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FOOD AND DRUGS CHAPTER I

FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER H --MEDICAL DEVICES PART 820 QUALITY SYSTEM REGULATION

美国食品及药品管理局

21 号联邦法规

食品及药品第一章

健康及医疗服务食品药品管理局

H 小章——医疗器械
820 部分 质量体系法规

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Subpart A--General Provisions

Sec.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 human blood and blood components are not subject to this part, but are subject to part 606 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,

A- 一般条款

820.1 范围

(a) 适用性

(1)在本质量体系规定中提出达到“当前良好生产实践”所必需的必要条件。本篇对所有提供人类使用的最终器械的设计、生产、包装、标识、储存、安装和服务的方法、设施和控制手段提出要求。本篇中所规定的要求，其意图是要确保最终器械是安全有效，并且符合联邦食品、药品、化妆品的法令（以下简称为法令）。本篇是对最终医疗器械的生产厂家的基本要求。如果生产厂家从事的经营活动只涉及本篇所规定要求的一部分，而不涉及其它要求，生产厂家只需要符合与其所从事的经营活动有关的要求。对于I类器械，设计控制只适用于 820.30(a)(2)中列出的那些器械。本规定不适用于生产最终器械的部件或零件的生产厂家，但是鼓励这种类型的生产厂家以本规定的相关条款作为指导。本篇补适用于人类血液制品和血液成分制品的生产厂家，但本部法规第 606 篇对该类生产厂家适用。作为生产细胞、组织、细胞和组织的培养装置(HCT/Ps)为产品的厂家，已经在 1271.3(d)中做出定义，属于医疗器械（符合上市前评审或者通告，或者豁免通告，需要符合公共卫生法案第 351 部分中递交申请，提供器械预防措施，提供生物制品申请许可的规定），需要符合本篇及符合原料物质合格程序装置 1271 部分D小章。如果在 1271 部分和本篇的其它部分发生法规适用性抵触，本法规明确适用于产生疑问的器械而取代其它更多通用之规定。

that are medical devices (subject to premarket review or notification, or exempt from notification, under an 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.

(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.

(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.

(b) *Limitations.*

The quality system regulation in this part supplements regulations in other parts of this chapter except where

(2)本篇中的条款应适用于任何在本篇中规定的，预期用于人类的最终器械，这样的器械可在美国各州、哥伦比亚地区和波多黎各共和国生产或进口到这些国家。
(3)本法规中出现的术语“适当处”被使用过多次次。当一个要求被“适当处”修饰时，这一要求就被认为是“适当的”，除非制造商能以文件的形式提出其它的正当理由。如果不实施某个要求就会导致产品不满足其规定的要求或制造商不能开展必要的纠正措施，则可认为这一要求是“适当的”。

(b) 局限性
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法规的补充。如果在本部分和本篇的其它部分发生法规适用性抵触，本法规明确适用于产生疑问的器械而取代其它更多通用之规定。

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

(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.

(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.

(c)权威性

820部分内容的是参照权威法案501，502，510，513，514，515，518，519，520，522，701，704，801，803（21 U.S.C. 351，352，360，360c，360d，360e，360h，360i，360j，360l，371，374,381，383）而制定和发布的。如果器械没有符合本部分的任何适用条款会按照501(h)法案，可认为该种器械为伪劣产品，任何造成器械不符合性的人员都要负相关责任。

(d)国外生产厂家

如果生产厂家（指有器械进口到美国的生产厂家）不允许美国食品及药品管理局进行或完成对国外设施的检验以验证其是否符合本篇要求，那么，根据法令 801(a)章节，对于在该设施中生产的供进口到美国的产品，其设计、生产、包装、标识、储存、安装和维修方法及其配套设施和控制手段均视为不符法令 501(f)章节及本篇中的规定要求，同时，根据法令 501(h)章节，在该设施中生产的产品为不合法规要求的产品。

(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 Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 1-301-443-6597, FAX 301-443-8818.
(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.
[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]

Sec. 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.

(e) 豁免或特别许可（准许与要求有差异）

(1) 任何人想要申请有关器械质量体系要求的豁免或特别许可，必须根据法令 520(f)(2)章节中规定进行。必须根据本部法规 10.30 中阐明的 FDA 管理程序提交豁免或特别许可申请。可以从以下部门获取指导：医疗器械和放射健康中心，小型制造商协助部，(HFZ-220)，1350 Piccard Dr.，Rockville，MD 20850，美国， 电话：1-800-638-2041 或 1-30144-6597，传真：301-443-8818。

(2) 如果确定特别许可是最符合公众健康的利益，那么 FDA 可以提出和批准特别许可（准许与医疗器械质量体系要求有差异）。只有当公众健康对这种器械有需求并且该器械不得到特别许可就不可能充分满足需求时，这种特别许可才能继续保持有效。

[参考 61 FR 52654，1996 年 10 月 7 日， 修订后的 65 FR 17136，2000 年 3 月 31 日； 65 FR 66636，2000 年 11 月 7 日； 69 FR 29829， 2005 年 5 月 25 日]

820.3 定义

(a) 法令

是指经修订后的联邦食品、药品和化妆品法令 (secs.201-903,52 Stat，1040 et seq.,修订后的(21 U.S.C 321-394))。法令 201 章节中的所有定义应适用于本篇。

(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.

