Hongmcd 龙德医疗器械工具丛书

龙德 医疗器械法规中英文对照系列

供内部学习使用

FDA医疗器械质量体系法规QSR820 中英对照版

FDA 21CFR820 Quality System Regulation

（法规原文更新至2018年2月27日）

第1版

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前言

美国医疗器械质量体系法规，即 21 CFR Part 820 法规。该法规描述了现行的生产管理规范的要求（CGMP），规定预期用于人体的所有成品器械的设计、制造、包装、标签、存储、安装和服务中使用的方法以及所用的设施和控制方法。本法规制定的目的是为了确保成品器械的安全有效，并符合联邦食品、药品和化妆品法令。

本书中英对照内容仅代表编者自己的观点，如读者发现有任何纰漏或不当之处，欢迎指正。

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本书仅供行业内部学习参考使用，法规权威解释以原文为准，所引用原法规更新至 2018 年 2 月 27 日，为避免引起误导，建议读者以本法规正规发布官网的最新法规为准。

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AUTHORITY: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

SOURCE: 61 FR 52654, Oct. 7, 1996, unless otherwise noted.

Subpart A—General Provisions

§820.1 Scope.

(a) Applicability：

(1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged. With respect to class I devices, design controls apply only to those devices listed in §820.30(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of blood and blood components used for transfusion or for further manufacturing are not subject to this part, but are subject to subchapter F of this chapter. Manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in §1271.3(d) of this chapter, that are medical devices (subject to premarket review or notification, or exempt from notification, under an

A 部分-总则

§820.1 范围

（a）适用性：

（1）在本质量体系法规中阐述了现行的良好生产质量管理规范（CGMP）的要求。本部分中的要求规定预期用于人体的所有成品器械的设计、制造、包装、标签、存储、安装和服务中使用的方法以及所用的设施和控制方法。本部分的要求可确保成品器械的安全有效，并符合联邦食品、药品和化妆品法令。本部分内容确定了适用于成品医疗器械制造商的基本要求。如果制造商只从事本部分要求的某些操作，而不是其他部分，制造商只需符合适用于其所从事业务的操作要求。对于Ⅰ类器械，设计控制仅适用于820.30（a）(2)部分列出的那些器械。本法规不适用于成品器械的组件或部件的制造商，但鼓励这样的制造商使用本法规中的适宜条款做指南。用于输血或进一步加工的血液和血液成分的制造商不受本部分管制，但需遵守本章 F 子章节的要求。依照本部分 1271.3（d）的规定，人体细胞、组织及基于细胞、组织的产品(HCT/Ps)也属于医疗器械（依据法令的器械条款的递交申请提交上市前评审或通告，或豁免通告，或者依照《公共健康服务法令》中第 351 节提交生物产品许可的申请），

application submitted under the device provisions of the act or under a biological product license application under section 351 of the Public Health Service Act) are subject to this part and are also subject to the donor-eligibility procedures set forth in part 1271 subpart C of this chapter and applicable current good tissue practice procedures in part 1271 subpart D of this chapter. In the event of a conflict between applicable regulations in part 1271 and in other parts of this chapter, the regulation specifically applicable to the device in question shall supersede the more general.

其制造商应该遵守本部分，也要遵守本章节的 1271（c）部分中捐赠程序，并适用于本章节的的 1271（d）部分中的现行良好人体组织实施程序。如果 1271 中的适用法规和本章节的其它部分存在冲突，那么特定适用于所考虑的器械法规应取代任何其他一般性适用要求。

(2) The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

（2）本部分条款可适用于本部分规定的、预期用于人体的在美国任何州或地区、哥伦比亚地区或波多黎各自治邦制造、进口或用于进口的任何成品器械。

(3) In this regulation the term “where appropriate” is used several times. When a requirement is qualified by “where appropriate,” it is deemed to be “appropriate” unless the manufacturer can document justification otherwise. A requirement is “appropriate” if nonimplementation could reasonably be expected to result in the product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action.

（3）本法规中使用几次的术语“适当时”。当一个要求被“适当时”修饰时，这一要求就被认为“适当的”，除非制造商能以文件的形式提出其他的正当理由。一个要求是“适当的”，如果没有实施，可预期会导致产品不符合规定要求或制造商不能进行任何必要的纠正措施。

(b) The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulations specifically

（b）除非明确声明有其他情况，否则本部分中质量体系法规是对本章其他部分的法规的补充。本部分适用法规与本章节其他部分发生冲突时，那么特定适用于所考虑的器械

applicable to the device in question shall supersede any other generally applicable requirements.

法规应取代任何其他一般性适用要求。

(c) Authority. Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383). The failure to comply with any applicable provision in this part renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

（c）权威性：820 部分是按照法令的第 501，502，510，513，514，515，518，519，520，522，701，704，801，803 节制定和发布的（21 美国代码为 351,352,360,360c,360d,360e,360h,360i,360j,360l,371,374,381,383）。如果器械没有符合本部分的任何适用条款，按照法令的 501(h)章节，可认为该种器械为伪劣产品，对这种器械和其责任人要采取法规行动。

(d) Foreign manufacturers. If a manufacturer who offers devices for import into the United States refuses to permit or allow the completion of a Food and Drug Administration (FDA) inspection of the foreign facility for the purpose of determining compliance with this part, it shall appear for purposes of section 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part and that the devices manufactured at that facility are adulterated under section 501(h) of the act.

（d）国外制造商：如果将器械进口到美国的制造商拒绝接收 FDA 对其国外工厂的检查，以确定是否符合本部分 801(a)法案的内容，则可认为生产该器械所使用的方法，设施、设备，以及在该厂制造的、将要进口到美国的器械的设计安装或服务不符合法令的 520(f)章节和本部分内容的要求，并且按照法令的 501（h）章节的规定，认定该厂制造的器械为伪劣产品。

(e) Exemptions or variances. (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f) (2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in §10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002, 1-800-638-2041 or 301-796-7100, FAX: 301-847-8149.

