.
- d) **NOTE** Materials may include requirements for integrity (free from cracks, inclusions, etc.) and details such as mechanical properties, hardness, heat treat condition, chemical composition, constituent components, and associated requirements;

- e) product verification methods and techniques, including acceptance criteria that meet the applicable API product specification to which the managed product was originally manufactured;
- f) testing requirements, including:
 - testing of the managed product required to meet functional specification, technical specification, and the applicable API product specification to which the product was originally manufactured,
 - testing after repairs,
- g) maintenance requirements to maintain product conformance to the technical specification.

5.3.3.3 Manufacturing Records

Manufacturing records for the managed product, and for any replacement parts used in any assembly, shall, as a minimum, be in accordance with the records required to be supplied to the customer by the API product specification used to manufacture the managed product. Manufacturing records for any replacement parts in all assemblies shall be in accordance with the records required to be supplied to the customer by the API product specification in place at the time of the managed product manufacture.

The service provider shall maintain records required to be supplied to the customer by API product specification for manufacture of repaired or replacement components and additional manufacturing records required by the product owner. Required manufacturing records shall be maintained on the managed product from the time the product is originally manufactured until the product is decommissioned in accordance with the LCMP (see 7.10).

5.3.3.4 Traceability

The managed product shall have traceability since manufacture, in accordance with the API product specification. Traceability shall also apply to constituent components that have a traceability requirement in the API product specification.

5.3.3.5 Usage History

Usage history (see 7.8) requirements shall be the same as LCM-2 (see 5.3.2.5).

5.3.3.6 Repair and Maintenance History

Repair and maintenance history requirements shall be the same as LCM-2 (see 5.3.2.6).

5.3.3.7 Product Conformance

The managed product shall conform to the applicable API product specification in effect at the time of manufacture. The managed product shall have been manufactured under a quality management system in conformance with API Q1. This quality management system shall have been certified by a certification body (see 3.1.1) at the time of manufacture. Constituent components of managed products shall conform to the requirements of the current product definition.

6 Product Definition Changes

The service provider shall maintain a documented procedure to plan and control product definition changes for the managed product in service.

The procedure shall include the following requirements.

- a) Identify the original technical specification and applicable industry product specification requirements.
- b) Identify deviations from the original technical specification and/or industry product specification requirements.
- c) Determine the verifiable product characteristics that are affected by the deviations from the technical specification.
- d) Identify product verification methods and techniques including acceptance criteria for the changed product characteristics.
- e) Identify the required revisions to the technical specification.
- f) Create a revised technical specification and perform design verification activities.
- g) Determine and perform required design validation activities.
- h) Establish requirements for approval.
- i) Document a revised product definition.

Product definition changes shall be reviewed, verified, validated, and approved before use. These changes shall require the same controls as those used in the previous product definition development. Product definition changes shall be communicated to the owner of the managed product. The review of product definition changes shall include evaluation of the effect of the changes on the product and/or its constituent components already in service.

Records of product definition changes, reviews of those changes, and actions shall be maintained until the product is decommissioned in accordance with the LCMP (see 7.10).

NOTE Management of change may apply to product definition or original performance requirements as specified in API Q2.

7 Life Cycle Management Plan Requirements

7.1 General

The service provider shall develop, document, and maintain the life cycle management plan (LCMP) to ensure conformance to applicable requirements. The service provider shall ensure the execution of the LCMP.

7.2 Plan Content

The LCMP is a service quality plan and shall address all of the service quality plan requirements of API Q2. In addition to the requirements of Q2, the LCMP shall address the following:

- a) description of the managed product (see 7.4). For LCM-3, managed products shall include reference to applicable API product specification;
- b) identification, marking, and traceability (see 7.5);
- c) repair and maintenance (see 7.6);

- d) installation, physical arrangement, and service environment (see 7.7);
- e) recording of usage history (see 7.8);
- f) preservation of product (see 7.9);
- g) decommissioning (see 7.10).

Items of the LCMP identified as not applicable to a managed product shall be justified and documented.

NOTE 1 Requirements addressed in the LCMP may be included directly or by reference to other documents available to the service provider.

NOTE 2 A single LCMP may cover multiple products or different configurations of a single product.

7.3 Plan Approval

The LCMP and any revision shall be documented and approved by the service provider. Records of LCMP approvals shall be maintained. When required by contract, the LCMP and any revisions shall be communicated to the owner.

7.4 Description of the Managed Product

The LCMP shall include a description of the managed product to be covered by the LCMP and the required LCM status to which the item is maintained.

NOTE Characteristics such as size, model, type, function, location, capacity, or manufacturer may be used to describe the managed product.

