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FDA PROPOSED QUALITY MANAGEMENT SYSTEM REGULATION (QMSR) EXPERT ANALYSIS PART 1: UNDERSTANDING DEFINITIONS

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About MEDIcept

MEDIcept strives to provide our clients with proven, trusted, and cost-effective solutions. We are an international consulting firm specializing in medical device, IVD, combination product, and biotechnology Regulatory, Quality, Clinical, Auditing, and Educational Services. Since 1996, we have worked with thousands of companies to solve their most critical FDA, global regulatory authority, and ISO issues. Our integrated solutions are rooted in our direct experience and span all stages of the product life.

Our staff includes former FDA and Notified Body personnel and industry experts with an in-depth functional knowledge of medical devices, IVDs, combination products, and biotechnology. Compliance requires the navigation of a complex maze of requirements. MEDIcept can provide state-of-the-art interpretation of those regulations, guidance documents, and standards and provides our client with the information they need to comply safely and cost-effectively.

We use our expertise to quickly identify the root cause, coalesce corrective actions, and provide easy to understand structured solutions or recommended improvements. Since we know corrective action implementation is where many projects fail, we do not just write an action list. We make sure all stakeholders understand why the solutions were chosen and why they are needed. We work hand-in-hand with clients to implement the solutions, so the solutions have been culturally absorbed when the project is done.

MEDIcept is committed to providing our clients with what they need. We are committed to quality deliverables because we value our clients' time and resources. This is why 90% of our clients come back to us repeatedly to solve new issues and recommend us to their colleagues.

U.S. FDA Proposed QMSR HOW TO SUBMIT COMMENTS

You may submit comments on the proposed regulation as follows:

Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 24, 2022. The https://www.regulations.gov/ electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 24, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Submitting electronic comments:
Federal eRulemaking Portal - https://www.regulations.gov.
Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

On February 23, 2022, the U.S. FDA published the Draft Proposed Rulemaking for the new "Quality Management System Regulation" (QMSR) with public comments due by May 24, 2022. It is imperative that the entire industry thoroughly understand the new Proposal and any nuances. Further, it is important that everyone avail themselves of the opportunity to submit comments to the FDA before the due date.

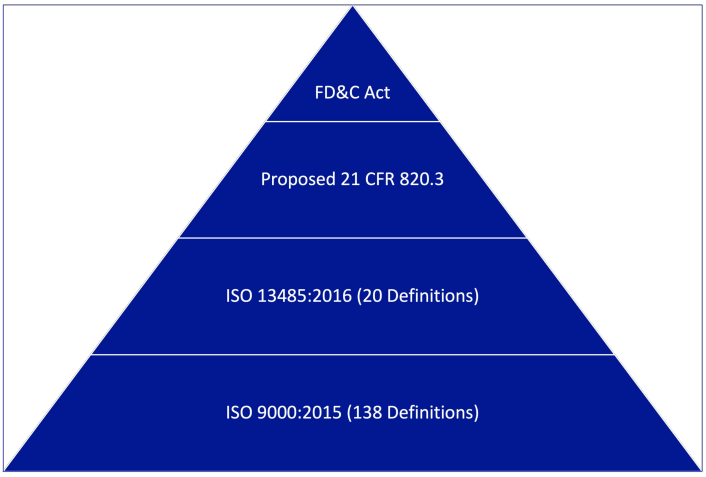
This White Paper is Part 1 of a planned series of technical analyses to help inform any interested parties. In order to understand any regulatory requirements or standards, the discussion must be grounded in a firm understanding of terminology and definitions.

FDA proposes to incorporate by reference the international standard specific for device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016 "Medical devices – Quality management systems – Requirements for regulatory purposes." FDA also proposes additional requirements to align with existing requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act). Some of those additions and revisions are related to definitions. In fact, the Proposed Rulemaking recommends certain definitions be withdrawn, others are retained, and one new definition for "Customer" be added.