（e）豁免或特殊许可：（1）任何申请对器械质量体系要求豁免或特殊许可的人员都要遵守法令的 520（f）（2）的要求。按照本章 10.30 中阐述的程序要求（FDA 的管理程序），将豁免或特殊许可的申请提交给 FDA。可从 FDA，器械辐射健康中心，小制造商部门、国际和消费者援助司获得指南。Guidance is available from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002, 1-800-638-2041 or 301-796-7100, FAX: 301-847-8149.

(2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

（2）当机构确定这样的特殊许可是为了公众健康的最佳利益，FDA 可鼓励并允许器械的质量体系要求有一些特殊许可。只要公众健康需要这种器械，且若没有这种特殊许可器械就无法获得，那么这种特殊许可就将始终有效。

[61 FR 52654, Oct. 7, 1996, as amended at 65 FR 17136, Mar. 31, 2000; 65 FR 66636, Nov. 7, 2000; 69 FR 29829, May 25, 2005; 72 FR 17399, Apr. 9, 2007; 75 FR 20915, Apr. 22, 2010; 80 FR 29906, May 22, 2015]

[61 FR 52654, Oct. 7, 1996, as amended at 65 FR 17136, Mar. 31, 2000; 65 FR 66636, Nov. 7, 2000; 69 FR 29829, May 25, 2005; 72 FR 17399, Apr. 9, 2007; 75 FR 20915, Apr. 22, 2010; 80 FR 29906, May 22, 2015]

§820.3 Definitions.

(a) Act 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.

(b) Complaint 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.

(c) Component 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.

(d) *Control number* 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.

(e) *Design history file* (*DHF*) means a compilation of records which describes the design history of a finished device.

(f) Design input means the physical and performance requirements of a device that are used as a basis for device design.

820.3 定义

（a）法令：法令是指联邦食品、药品和化妆品法令，修订 (secs. 201-903, 52 Stat. 1040 et seq., 修订 (21 U.S.C. 321-394)).法令中 201 部分中规定的所有定义都适用于本部分的法规。

（b）投诉：投诉是指任何以书面、口头、电子的形式提出的，已放行销售的医疗器械在其特性、质量、耐用性、可靠性、安全性、有效性及性能相关方面存在不足的行为。

（c）组件：组件是指任何原材料、物质、零件、部件、软件、固件、标识或装配件，可作为已完成的、已包装的和已加贴标签的器械的一部分。

（d）控制码：控制码是指任何有鉴别性的符号，如：字母或数字有区别的组合，或者两者均有区别的组合，从中可以确定成品器械的批或单元的生产、包装、标识和销售的历史。

（e）设计历史文档（DHF）：是指，描述了一个成品器械的设计历史记录汇编。

（f）设计输入：是指器械的物理和性能要求，其可作为器械的设计基础。

(g) Design output 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.

（g）设计输出：是指每一设计阶段和总体设计的设计结果。成品设计输出是器械主记录的基础。总体成品器械的设计输出是由器械、器械的包装、标贴和器械主记录构成。

(h) Design review 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.

（h）设计评审：是指对设计形成文件的、全面的、系统的检查以便评价设计需求的充分性，设计满足需求的能力以及识别问题。

(i) Device history record (DHR) means a compilation of records containing the production history of a finished device.

（i）器械历史记录（DHR）：是指包含成品器械的生产历史记录汇编。

(j) Device master record (DMR) means a compilation of records containing the procedures and specifications for a finished device.

（j）器械主记录（DMR）：是指包含成品器械的程序和规格的记录汇编。

(k) *Establish* means define, document (in writing or electronically), and implement.

（k）建立：是指规定、记录（书面的或电子的）和实施。

(l) *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.

（l） 成品器械：是指任何适用于使用或能够运行的器械或器械的附件，无论其是否经包装、标识或灭菌。

(m) Lot or batch 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.

（m）批：是指一个或多个组件或成品器械，其可由单一型号、规格、类型、尺寸、成分或软件版本构成，这些器械或组件是在相同的条件下生产的，在规定的范围内有相同的特性和质量。

(n) Management with executive responsibility 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.

（n）行政管理者：是指有权确定质量方针和质量体系或对质量方针和质量体系做出更改的制造商的高级雇员。

(o) 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.

（o）制造商：是指任何对成品器械进行设计、生产、制作、组装或加工的个人。制造商包括但并不局限于那些进行合约灭菌、安装、重新标识、重新制造、重新包装、规格开发的企业或法人，或者进行上述操作的境外的一级分销商。

(p) Manufacturing material 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.

（p）制造材料：是指任何用在或用于利于生产过程的材料或物质，在生产过程中产生的伴随物或副产物，其作为残留物或杂质存在于成品器械，其产生不是设计出来的，也不是制造商想要的。

(q) Nonconformity means the nonfulfillment of a specified requirement.

（q）不合格：是指不满足规定要求。

(r) Product means components, manufacturing materials, in- process devices, finished devices, and returned devices.

（r）产品：是指组件、生产材料、过程中的器械、成品器械和返回器械

(s) Quality means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

（s）质量：是指器械满足包括安全和性能等使用适合性的能力所体现的特征及特性的总和。

(t) Quality audit 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.

（t）质量审核：是指按照规定的时间间隔及足够的频率对制造商的质量体系进行系统的、独立的检查，以确定质量体系活动以及这些活动的结果符合质量体系程序，并确保质量体系程序得到有效的实施并适合于实现质量体系的目标。

(u) *Quality policy* means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

（u）质量方针：是指与组织质量有关的总的目的和方向，质量方针是由行政管理者制定。

(v) Quality system means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

（v）质量体系：是指实施质量管理所需的组织结构、职责、程序、过程和资源。

(w) 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.

（w）二次加工制造商：是指加工、处理、翻修、再次包装、修复或对成品器械采取其他措施来对器械的性能或安全规格或预期用途做重要更改者。

(x) Rework means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

（x）返工：是指对不合格产品采取的措施以便使其在放行和销售前满足规定的器械主记录的要求。

(y) Specification means any requirement with which a product, process, service, or other activity must conform.

