



CGA M-7—2022

STANDARD FOR QUALIFYING SUPPLIERS USED BY MEDICAL GAS MANUFACTURERS, EQUIPMENT MANUFACTURERS, AND DISTRIBUTORS

SIXTH EDITION

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NOTE—Technical changes from the previous edition are underlined.

NOTE—Appendices A, B, C, D, E, F, and G (Informative) are for information only.

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1 Introduction

This publication provides guidance for medical gas manufacturers, medical gas equipment manufactures, and distributors to follow when developing procedures for qualifying suppliers who provide medical gases and/or medical equipment, parts, or services, including the services of contract drivers delivering medical gases.

2 Scope

This publication applies to medical gas manufacturers, medical gas equipment manufactures, and distributors developing company-specific standard operating procedures (SOP) for qualifying suppliers who provide medical gases and/or, medical devices, equipment, components, or services, including the services of contract drivers delivering medical gases.

It may be used when qualifying new suppliers or when requalifying existing suppliers of medical gases including other gases, which includes:

- original manufacturers of medical oxygen, nitrogen, carbon dioxide, helium, nitrous oxide, and air by compression, that swap with or directly supply to other original manufacturers or their customers;
- subsequent manufacturers of medical gases obtaining medical gases from an original manufacturer;
- subsequent manufacturers of medical gases obtaining medical gases from another subsequent manufacturer; and
- original manufacturers of medical gases obtaining feed gas sources for their purification processes.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Assessment

Review to determine which purchased medical gases, medical equipment, products, components, or services can affect the identity, strength, quality, or purity of a medical gas.

3.2.2 Conditional qualification

Supplier who has not been qualified but based on objective evidence can reasonably be expected to supply conforming material or services.

3.2.3 Critical ranking

Rank assigned by a risk priority system and applied to a purchased product, component, and/or service as the result of the critical assessment review.

NOTE—Critical ranking can be assigned a numeric value.

3.2.4 Degree of criticality

Level of risk that nonconformance to a supplier's requirements has on the acceptability of a purchased product, component, or service.

3.2.5 Designated medical gas

Drug that is manufactured or stored in a liquefied, nonliquefied, or cryogenic state that is administered as a gas and is defined in the United States by the Federal *Food, Drug, and Cosmetic Act*, 21 USC 360ddd [1].¹

3.2.6 Existing supplier

Qualified supplier with conditional qualification from which an existing product, component, or service has been purchased.

3.2.7 Medical gas

Liquefied or vaporized gas alone or in combination with other gases that is a drug or device as defined in the United States by the Federal *Food, Drug, and Cosmetic Act*, 21 USC 321(g)(1) and 321(h) or in the Canadian *Food and Drug Regulations* [1, 2].

3.2.8 New supplier

Company from which a medical gas manufacturer has never purchased a product, component, or service.

3.2.9 Original manufacturer

Entity that introduces or delivers for introduction a designated medical gas into interstate commerce.

3.2.10 Qualified supplier

Supplier that is evaluated and approved in accordance with a supplier qualification process.

3.2.11 Quality control unit (QCU)

Person or organizational element designated and trained to execute the QCU role and function.

NOTE—The QCU is responsible for the duties relating to quality control as defined in the current good manufacturing practices (CGMP).

3.2.12 Subsequent manufacturer

Entity that receives a designated medical gas from an original manufacturer or another subsequent manufacturer that will perform a manufacturing operation on the gas.

3.2.13 Supplier

Firm from whom products, components, or services are received.

3.2.14 Supplier file

Files that contain all pertinent records documenting the qualification of suppliers.

3.2.15 Supplier qualification

Process for evaluating, qualifying, and approving suppliers for purchased products, components, and/or services using critical ranking.

¹ References are shown by bracketed numbers and are listed in order of appearance in the reference section.

4 Product, component, and service assessment

The manufacturer of a product is responsible for determining the degree of criticality that products, components, or services that they purchase can have on final product quality. For example, the purchasing firm should determine whether variation in the purchased item or service or a contaminant contained in a purchased item, e.g., incompatible lubricant or sealant material, can affect product quality in a way that makes the item or service unacceptable.

An appropriate risk assessment may be used to determine the criticality of a component or service to a particular process or product.

Once a particular component or service is identified as potentially impacting the final product quality, the type of supplier evaluation needed shall be determined. The tables and calculations in Appendix A are provided as evaluation examples. A firm's experience with a supplier or the type of product supplied can dictate more stringent or less stringent assessment levels than those identified in Appendix A.

In the United States, the purchaser of a designated medical gas that will be used in further shall assure that purchased product originate from a holder of a New Drug Application (NDA) for that product. Designated medical gases may be purchased from an original or subsequent manufacturer.