The 1996 version of 21 CFR 820.3 has twenty-nine (29) definitions/sub-definitions. ISO 13485:2016 contains a total of twenty (20) definitions. However, everyone must realize that ISO 13485:2016 also has one Normative Reference ISO 9000:2015 "Quality management systems – Fundamentals and vocabulary."

For ISO standards, a Normative reference means that the entire normative standard is subsumed into the base standard. This means that ISO 9000:2015 in its entirety, all one hundred thirty-eight (138) definitions, are a part of ISO 13485:2016 except where definitions have been redefined within ISO 13485:2016. Therefore, by incorporation by reference of ISO 13485:2016, the FDA will also be requiring ISO 9000:2015 unless redefined.

This accumulation of incorporation by reference will require anyone trying to fully comply with the Proposed QMSR to have ready access to ISO 9000:2015. Practically requiring people to purchase both ISO 13485:2016 and ISO 9000:2015 in addition to understanding the revisions added by the newly Proposed 21 CFR 820.3 Definitions in the context of the FD&C Act.



The attached Table gives us a fuller view of this topic of cascading definitions to ensure everyone fully understands the terms and definitions, which will—if finalized as proposed—be enforceable by law. Please utilize this table to help inform your understanding and provide comments on any concerns.

Table of Definitions

Terms	Proposed QMSR (23Feb2022)	QS Regulation (7October1996) All definitions listed in 21 CFR 820.3	ISO 13485:2016 All definitions Clause 3	ISO 9000:2015 (Only terms also defined in the previous columns here)
Act		*21 CFR 820.3(a)* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-903, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-394)). All definitions in section 201 of the act shall apply to the regulations in this part.		
Advisory Notice			*Clause 3.1* notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the: — use of a medical device, — modification of a medical device, — return of the medical device to the organization that supplied it, or — destruction of a medical device Note 1 to entry: Issuance of an advisory notice can be required to comply with applicable regulatory requirements.	
Authorized Representative			*Clause 3.2* natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.	

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Clinical Evaluation			*Clause 3.3* assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer	
Complaint		*21 CFR 820.3(b)* means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.	*Clause 3.4* written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices *Note 1 to entry: This definition of "complaint" differs from the definition given in ISO 9000:2015.*	*Clause 3.9.3* expression of dissatisfaction made to an organization, related to its product or service, or to the complaints-handling process itself, where a response or resolution is explicitly or implicitly expected.
Component	Means any raw material, substance, piece, part, software, firmware, labeling, or assembly that is intended to be included as part of the finished, packaged, and labeled device.	*21 CFR 820.3(c)* means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.		
Control Number		*21 CFR 820.3(d)* means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.		

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Customer	Means persons or organizations, ***including users***, that could or ***do*** receive a product or a service that is intended for or required by this person or organization. ***A customer can be internal or external to the organization***.			*Clause 3.2.4* Person or organization that could or ***does*** receive a product or a service that is intended for or required by this person or organization. EXAMPLE: Consumer, client, ***end-user***, retailer, receiver of product or service from and internal process. ***Note 1 to entry: A customer can be internal or external to the organization.***
Design History File (DHF)		*21 CFR 820.3(e)* means a compilation of records which describes the design history of a finished device.		
Design Input		*21 CFR 820.3(f)* means the physical and performance requirements of a device that are used as a basis for device design.		
Design Output		*21 CFR 820.3(g)* means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.		

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Design Review		*21 CFR 820.3(h)* means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.		
Device History Record (DHR)		*21 CFR 820.3(i)* means a compilation of records containing the production history of a finished device.		
Device Master Record (DMR)		*21 CFR 820.3(j)* means a compilation of records containing the procedures and specifications for a finished device.		
Design Validation	Means establishing by objective evidence that device specifications conform with user needs and intended use(s).	*(Under Validation)* *21 CFR 820.3(z)(2)* means establishing by objective evidence that device specifications conform with user needs and intended use(s).		
Distributor			*Clause 3.5* natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user. Note 1 to entry: More than one distributor may be involved in the supply chain. Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.	