（y）规格：是指产品、过程、服务或其他活动必须满足的要求。

(z) Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

（z）确认：是指通过检查和提供客观证据确认能够持续的满足具体预期用途的特殊要求

(1) Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

（1）过程确认是指通过客观证据确定过程持续生产出满足其预先确定的规格要求的结果或产品。

(2) Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s).

（2）设计确认是指通过客观证据来确定器械规格符合用户需求和预期用途。

(aa) Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

(aa)验证：是指通过检查和提供客观证据以确认规定的需求得到满足。

(bb) *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) and that is also regulated as a device.

（bb）人细胞，组织，或细胞的，或基于组织的产品（HCT/P）规定为器械：是指 HCT/P，如本章 1271.3(d)部分定义的那样，未满足 1271.10(a)部分标准要求，也作为器械监管。

(cc) Unique device identifier (UDI) 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:

（cc）唯一器械识别码（UDI）:通过满足本章 830.20 部分的要求的器械的使用和销售能够充分识别器械的标识符，唯一器械识别码的组成：

(1) A device identifier—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and

(1) 器械标识符：UDI 的一个强制的，固定的部分，用于识别器械的特定版本或型号以及器械的标签商

(2) A production identifier—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(2) 生产标识符：UDI 的一个有条件的，可变的部分，用于识别包含于器械标签上的一个或多个以下内容：

(i) The lot or batch within which a device was manufactured;

(i) 器械生产的批号

(ii) The serial number of a specific device;

(ii) 特定器械序列号

(iii) The expiration date of a specific device;

(iii) 特定器械的有效期

(iv) The date a specific device was manufactured.

(iv) 特定器械的生产日期

(v) For an HCT/P regulated as a device, the distinct identification code required by §1271.290(c) of this chapter.

(v) 对于作为器械监管的 HCT/P，本章 1271.290(c)部分要求的不同的识别码

(dd) Universal product code (UPC) means the product identifier used to identify an item sold at retail in the United States.

（dd）通用产品代码（UPC）：用于识别在美国零售的商品的产品标识符

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

§820.5 Quality system.

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.

Subpart B—Quality System Requirements

§820.20 Management responsibility.

(a) Quality policy. Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

(b) Organization. Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.

(1) Responsibility and authority. Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

(2) Resources. Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

820.5 质量体系

每一个制造商应建立和保持一个适用于设计或制造的特定医疗器械的质量体系，并满足本部分的要求。

子部分 B——质量体系要求

820.20 管理职责

(a) 质量方针：行政管理者应制定企业的质量方针和目标，并做出质量承诺。行政管理者应确保质量方针在组织内各层次得到理解、实施和支持。

(b) 组织：每一个制造商应建立和保持适宜的组织结构，以确保器械的设计和生产按照本部分的要求进行。

(1) 职责和权限：每一个制造商应确定人员的职责、权限和相互关系，这些人员负责管理、执行和评价对质量有影响的工作，并提供执行这些任务所必需的独立性和权威性。

(2) 资源：每一个制造商应提供充足的资源以满足本部分的要求，包括为管理、工作实施，及包括内审在内的评价活动而指定经过培训的人员。

(3) Management representative. Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:
(i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and

(ii) Reporting on the performance of the quality system to management with executive responsibility for review.

(c) Management review. Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.
(d) Quality planning. Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.
(e) Quality system procedures. Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.

§820.22 Quality audit.

Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality

(3) 管理者代表：行政管理者应任命一名管理者代表并记录这样的任命，除其他方面的职责外，其应具有以下方面的职责和权限：

(i)确保质量管理体系按照本部分的要求得到有效的建立和保持；并

(ii)向负责审查的行政管理者汇报质量体系的执行情况。

(c) 管理评审：行政管理者应该按照已经建立的程序以规定的时间间隔及足够的频次评价质量体系的适应性和有效性以确保质量体系满足本部分的要求和制造商建立的质量方针和目标。质量体系评审的时间和结果应形成文件。

(d) 质量计划：每一个制造商应建立一个质量计划以规定与所设计和生产的器械有关的质量规范，资源和活动。制造商应确定质量要求是如何得到满足的。
(e) 质量体系程序：每一个制造商应建立质量体系程序和说明。适当时，应确定质量体系中所使用的文件结构。

820.22 质量审核

每一个制造商应建立质量审核程序并实施审核以确保质量体系符合已建立的质量体系要求并保持有效

system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.

性。质量审核的实施应当由与被审核事项没有直接责任关系的人进行。必要时要采取纠正措施，包括对缺陷项的再次审核。每一次质量审核的结果，包括实施的再审核都应当形成报告，且需要被对事项审核有责任的管理者审核。质量审核和再次审核的结果和日期应形成文件。

§820.25 Personnel.

820.25 人员

(a) General. Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

(a) 总则：每一个制造商应具有充足的人力资源，人员应具备必要的教育、背景、培训和经验以确保完成本部分所要求的所有活动被正确实施。

(b) Training. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.

(b) 培训：每一个制造商应建立一个识别培训需求的程序并确保所有人员能够接受适宜的培训以完成指定的职责。培训应形成文件。

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

（1）作为培训的一部分，人员应了解可能会由于其具体工作的不恰当的操作而造成器械缺陷。

(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

（2）进行验证和确认活动的人员应了解在工作中可能遇到的器械缺陷和故障。

Subpart C—Design Controls

子部分 C——设计控制

§820.30 Design controls.

820.30 设计控制

(a) General.

(1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(2) The following class I devices are subject to design controls:

(i) Devices automated with computer software; and

(ii) The devices listed in the following chart.

Section	Device
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.
880.6760	Restraint, Protective.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide Teletherapy.