5 Supplier qualification

5.1 General

The firm should have written supplier qualification procedures that include the methods used to evaluate suppliers for their degree of criticality and verifiability of the products, components, or services they supply. Methods for evaluating suppliers generally include the use of a supplier quality questionnaire and, if appropriate, a quality audit. Under certain circumstances such as competitor suppliers other means of evaluation may be used.

In Canada, quality agreements between supplier and purchaser are required.

Critical products, components, and services can only be purchased from qualified suppliers. If a product, component, or service must be obtained from a supplier not yet qualified by the firm, QCU-approved deviation is needed before using that supplier. For designated medical gases, the firm shall also have written procedures for verification that the product was originally produced under an NDA.

5.2 Types of suppliers

Firms should evaluate and qualify existing suppliers and new suppliers. The firm's written SOP should describe how new suppliers obtain existing supplier status. This change in status should be predicated on the vendor consistently supplying materials or services that meet requirements.

In the United States, suppliers of designated medical gases shall be certified in accordance with 5.3. In some cases, a designated medical gas supplier can also be a competitor. Due to proprietary business relationships, a modification to the method for supplier qualification may be required, see 5.3.3.

In Canada, suppliers of medical gases shall hold a drug establishment license (DEL) and be qualified by a firm's written SOP.

5.2.1 Existing supplier

Existing suppliers may be granted temporary conditional qualification based on an objective review of the supplier's historic ability to supply conforming material or services. Temporary conditional qualification is only necessary until a formal supplier qualification is performed.

Existing suppliers should be evaluated on the risk of supplied material or services and for their ability to consistently meet purchasing requirements or specifications for the material or service provided. Periodic evaluation may be predicated on the risk evaluation and supplier's performance but should not exceed 5 years. Past performance should be reviewed when determining whether existing suppliers remain qualified.

5.2.2 New supplier

New suppliers should be selected based on their ability to supply products, components, or services that consistently meet the quality characteristics established by the firm. New suppliers should only be granted conditional qualification if approved by the QCU.

The firm's QCU should ensure new suppliers are evaluated in accordance with the firm's procedures before the supplier is placed on a qualified supplier list. Examples of new supplier evaluation criteria may include:

- ability to meet specifications;
- effectiveness of internal quality systems;
- industry performance and recognition;
- availability and shipping time frame; and
- resource capability, such as, adequate facilities, adequate equipment, and qualified employees.

5.3 Medical gases

For facilities manufacturing medical gases intended to be used in the United States as designated medical gases, additional requirements apply from a certification perspective depending on if the supplier is an original manufacturer or a subsequent manufacturer. Appendix B provides an example of a checklist that may be used to assist in qualifying a designated medical gas supplier. The items in the checklist reflect the requirements listed in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 211 [3]. While the checklist does not reflect the requirements in GUI-0031, *Good manufacturing practices for medical gases*, it may be used to support the requirements of the quality agreements in Canada [4].

5.3.1 Original manufacturers

Original manufacturers shall obtain certification of designated medical gases that they manufacture. Certification is requested by an original manufacturer from the U.S. Food and Drug Administration (FDA). Unless FDA denies the request within 60 days of the receipt date, certification is deemed granted.

In Canada, original manufacturers shall obtain a DEL for medical gases that they manufacture.

Original manufacturers that obtain a medical gas from any other original manufacturer shall verify that the other original manufacturer in the United States holds an NDA or in Canada holds a DEL for the supplied medical gas.

Although product certification documentation is not a regulatory requirement, the supplier may be contractually required to provide a certificate of analysis, certificate of conformance, or letter of conformance.

5.3.2 Subsequent manufacturers

Subsequent manufacturers shall verify that the original manufacturer in the United States holds an NDA or in Canada holds a DEL for the supplied medical gas.

Subsequent manufacturers shall verify their medical gas suppliers have a system to verify sourced medical gases were provided to that supplier by a manufacturer holding an NDA or DEL.

Subsequent manufacturers should qualify their bulk medical gas supplier(s), however there is no requirement for subsequent manufacturers of medical gas to acquire and maintain a fingerprint analysis on the bulk medical gas supplier's raw material.

5.3.3 Competitor supplier

A competitor can be a supplier of finished product. A competitor supplier is similar to an existing supplier. Due to the proprietary nature of the business relationship, certain confidential aspects of a quality questionnaire or audit may not apply to a competitor supplier.

A competitor supplier may be reluctant to allow an actual site audit. If a competitor supplier's product is manufactured at a facility that is registered under the NDA in the United States or holds a DEL in Canada, a site audit may not be required.

The completion of a competitor supplier qualification document by the supplier and subsequent review and acceptance by the purchasing firm's QCU may replace an extensive questionnaire or site audit. Competitor suppliers are either original manufacturers or subsequent manufacturers, see 5.3.1 and 5.3.2. See Appendix C for an example of a competitor supplier qualification document for an original manufacturer of a medical gas (i.e., bulk gas). See Appendix D for an example of a competitor supplier qualification document for a subsequent manufacturer of a medical gas or medical gas mixture (i.e., cylinder gases). The customer shall define the frequency of completing these documents.