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Establish		*21 CFR 820.3(k)* Means define, document (in writing or electronically), and implement.		
Federal Food, Drug, and Cosmetic Act	Means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., as amended.			
Finished device	Means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.	*21 CFR 820.3(l)* means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.		
Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device	Means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) of this chapter and that is also regulated as a device.	*21 CFR 820.3(bb)* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.		
Implantable Medical Device			*Clause 3.6* medical device which can only be removed by medical or surgical intervention and which is intended to: — be totally or partially introduced into the human body or a natural orifice, or — replace an epithelial surface or the surface of the eye, and — remain after the procedure for at least 30 days. Note 1 to entry: This definition of implantable medical device includes active implantable medical device.	

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Importer			*Clause 3.7* natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.	
Labeling	Section 201(m) defines 'labeling' as: 'all labels and other written, printed, or graphic matter. (1) upon any article or any of its containers or wrappers, or. (2) accompanying such article' at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.		*Clause 3.8* label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents	
Life-cycle			*Clause 3.9* all phases in the life of a medical device, from the initial conception to final decommissioning and disposal	
Lot or batch		*21 CFR 820.3 (m)* means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.		

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Management with Executive Responsibility / **Top Management**	**Top Management** means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and ***quality management system***.	**Management with Executive Responsibility** *21 CFR 820.3(n)* means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and ***quality system***.		**Top Management** Clause 3.1.1 Person or group of people who directs and controls an organization at the highest level. Note 1 to entry: Top management has the ***power to delegate authority and provide resources within the organization.*** Note 2 to entry: If the scope of the management system covers only part of an organization, then top management refers to those who direct and control that part if the organization. Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

Terms	Proposed QMSR (23Feb2022)	QS Regulation (7October1996) All definitions listed in 21 CFR 820.3	ISO 13485:2016 All definitions Clause 3	ISO 9000:2015 (Only terms also defined in the previous columns here)
Manufacturer	Means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes, but is not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.	*21 CFR 820.3(o)* means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.	Clause 3.10 natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). Note 1 to entry: … Note 2 to entry: … Note 3 to entry: … Note 4 to entry: … Note 5 to entry: … Note 6 to entry: … Note 7 to entry: …	
Manufacturing Material / **Process Agent**	**Process Agent** means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.	**Manufacturing Material** *21 CFR 820.3(p)* means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.		

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Medical Device			*Clause 3.11* instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: — diagnosis, prevention, monitoring, treatment or alleviation of disease; — diagnosis, monitoring, treatment, alleviation of or compensation for an injury; — investigation, replacement, modification, or support of the anatomy or of a physiological process; — supporting or sustaining life; — control of conception; — disinfection of medical devices; — providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.	

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			Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include: — disinfection substances; — aids for persons with disabilities; — devices incorporating animal and/or human tissues; — devices for in vitro fertilization or assisted reproduction technologies	
Medical Device Family			*Clause 3.12* group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function	
Nonconformity	Means the nonfulfillment of a ***specified requirement***.	*21 CFR 820.3(q)* means the nonfulfillment of a ***specified requirement***.		*Clause 3.6.9* Non-fulfilment of a ***requirement.*** Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.
Performance Evaluation			*Clause 3.13* assessment and analysis of data to establish or verify the ability of an in vitro diagnostic medical device to achieve its intended use	

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Post-market Surveillance			*Clause 3.14* systematic process to collect and analyze experience gained from medical devices that have been placed on the market	
Process validation	Means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.	*(Under Validation)* *21 CFR 820.3(z)(1)* means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.		