(a) 总则

(1) 任何II类和III类器械的制造商和本章节段落(a)中第(2)节列出的Ⅰ类器械的制造商，应建立和保持程序以控制器械的设计，确保规定的设计要求得到满足。

(2) 下述Ⅰ类器械属于设计控制的范围：

（i）由计算机软件进行驱动的器械；以及

(ii) 下表列出的器械：

章节	器械
868.6810	导管,气管支气管吸引。
878.4460	手套，外科医师的。
880.6760	限位器，防护的。
862.5650	系统，涂药器，放射性核素，手工的。
892.5740	源，放射性核素远程治疗。

(b) Design and development planning. Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

(b)设计与开发的计划：每一个制造商应建立和保持设计和开发活动的计划，并规定实施职责。计划应识别和描述各不同部门或活动的接口，这些部门或活动提供设计和开发过程的输入。随设计和开发的进展，计划应得到评审、更新和批准。

(c) Design input. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

(c)设计输入：每一个制造商应建立和保持程序以确保与器械相关的设计需求是适宜的，并阐述器械的预期用途，包括用户和患者的需求。程序应为阐述不完整、不明确、不一致需求提供方法。设计输入的要求应形成文件并由指定的人员评审和批准。应记录批准日期和批准人的签名。

(d) Design output. Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the

(d)设计输出：每一个制造商应建立和保持程序以规定和记录设计输出，以便对设计输入要求的符合性进行充分的评价。设计输出程序应包含或引用接收准则，确保识别出那些对器械的正常运作十分必要的设计输出。设计输出在发布前应得到记录、评审和批准。应记录批准日期和批准人的签名。

individual(s) approving the output, shall be documented.

(e) *Design review.* Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).

(e)设计评审：每一个制造商应建立和保持设计评审程序，以确保对设计结果的正式评审在器械设计开发的适宜阶段得到策划和实施。程序应当确保每一个设计评审阶段的参加者包括：所评审的设计阶段有关的所有职能的代表，以及不直接负责所评审的设计阶段的人员，以及所需的专家。设计评审的结果，包括设计识别、日期和完成评审的人员，应当记录在设计历史记录（DHF）中。

(f) Design verification. Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

(f)设计验证：每一个制造商应建立和保持设计验证程序。设计验证应确保设计输出满足设计输入的要求。设计验证的结果，包括设计识别、方法、日期和完成验证的人员，应当记录在设计历史记录（DHF）中。

(g) Design validation. Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk

(g)设计确认：每一个制造商应建立和保持器械设计确认程序。设计确认应当对初始生产单元、批次或者其等效物在规定的操作条件下完成。设计确认应确保器械符合规定的用户需求和预期用途，应包括在真实或模拟使用条件下对生产单元的测试。适当时，设计确认应包括

analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

软件的确认和风险分析。设计确认的结果，包括设计识别、方法、日期和完成确认的人员，应当记录在设计历史记录（DHF）中。

(h) *Design transfer.* Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

(h)设计转换：每一个制造商应建立和保持程序以确保器械的设计能够正确的转换成生产规范。

(i) Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

(i)设计变更：每一个制造商应建立和保持程序，程序应包括设计变更的识别、记录、确认，适当时包括变更实施前的验证、评审和批准。

(j) Design history file. Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

（j）设计历史文档：每一个制造商应建立和保持每一类器械的设计历史记录。DHF 应包括或引用必要的记录，这些记录应能证明器械的设计是按照符合已批准的设计计划和本部分要求来完成的。

Subpart D—Document Controls

子部分 D－－文件控制

§820.40 Document controls.

820.40 文件控制

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:

制造商应建立和保持程序控制所有本部分要求的文件，程序应规定以下内容：

(a) Document approval and distribution. Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be

(a)文件的批准和发布：每一个制造商应指定人员在文件发布前，评审文件的适应性和批准文件，以确定满足本部分的要求。文件的批准包括批准的日期和批准人的签名应形成文件。满足本部分要求的文件应

documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.

在使用现场方便获得，或必要时获得。应及时清除使用现场所有的作废文件，以防止非预期的使用。

(b) Document changes. Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

(b)文件更改：除非有其他的特殊指定，否则，对文件的更改应得到执行最初审核和批准的相同功能或组织的人员进行评审和批准。应及时将文件的更改通知有关人员。每一个制造商应保持文件的更改记录。更改记录应包括对更改的描述，受更改影响的文件的识别，批准人的签字，批准日期和更改生效的时间。

Subpart E—Purchasing Controls

子部分 E——采购控制

§820.50 Purchasing controls.

820.50 采购控制

Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

每一个制造商应建立和保持程序以确保所有采购的或以其他方式接收到的产品和服务满足规定的要求。

(a) Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:

（a）供应商、承包商和顾问的评价。每一个制造商应建立和保持供应商、承包商和顾问必须满足的要求，其中包括质量要求。每一个制造商应：

(1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.

(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.

(3) Establish and maintain records of acceptable suppliers, contractors, and consultants.

(b) Purchasing data. Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with §820.40.

Subpart F—Identification and Traceability

§820.60 Identification.

Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups.

§820.65 Traceability.

（1）以满足规定的要求包括质量要求的能力为基础，评价和选择潜在的供应商、承包商和顾问。评价应形成文件。

（2）以评价的结果为基础，确定产品、服务、供应商、承包商和顾问的控制的类型和程度。

（3）建立和保持可接受的供应商、承包商和顾问的记录。

（b）采购资料：每一个制造商应建立和保持所采购的或以其他形式接收的产品和服务的资料，该资料能清楚的描述或引用规定的要求包括质量体系要求。如果可能，采购文件应包括这样的协议，即供应商、承包商和顾问同意将有关产品或服务的更改通知给制造商，以便使制造商判断更改是否对成品器械的质量有影响。应按照 820.40 要求批准采购资料。

子部分 F——标识和可追溯性

820.60 标识

在产品的接收、生产、销售和安装的所有阶段中，每一个制造商应建立和保持标识产品的程序，以防止混用。

820.65 可追溯性

Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

外科植入器械、支持或维持生命的器械、或按照标识上提供的使用说明进行正确使用时产生操作故障会对使用者产生重大伤害的器械，其制造商应建立和保持程序，用控制数字识别每一单件、批次的成品器械和组件（适当时）。程序应便于纠正措施的实施。这样的标识应记录在器械历史记录（DHR）中。

Subpart G—Production and Process Controls

子部分 G－－生产和过程控制

§820.70 Production and process controls.