The competitor supplier qualification document requires that a supplier certifies compliance to the industry-specific regulatory requirements. The following requirements apply to manufacturing sites that supply finished medical product:

- finished medical product meets a specific *United States Pharmacopeia* and *National Formulary (USP–NF)* monograph [5];
- testing methods used for product release satisfies compendial test methods or a validated equivalent;
- product is manufactured under CGMP controls;
- manufacturing process and distribution (if applicable) is validated;
- validated systems are maintained under management of change (MOC) control;
- manufacturing facility is properly registered with the FDA or Health Canada (include a listing of registration numbers); and
- finished medical product is released by a QCU.

5.3.4 Contract drivers

Contract drivers are service suppliers that fill, transport, and offload product on behalf of a company. They do not provide the container used to transport the product.

In the United States, contract driver service suppliers are not required to register or list with FDA, nor complete a quality agreement with the company whose product they are transporting.

In Canada, contract driver service suppliers are not required to obtain a DEL, providing the company utilizing the contract service has a DEL. It is the responsibility of the contracting company to have a quality agreement in place governing the use of contract services including the following regulatory documents.

Quality agreements between service suppliers and the company whose product they are delivering shall identify:

- The DEL and Drug Identification Number (DIN) held by the company whose product is being delivered;
- Whose SOP requirements shall be used for the filling and offloading product and where those SOPs are maintained to support periodic regulatory auditing;
- Whose training requirements shall be used to train contract drivers including training content, who is responsible to provide the training, the frequency of the training, and how the training shall be documented;
- Who has the responsibility to qualify and authorize individual contract drivers to fill on behalf of the company whose product is being delivered; and
- Where training documentation is maintained to support periodic regulatory auditing.

5.3.4.1 Standard operating procedure requirements

If the product owner's SOPs are used, the product owner shall periodically verify that those SOPs are current and the contract driver is complying with these SOPs.

If the contract driver's company SOPs are used and the contract driver is also a DEL and DIN holder, the product owner can rely on the quality agreement that those SOPs are adequate for the activities performed. If the contract driver's company SOPs are used and the contract driver does not hold a DEL or DIN, the product owner shall periodically verify that those SOPs are adequate for the activities performed and the contract driver is complying with their SOPs.

5.3.4.2 Training requirements and documentation

If the product owner's training requirements are used, the product owner is responsible for the content and identifying the frequency for the training. The product owner may provide the training directly and maintain the training documentation or require the contract driver company to perform the training. If the latter the product owner shall assure the training is conducted in accordance with the training requirements. The product owner may require copies of the training documentation or permit the documentation to be maintained and retained by the contract driver's company provided this is explicitly stated in the quality agreement.

If the contract driver's company training requirements are used and the contract driver is also a DEL and DIN holder, the product owner can rely on the quality agreement that those training requirements are adequate for the activities performed. If the contract driver's company training requirements are used and the contract driver does not hold a DEL or DIN, the product owner shall periodically verify that those training requirements are adequate for the activities performed and the contract driver's company is complying with these training requirements and maintaining proper documentation.

5.4 Medical devices

Suppliers of finished medical devices such as valve integrated pressure regulators (VIPRs) and suppliers of medical device gas mixtures, which may be used in further manufacturing shall be qualified in accordance with device regulations. While Appendix E provides the direct references to 21 CFR Part 820, depending on the regulatory authority GUI-0073, *Guidance on Medical Device Compliance and Enforcement*, or ISO 13485, *Quality management systems* may be applicable [3, 6, 7].

5.5 Non-regulated parts and services

Suppliers of non-regulated parts, such as pumps and hoses, and services, such as maintenance and repair, should be qualified consistent with the impact those parts or services can have on products being manufactured.

To assist in evaluating these suppliers a questionnaire should be used to assess the robustness of the supplier's quality system. If the supplied product, component, or service has an impact on the quality of the final product or the safety of the firm's employees during the manufacture or distribution operations, a supplier questionnaire should be completed at a minimum. See Appendix F for an example of a checklist that may be used to assist in qualifying suppliers of non-regulated parts and services.

5.6 Supplier audits

An audit should be considered when the product, component, or service provided by the supplier is critical for maintaining or providing acceptable final product quality. If the existing supplier's performance is not considered acceptable, an audit may be warranted. Appendix A provides a means to determine when supplier audits are recommended.

Supplier audits can be conducted by the purchaser either by telephone or by site visit. See Appendix G for an example of an audit agenda. In lieu of conducting an audit of a competitor, a competitor supplier qualification document can be used.