7.5 Identification, Marking, and Traceability

The LCMP shall specify or make reference to method, location, and content of marks applied to managed products. Traceability requirements for managed products shall be specified as part of the LCMP in accordance with requirements of product definition and applicable LCM status (see 5.3.1.4, 5.3.2.4 or 5.3.3.4).

LCMP shall contain the minimum marking information (including maintenance and replacement) required by the applicable industry specification, the current LCM status and be traceable to the service provider. When marking indicates managed product capabilities, then marking shall indicate capabilities in accordance with the product definition.

Records of identification, marking, and traceability shall be maintained.

NOTE Where the mark cannot be physically applied to the product, it may be applied to a tag, container, or related item. Existing traceability and identification markings may be used for this purpose if appropriate.

7.6 Repair and Maintenance

The life cycle management plan shall include repair and maintenance requirements to maintain product conformance to the stated product definition.

Repair and maintenance requirements shall include or reference:

- a) product characteristics to be assessed, including acceptance criteria, before the start of repair or maintenance activities;

- b) activities to be performed and the frequency of those activities;
- c) condition monitoring requirements, as applicable;
- d) competency requirements for personnel performing repair and maintenance including education, training, skills and experience;
- e) environmental restrictions, if any, for performing repair and maintenance;
- f) requirements for validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement:
 - validation shall demonstrate the ability of these processes to achieve planned results,
 - when repair activities include nondestructive examination, welding, or heat treating, there shall be a requirement in the plan to validate these processes;
- g) list of spare parts required by the customer and/or technical requirements, including those recommended by the original equipment manufacturer or current product definition, as applicable;
- h) recordkeeping and status reporting requirements;
- i) product characteristics to be assessed, including acceptance criteria, after completion of repair or maintenance activities.

7.7 Installation, Physical Arrangement, and Service Environment

The LCMP shall include or make reference to requirements for installation, physical arrangement, or service environment where these items affect conformance to the product definition.

Records of conformance to requirements shall be maintained.

7.8 Usage History

The LCMP shall include requirements for records of operating parameters identified as affecting the continued service of a managed product that are not verifiable through subsequent inspection or testing during the life of managed product. As a minimum, the LCMP shall include the parameters required by the equipment operating manual to be monitored.

7.9 Preservation of Product

The LCMP shall include requirements for transportation, handling, packaging, storage, and protection when required for conformance to product definition.

7.10 Decommissioning

The LCMP shall include requirements for end-of-life determination and required decommissioning activities.

As a minimum, decommissioning activities should address the following:

- a) risk assessment, including legal requirements, hazards to personnel or environment;
- b) activities to be undertaken to decommission the managed product:

- steps to be taken before decommissioning,
 - activities to decommission,
 - disposition of equipment after decommissioning;
- c) identification of decommissioned managed product to preclude future use;
- d) verification of decommissioning; and
- e) recordkeeping and status reporting requirements.

NOTE If it is not possible to remove the equipment, additional actions after decommissioning may be required to ensure compliance to legal requirements, e.g. environmental monitoring or equipment access control. If such actions are required, they may be specified in the decommissioning plan.

Annex A

(informative)

Summary of LCM 1–3 Requirements

Table A.1 is provided as a guide to allow users of this document to gain a high level of understanding of the requirements of the document for each of the different LCM statuses. It is not intended to be used as a replacement for the requirements in the body of the document.

Table A.1—Summary of LCM 1–3 Requirements

Requirements	LCM-1	LCM-2	LCM-3
Summary	Some traceability, product definition may be changed	Full traceability, product definition may be changed	Full traceability, product definition cannot be changed, limited to products covered by API product specifications
Product Identification	OEM and date of manufacture known, marked legibly (see 5.3.1.1)		Made in accordance to API Q1 and API product specification, OEM and date of manufacture known, marked legibly (see 5.3.3.1)
Product Definition	Established and documented by the service provider- changes are allowed to Product Definition (see 5.3.1.2)		Original technical specification and original API product specification (see 5.3.3.2)
Manufacturing Record	Records required by industry product specifications (see 5.3.1.3)		Records required by original API product specification (see 5.3.3.3)
Traceability	Traceability to current configuration (see 5.3.1.4)	Traceable as required by industry product specification or product definition (see 5.3.2.4)	Traceable as required by original API product specification (see 5.3.3.4)
Usage History	Begins at inclusion into LCM program (see 5.3.1.5)	Begins at time product is initially placed into service (see 5.3.2.5)	
Repair and maintenance Record	Begins at inclusion into LCM program (see 5.3.1.6)	Begins at time product is initially placed into service (see 5.3.2.6)	

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- [1] ISO 9000, *Quality management systems—Fundamentals and vocabulary*
- [2] ISO 13879, *Content and drafting of a functional specification*
- [3] ISO 13880, *Content and drafting of a technical specification*



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