820.70 生产和过程控制

(a) General. Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:

（a） 总则：每一个制造商应建立、实施、控制和监视生产过程以确保器械符合其规格。在生产过程中会导致生产的器械与器械规格有偏差，制造商应建立和保持过程控制程序，描述任何必要的过程控制以确保符合规格要求，过程控制应包括：

(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

（1）形成文件的指导书，标准的操作程序（SOP’S），规定和控制生产方式的方法；

(2) Monitoring and control of process parameters and component and device characteristics during production;

（2）生产过程中，过程参数、组件和器械特性的监视和控制；

(3) Compliance with specified reference standards or codes;

（1）对规定的参考标准或代码的符合性；

(4) The approval of processes and process equipment;

（2）过程和过程设备的批准；以及

and

(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

（5）工艺准则应以形成文件的标准或经确定和批准的代表性的样品的形式来表示。

(b) Production and process changes. Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to §820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with §820.40.

（b）生产和过程变更：每一个制造商应建立和保持对规格、方法、过程或程序变更的程序。这样的变更应在实施之前按照 820.75 要求进行验证，或适当时进行确认，并应将这些活动形成文件。变更应按照 820.40 的规定进行批准。

(c) Environmental control. Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed.

（c）环境控制：当环境条件合理预期会对产品质量有不良影响时，制造商应建立和保持程序以充分的控制这些环境条件。应对环境控制系统进行周期性的检查，以验证该系统(包括必要的设备)充分适宜并运行良好。这些活动应形成文件并得到评审。

(d) Personnel. Each manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality. The manufacturer shall ensure that maintenance and other personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual.

（d）人员：如果人员和产品或人员和环境的接触合理预期会对产品质量产生不良影响，每一个制造商应建立和保持对健康、清洁、人员规范和服装的要求。制造商应确保所有特殊环境条件下临时工作的维修人员和其他人员接受适当培训或在训练有素的人员监督下工作。

(e) Contamination control. Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

（e）污染控制：每一个制造商应建立和保持程序，以防止合理预期会对产品质量有不良影响的物质污染设备或产品。

(f) Buildings. Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mixups, and assure orderly handling.

（f）建筑物：建筑物的应经过适宜的设计，并要有足够的空间来完成必要的操作，防止混用，保证有序操作。

(g) Equipment. Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

（g）设备：每一个制造商应确保生产过程中使用的所有设备满足规定的要求，并对其进行适宜的设计、构造、放置和安装以便于维护、调试、清洁和使用。

(1) Maintenance schedule. Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.

（1）维护计划：每一个制造商应建立和保持对设备的调整、清洁和其他维护的计划，以确保满足生产规范。维护活动包括维护活动的日期和人员都应形成文件。

(2) Inspection. Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.

（2）检查：每一个制造商应按照已建立的程序完成周期的检查以确保符合使用的设备维修计划。检查包括检查的日期和人员应形成文件。

(3) Adjustment. Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.

（3）调试：每一个制造商应确保将设备的任何固有边界或容许公差明示在需周期性调试的设备上或附近，或使完成这些调试校准的人员能够方便获得。

(h) Manufacturing material. Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

（h）制造材料：当制造材料合理预期会对产品质量有不良影响时，制造商应建立和保持对这类材料的报废和使用程序以确保对其报废或限制到不会对器械质量造成不良影响的数量。报废或减少使用制造材料应形成文件。

(i) Automated processes. When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

（i）自动化过程：如果在生产或质量体系中使用计算机或自动化的数据处理系统时，制造商应按照已制定的方案，对计算机软件的预期用途进行确认。所有的软件变更都应当在其批准和发布前对变更进行确认。这些确认活动和结果应形成文件。

§820.72 Inspection, measuring, and test equipment.

820.72 检验、测量和实验设备

(a) Control of inspection, measuring, and test equipment. Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked,

(a)检验、测量和实验设备的控制。每一个制造商应确保所有的检验、测量和实验设备能适用于其预期的目的并能产生有效结果。这些设备包括机械设备、自动化设备、电子检验和实验设备。每一个制造商应建立和保持程序以确保设备能够定期的校准、检定、检查和维护。程

and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

(b) Calibration. Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.

(1) Calibration standards. Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

(2) Calibration records. The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

§820.75 Process validation.

序还应包括设备的搬运、防护和贮存的规定，以便使其精确性和使用的适应性得到保持。这些活动应形成文件。

(b)校准：校准程序应包含准确度和精确度的明确指导和极限值。当未满足准确度和精确度的极限值时，应提供补救措施以再次确定极限值并评价是否对器械质量有任何不良影响。这些活动应形成文件。

（1）校准标准：检验、测量和实验设备所使用的校准标准应可追溯到国家或国际标准。如果没有国家或国际标准或国家或国际标准不适用时，制造商应使用独立的、可重现的标准。如果没有适用的标准，制造商应建立和保持自己内部的标准。

（2）校准记录：设备的标识、校准日期、校准人员和下次校准日期形成文件。这些记录应在设备的零件上或附近，或使使用设备的人员及负责校准设备的人员能方便获得。

820.75 过程确认

(a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.

（a）如果一个过程的结果不能被后续的检验和实验过程得以充分验证，则应按照规定的程序对该过程进行高级别保证及批准的确认。确认活动和结果、包括日期和批准确认活动人员的签名，适当时主要的设备确认，应形成文件。

(b) Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

（b）每一个制造商应建立和保持程序来监测及控制确认过程的过程参数以确保规定的要求继续得到满足。

(1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).

(1) 每一个制造商应确认确认过程由有资格的人员来完成。

(2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.