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Product	Means components, ***process agents***, in-process devices, finished devices, and returned devices.	*21 CFR 820.3(r)* means components, ***manufacturing materials***, in- process devices, finished devices, and returned devices.	Clause 3.15 result of a process Note 1 to entry: There are four generic product categories, as follows: — services (e.g. transport); — software (e.g. computer program, dictionary); — hardware (e.g. engine mechanical part); — processed materials (e.g. lubricant). Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example, the offered product "automobile" consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman). Note 2 to entry: Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:	*Clause 3.7.6* Output of an organization that can be produced without any transaction takin place between the organization and the customer. Note 1 to entry: Production of a product is achieved without any transaction necessarily taking place between provider and customer, but can often involve this service element upon its delivery to the customer. Note 2 to entry: The dominant element of a product is that it is generally tangible. Note 3 to entry: Hardware is tangible and its amount is a countable characteristic (e.g. fuels and soft drinks). Hardware and processed materials are often referred to as goods. Software consists of information regardless of delivery method (e.g. computer program, mobile phone app, instruction manual,

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			— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return); the delivery of an intangible — an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired); product (e.g. the delivery of information in the context of knowledge transmission); the creation of ambience for the customer (e.g. in hotels and restaurants). Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures. Hardware is generally tangible, and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods. ***Note 3 to entry: This definition of "product" differs from the definition given in ISO 9000:2015.***	dictionary content, musical composition copyright, driver's license).
Purchased Product			*Clause 3.16* product provided by a party outside the organization's quality management system Note 1 to entry: The provision of product does not necessarily infer a commercial or financial arrangement.	

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Quality		*21 CFR 820.3(s)* means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.		*Clause 3.6.2* Degree to which set of inherent characteristics of an object fulfils requirements. Note 1 to entry: The term "quality" can be used with adjectives such as poor, good or excellent. Note 2 to entry: "Inherent", as opposed to "assigned" means existing in the object.
Quality Audit		*21 CFR 820.3(t)* means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.		
Quality Policy		*21 CFR 820.3(u)* means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.		*Clause 3.5.9* Policy related to quality. Note 1 to entry: Generally, the quality policy is consistent with the overall policy of the organization, can be aligned with the organization's vision and mission and provides framework for the setting of quality objectives.

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Quality System		*21 CFR 820.3(v)* means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.		
Remanufacturer	Means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.	*21 CFR 820.3(w)* means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.		
Rework	Means action taken on a nonconforming product so that it will fulfill the specified requirements ***before it is released for distribution.***	*21 CFR 820.3(x)* means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.		*Clause 3.12.8* Action on a nonconforming product ***or service*** to make it conform to the requirements. Note 1 to entry: Rework can affect or change parts of the nonconforming product ***or service***.
Risk			*Clause 3.17* combination of the probability of occurrence of harm and the severity of that harm ***Note 1 to entry: This definition of "risk" differs from the definition given in ISO 9000:2015.***	*Clause 3.7.9* Effect of uncertainty Note 1 to entry: … Note 2 to entry: … Note 3 to entry: … Note 4 to entry: … Note 5 to entry: … Note 6 to entry: …
Risk Management			*Clause 3.18* systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk	

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Specification		*21 CFR 820.3(y)* means any requirement with which a product, process, service, or other activity must conform.		
Sterile Barrier System			*Clause 3.19* minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.	
Sterile Medical Device			*Clause 3.20* medical device intended to meet the requirements for sterility Note 1 to entry: The requirements for sterility of a medical device can be subject to applicable regulatory requirements or standards.	
Unique Device Identifier (UDI)		*21 CFR 820.3(cc)* means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of: …		
Universal Product Code (UPC)		*21 CFR 820.3(dd)* means the product identifier used to identify an item sold at retail in the United States.		

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Validation		*21 CFR 820.3(z)* means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.		*Clause 3.8.13* Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application has been fulfilled. Note 1 to entry: the objective evidence needed for validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents. Note 2 to entry: The word "validated" is used to designate the corresponding status. Note 3 to entry: the use conditions for validation can be real or simulated.

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Verification	Means confirmation ***by examination and provision*** of objective evidence that specified requirements have been fulfilled.	*21 CFR 820.3(aa)* means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.		*Clause 3.8.12* Confirmation, ***through the provision*** of the objective evidence, that specified requirements have been fulfilled. Note 1 to entry: The objective evidence needed for a verification ***can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents***. Note 2 to entry: The activities carried out for verification are sometimes called a qualification process. Note 3 to entry: The word “verified” is used to designate the corresponding status.