(2) 对于确认过程，监测以及控制方法和数据，实施确认的日期，适当时实施确认的人员或使用的主要设备，应形成文件。

(c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

（c）当过程有更改或出现偏差时，制造商应评审和评价过程，适当时，进行再确认。这些活动应形成文件。

Subpart H—Acceptance Activities

子部分 H——验收活动

§820.80 Receiving, in-process, and finished device acceptance.

820.80 进货产品、过程产品和成品的验收

(a) General. Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other

（a）总则：每一个制造商应建立和保持验收活动的程序。验收活动应包括检验、实验或其他验证活动。

(b) Receiving acceptance activities. Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be

（b）进货产品的验收活动。每一个制造商应建立和保持进货产品的验收程序。应对进货产品进行检验、

inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.

实验或其他验证以确保符合规定的要求。对进货产品的接收或拒收应形成文件。

(c) In-process acceptance activities. Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented.

（c）过程产品的验收活动：每一个制造商应建立和保持过程产品的验收程序以确保满足规定的过程产品要求。这样程序的应确保过程产品处于受控的状态，直到所要求的检验、实验或其他验证活动得以完成，必要时得到批准和记录。

(d) Final acceptance activities. Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:

（d）最终产品的验收活动。每一个制造商应为最终产品的验收建立和保持程序以确保成品器械的每一次生产运行，批量的或批器械均满足验收准则。成品器械在放行前应接受严格的检查或得到充分的控制。对成品器械放行销售前应完成下列活动：

(1) The activities required in the DMR are completed;

(1) 完成器械主记录中要求的活动；

(2) the associated data and documentation is reviewed;

(2) 相关的资料和文件经过评审；

(3) the release is authorized by the signature of a designated individual(s); and

(3)有指定的人员签名的授权才能放行产品；

(4) the authorization is dated.

(4)批准日期

(e) Acceptance records. Each manufacturer shall document acceptance activities required by this part. These records shall include:

（e）验收记录：每一个制造商应记录本部分所要求的验收活动，记录应该包括：

(1) The acceptance activities performed;

(2) the dates acceptance activities are performed;

(3) the results;

(4) the signature of the individual(s) conducting the acceptance activities; and

(5) where appropriate the equipment used. These records shall be part of the DHR.

§820.86 Acceptance status.

Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

Subpart I—Nonconforming Product

§820.90 Nonconforming product.

(a) Control of nonconforming product. Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible

(1) 所完成的接收活动

(2) 实施验收活动的日期

(3) 结果

(4) 执行验收活动人员的签名

(5) 适当时，所使用的设备。这些记录应作为器械历史记录的一部分。

820.86 验收状态

每一个制造商应采用适宜的方法识别产品的验收状态，以标明产品对验收准则的符合性或不符合性。在验收状态的标识应当贯穿整个产品的制造、包装、标识、安装和服务的过程中，以确保产品只有在满足所要求的验收活动后才能得到销售、使用或安装。

子部分 I——不合格产品

820.90 不合格产品

(a)不合格产品的控制：每一个制造商应建立和保持程序以控制不符合规定要求的产品。这些程序应规定对不合格产品的标识、记录、评价、隔离和处置。对不合格产品的评价应包括确定是否有必要进行调查或告知负责不合格产品的组织或人员。评价和所作的任何调查应形成文件。

for the nonconformance. The evaluation and any investigation shall be documented.

(b) Nonconformity review and disposition.

(1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

Subpart J—Corrective and Preventive Action

§820.100 Corrective and preventive action.

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.

(b)不合格产品的评审和处置

(1) 每一个制造商应建立和保持程序以规定对不合格产品的评审的职责和处置权限。这些程序中应阐明评审和处置过程。对不合格产品的处置应形成文件。文件应包括对使用不合格产品的合理解释以及授权使用不合格产品人员的签字。

(2) 每一个制造商应建立和保持返工的程序，包括返工后对不合格产品的重新测试和重新评价，以确保产品满足现有的经批准的规格。返工和再评估的活动，包括返工对产品造成的任何不良影响的确定，应记录在器械历史记录（DHR）中。

子部分 J－－纠正和预防措施

820.100 纠正和预防措施

(a）每一个制造商应建立和保持实施纠正和预防措施的程序。程序应包括下列要求；

(1) 分析过程、操作、让步、质量审核报告、质量记录、服务记录、投诉、退回的产品和其他有关质量资料的信息来源，以识别现存的或潜在的造成不合格产品的原因，或

Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

Subpart K—Labeling and Packaging Control

§820.120 Device labeling.

Each manufacturer shall establish and maintain procedures to control labeling activities.

(a) Label integrity. Labels shall be printed and applied so as to remain legible and affixed during the customary

其他质量问题。必要时，使用适宜的统计技术方法来识别反复发生的质量问题；

(2) 调查与产品、过程和质量体系有关的不合格的原因；

(3) 识别需要采取纠正以及防止不合格产品的再次发生及其他质量问题的措施；

(4) 验证或确认纠正和预防措施以确保这样的措施是有效的，并不会对成品器械产生不良影响。

(5) 实施和记录所需方法和程序的更改，以纠正和防止识别出的质量问题。

(6) 确保质量问题或不合格产品有关的信息能传达给那些直接负责该产品质量保证或防止此类问题发生的人员。

(7) 针对识别出的质量问题，提交相关信息以及纠正和预防措施，用来进行管理评审。

（b）本章节中所要求的所有活动和活动的结果应形成文件。

子部分 K——标识和包装控制

820.120 器械标识

每一个制造商应建立和保持程序以控制器械的标识活动。

(a) 标签的完整性。在加工、储存、搬运、销售、和适当时使用的通常

conditions of processing, storage, handling, distribution, and where appropriate use.

条件下，打印及采用的标签应保持清晰并粘贴上的。

(b) Labeling inspection. Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct unique device identifier (UDI) or universal product code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.

(b)标识的检查。经过指定人员的对标识的准确性进行检查后才能对标识进行放行用于存贮或使用，适用时，包括正确的唯一器械标识符(UDI)或通用产品代码(UPC)，有效期，控制码，存贮指导说明，操作说明，和任何附加的过程说明。放行的日期和执行检查的人员的签名应记录在器械历史记录(DHR)中。

(c) *Labeling storage.* Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mixups

(c) 标识的存贮。每一个制造商应采用提供恰当的标识及防止混用的方式存贮标识。

(d) Labeling operations. Each manufacturer shall control labeling and packaging operations to prevent labeling mixups. The label and labeling used for each production unit, lot, or batch shall be documented in the DHR.

(d) 标识的操作。每一个制造商应控制标识和包装操作以防止标识的混用。每一批产品标签和标识的使用都应记录在器械历史记录(DHR)中。

(e) Control number. Where a control number is required by §820.65, that control number shall be on or shall accompany the device through distribution.

(e) 控制码。按照 820.65 的要求要有控制码，在整个器械的销售过程中，控制码应始终在器械上或伴随器械附近。

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

§820.130 Device packaging.

820.130 器械包装

Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to

每一个制造商应确保器械的包装和货运集装箱的设计和构造，都能防

protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

Subpart L—Handling, Storage, Distribution, and Installation

§820.140 Handling.

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

§820.150 Storage.

(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

§820.160 Distribution.

(a) Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution.

止器械在通常的处理、存贮、搬运和销售时发生变更或损害。

子部分 L－－搬运、存贮、销售和安装

820.140 搬运

每一个制造商应建立和保持程序以防止在搬运的过程中发生器械的混淆、损害、破坏、污染或其他对产品有不良影响的事件的发生。

820.150 存贮

（a）每一个制造商应建立和保持程序以控制产品的存贮区域和库房，以防止器械的混淆、损害、破坏、污染或其他对产品待使用或销售有不良影响，并防止使用或销售过期的、作废的或受损的产品。当产品质量随时间恶化时，应以适当的存货周转方式储存，适当时还要评价产品存贮条件。

（b）每一个制造商应建立和保持程序，描述授权接收并将产品运送到存贮区域和库房的方法。

820.160 销售

（a）每一个制造商应为控制和销售成品器械建立和保持程序，以确保只有经批准放行的器械才能销售。应对采购订单进行评审以确保在器械放行销售前解决一些模糊问题及错误。当器械的使用性能或质量随

Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.

者时间的推移发生恶化，这些程序以确保过期的器械或恶化程度不受接受器械不被销售出去。

(b) Each manufacturer shall maintain distribution records which include or refer to the location of:

(1) The name and address of the initial consignee;

(2) The identification and quantity of devices shipped;

(3) The date shipped; and

(4) Any control number(s) used.

（b）每一个制造商应保持销售记录，销售记录应包括下列内容或指出出处；

(1) 第一收获人的名称和地址；

(2) 所发运的器械的数量和标识；

(3) 发运日期；以及

(4) 所使用的任何控制码。

§820.170 Installation.

820.170 安装

(a) Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.

（a）每一个需要有安装的器械的制造商应建立和保持充分与适宜的安装和检查指导说明，适用时包括测试程序。指导书和程序应包括确保恰当安装的指导以便使器械在安装后能按预期运行。制造商销售器械时，应附带指导书和程序，或让安装人员获得指导书和程序。

(b) The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.

（b）安装人员应确保对器械的安装、检查、和所要求的任何测试应按照制造商的指导说明和程序进行，并应记录检验和任何测试结果以证实安装的正确性。

Subpart M—Records

§820.180 General requirements.

All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up

(a) Confidentiality. Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.

(b) Record retention period. All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.

(c) Exceptions. This section does not apply to the reports required by §820.20(c) Management review, §820.22 Quality audits, and supplier audit reports used to meet the requirements of §820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and

子部分 M－－记录

820.180 总要求

本部分所要求的所有记录应保持在生产产地，或制造商的负责部门和 FDA 执行检验的人员能够获得记录的地方。这些记录包括不在检验现场存储的记录都应便于 FDA 人员的评审和复印。这些记录应清晰、易于识别，保存时应防止破损最小化并预防丢失。用自动存贮系统保存的记录应该有备份。

(a) 机密性。制造商认为应保密的记录要作标识以帮助 FDA 确定根据本章第 20 部分的《公共信息条例》哪些信息是否可以公开。

(b) 记录的保持期限。本部分所要求的所有记录都应有一定的保持期限，该保持期限应相当与所规定的医疗器械的设计及预期寿命，但在任何情况下都不能少于从制造商放行产品进行销售的日期起的 2 年。

(c) 例外。本章节不适用于管理评审（820.20c）报告、质量审核（820.22）的报告和用于满足 820.50(a)供应商、承包方和顾问评价的要求的供应商审核报告，但适用于这些规定中所要求的程序。按照 FDA 制定人员的要求，行政管理者应能书面形式证明管理评审、本部分所要求的质量审核和供方审核（适用时）已

quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.

经完成并形成文件、并记录完成的日期和任何采取的纠正措施。

§820.181 Device master record.

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with §820.40. The DMR for each type of device shall include, or refer to the location of, the following information:

820.181 器械主记录

每一个制造商应保持器械主记录（DMR’s）。每一个制造商应确保每一个器械主记录的制定和批准应符合820.40 的要求。每一型号的器械主记录应包括下列信息或指出出处。

(a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;

(a) 器械规格，其中包括适当的图纸、成份、配方设计、成分规格和软件规格；

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;

(b) 生产过程规范包括适当的设备规格、生产方法、生产程序和生产环境规范；

(c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;

(c) 质量保证程序和规范，包括验收准则和使用的质量保证设备；

(d) Packaging and labeling specifications, including methods and processes used; and

(d) 包装和标识规格，包括所使用的方法和过程；以及

(e) Installation, maintenance, and servicing procedures and methods.

(e) 安装、维护和服务程序和方法。

§820.184 Device history record.

Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information:

(a) The dates of manufacture;

(b) The quantity manufactured;

(c) The quantity released for distribution;

(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;

(e) The primary identification label and labeling used for each production unit; and

(f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

§820.186 Quality system record.

840.184 器械历史记录

每一个制造商应保持器械历史记录（DHR’s）。每一个制造商应建立和保持程序以确保保持每一批产品的器械历史记录并能证明器械的生产是符合 DMR 和本部分要求。器械历史记录应包括下列信息或指出出处。

(a) 生产日期；

(b) 生产数量；

(c) 放行销售数量；

(d) 能证明器械生产是符合 DMR 要求的验收记录；

(e) 每一个生产批所使用的主要识别标签和标识；

(e) 任何唯一器械识别码（UDI）或通用产品代码（UPC）以及任何其他器械的识别码和控制码；

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

820.186 质量体系记录

Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by §820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with §820.40.

每一个制造商应保持一个质量体系记录（QSR）。QSR 应包括（或指出出处）本部分所要求的活动的程序和文件，这些活动不是针对特殊类型的器械，包括但不局限于 820.20 所要求的记录。每一个制造商应确保 QSR 的制定和批准符合 820.40 的要求。

§820.198 Complaint files.

820.198 投诉文档

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

(a) 每一个制造商应保持投诉文档。每一个制造商应建立和保持程序以确保由正式指定的部门负责接收、评审和评价投诉。这样的程序应确保；

(1) All complaints are processed in a uniform and timely manner;

(1) 适当及时地处理所有的投诉；

(2) Oral complaints are documented upon receipt; and

(2)收到口头投诉要及时记录；以及

(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.

(3)要对投诉进行评价以确定所投诉的事件是否需要按照本章 803（医疗器械报告）的要求报告给 FDA。

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

（b）每一个制造商要评审和评价所有的投诉以确定是否有必要进行调查。当没有进行调查时，制造商应保持记录，其中包括记录没有进行调查的原因以及决定不进行调查的负责人的名字。

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been

（c）除非已经调查过类似的投诉，否则对器械、标签或包装的任何不符合其规格的投诉都应进行评审、评价和调查。

performed for a similar complaint and another investigation is not necessary.

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by §820.198(e), records of investigation under this paragraph shall include a determination of:

(1) Whether the device failed to meet specifications;

(2) Whether the device was being used for treatment or diagnosis; and

(3) The relationship, if any, of the device to the reported incident or adverse event.

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;

(4) The name, address, and phone number of the complainant;

（d）如果按照本章 803 的要求，要由指定的人员对必须报告给 FDA 的投诉事件进行快速的评审、评价和调查，并将该文档单独保存或做明显的标识。除了 820.198（e）所要求的信息，本段的调查记录确定以下问题；

(1) 器械是否有没有满足的规格；

(2) 器械是否正在用于诊断或治疗；以及

(3) 器械与所报告的事故或不良事件的关系，若有的话；

（e）当按照本章节进行调查时，应由指定的部门保持调查记录，调查记录包括；

(1) 器械的名称；

(2) 收到投诉的日期；

(3) 所使用的任何器械唯一识别码（UDI）或通用产品代码（UPC）以及任何其他器械的识别码和控制码；

(4) 投诉人的联系电话、地址和姓名；

(5) The nature and details of the complaint;

(6) The dates and results of the investigation;

(7) Any corrective action taken; and

(8) Any reply to the complainant.

(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

(1) A location in the United States where the manufacturer's records are regularly kept; or

(2) The location of the initial distributor.

[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 71 FR 16228, Mar. 31, 2006; 78 FR 58822, Sept. 24, 2013]

Subpart N—Servicing

§820.200 Servicing.

(5) 投诉的性质和细节；

(6) 调查的日期和结果；

(7) 所采取的任何纠正措施；

(8) 对投诉的任何回复。

（f）如果制造商正式指定的负责处理投诉的部门不在生产场地，则对投诉的调查和调查的记录应使生产厂地易于获得。

（g）如果制造商正式指定的负责处理投诉的部门不在美国，则本章节所要求的记录也应能在美国合理获得；

(1) 制造商的记录在美国的常规的放置地方；或

(2) 初始销售商所在地。

[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 71 FR 16228, Mar. 31, 2006; 78 FR 58822, Sept. 24, 2013]

子部分 N——服务

820.200 服务

(a) Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

(b) Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with §820.100.

(c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of §820.198.

(d) Service reports shall be documented and shall include:
(1) The name of the device serviced;

(2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
(3) The date of service;

(4) The individual(s) servicing the device;

(5) The service performed; and

(6) The test and inspection data.

[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 78 FR 58822, Sept. 24, 2013]

Subpart O—Statistical Techniques

（a）当规定有服务要求时，每一个制造商应建立和保持执行和验证服务满足规定要求的指导书和程序。

（b）每一个制造商应按照 820.100 的要求采用适宜的统计方法分析服务报告。

（c）如果按照本部分 803 的要求，接收的服务报告阐述的事件是必须报告给 FDA 的，则制造商应自动认为该报告为投诉，并应按照 820.198 的要求进行处理。

（d）服务报告应形成文件并包括：

(1) 所服务的器械的名称；

(2) 所使用的任何器械唯一识别码（UDI）或通用产品代码（UPC）以及任何其他器械的识别码和控制码
(2) 服务日期；

(3) 服务人员；

(4) 所执行的服务；以及

(5) 测试和检查数据。
[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 78 FR 58822, Sept. 24, 2013]

子部分 O——统计技术

§820.250 Statistical techniques.

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

820.250 统计技术

（a）适当时，每一个制造商应建立和保持识别有效统计技术的程序，这些统计技术可用于建立、控制和验证过程能力和产品特性的可接受性。

（b）当使用抽样方法时，应记录抽样计划并且要以有效的统计理论为基础。每一个制造商应建立和保持程序以确保抽样方法对预期用途的充分性和适宜性。当抽样计划发生变更时，可确保得到评审。应记录这些活动。

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