(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

(b) 抱怨
是指器械获准发运后，任何宣称有关器械一致性、质量、耐用性、可靠性、安全性、有效性或性能方面有缺陷的书面的、电子的或□头的通讯。

(c) 部件
是指任何原材料、物质、物件、零件、软件、固化软件、标签或组件，他们是要作为经包装并贴上标签的最终器械的一个部分。

(d) 控制号
是指任何形式的区别性代号，诸如字母和/或数字的组合，通过这一代号可以追溯一套、一组或一批最终器械的制造、包装、贴标签和发运记录。

(e) 设计历史文档(DHF)
是指说明最终器械设计历史的一套记录。

(f) 设计输入
是指对器械的物理和性能要求，用来作为设计的基础。

(g) 设计输出
是指各设计阶段和总设计最终阶段的设计成果。最终设计输出是产品主文档(DMR)的基础。全面的最终设计输出由器械、包装和标签以及 DMR 组成。

master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

(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.

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

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

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

(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.

(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

(h) 设计评审
是指对设计进行的综合性、系统性的评审并形成文件，以评估设计要求是否正确充分，并评估该设计是否能够达到这些设计要求，同时指出存在的问题。

(i) 产品历史文档 (DHR)
是指包含某一最终器械生产记录的一套文档。

(j) 产品制造性文档(DMR)
是指包括最终器械的生产程序和产品规范的一套文档。

(k) 建立
是指定义，编制文件（以书面或电子文件形式）并进行实施。

(l) 最终器械
是指任何能够使用并正常工作的器械及其附件不论是否经过包装、贴上标签或已灭菌。

(m) 一批或一组
是指由相同品种、型号、等级、尺寸、材料成分或软件版本组成的一个或多个部件或最终器械，这些部件或最终器械是在相同条件下生产出来，并在规定条件下具有统一的特性和质量。

under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

(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.

(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.

(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.

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

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

（n）最高管理者（有行政治能的管理者）
是指那些在生产厂家中有权制定或更改质量方针和质量体系的高级职员。

（o）生产厂家
是指设计、制造、装配、组装或加工最终器械的任何人。生产厂家包括但不限于那些进行承包灭菌、安装、重贴标签、重新制造、重新包装或规范开发的人员，以及实施这些功能的国外实体的直属分销商。

（p）制造材料
是指在生产过程中或为促进生产过程所使用的任何材料或物质，以及生产过程中产生的副成分或相伴成分，这种副成分作为残渣或杂质在最终器械内或表面出现，但这不是制造商设计或计划的。

（q）不符合
是指没有满足某个规定的要求。

（r）产品
是指部件、生产材料、正在生产的器械、最终器械和退回的器械。

devices.

(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.

(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.

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

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

(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,

(s) 质量
是指对器械特征和特性的总称，这些特征或特性保证器械能够适合使用，包括安全特性和运行性能。

(t) 质量审核
是指为确定质量体系行为以及该行为是否符合质量体系程序，该程序是否有效实施并且适合于达到该体系目标，对生产厂家的质量体系按规定的间隔和足够的次数所进行的有系统的、独立的检查。

(u) 质量方针
是指由最高管理者制定的有关质量方面的总体计划和方向。

(v) 质量体系
是指实施质量管理的组织结构、职责、程序、过程和资源。

(w) 再加工者(商)
是指加工、调节、革新、重新包装、重新储存、或采取其它行为对最终产品的性能、安全规范或预期用途产生重大修改的任何人。

or intended use.

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

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

(z) *Validation*
means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
(1) *Process validation*
means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.
(2) *Design validation*
means establishing by objective evidence that device specifications conform with user needs and intended use(s).

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

Sec. 820.5 Quality system.

Each manufacturer shall establish and maintain a

(x) 返工
是指对不合格品采取的措施，使它在获准发运之前符合规定的 DMR 的要求。

(y) 规范
是指产品、过程、服务或其它活动必须符合的要求。

(z) 确认
是指通过检查和提供客观依据表明针对某一特定用途的要求可以始终得到满足的认可。
(1) 过程确认
是指用客观证据证明某一过程生产的成果获产品始终符合预期的规范。
(2) 设计确认
是指用客观证据证明器械的规范符合用户的需求和预期用途。

(aa) 验证
是指通过检查和提供客观依据表明规定要求已经得到满足的认可。

820.5 质量体系

各生产厂家须制定和保持质量体系，该质量体系应适合其设计和生产特定医疗器械，并且符合本篇的要求。

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

Sec. 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.

(3) *Management representative.* Management with

B- 质量体系要求

820.20 管理职责

(a) 质量方针
最高管理者应制定质量方针和目标，并作承诺。最高管理者应确保组织结构内各级员工都能够理解，实施和保持此质量方针。

(b) 组织结构
各生产厂家应制定和保持合适的组织结构，以确保按照本篇要求进行器械的设计和生产。
(1) 职责和权限
各生产厂家应对所有负责管理、实施和评估质量工作的人员确定适合的职责、权限和相互关系，并且授予这些人员完成这些任务所必需的独立性和权限。
(2) 资源
各生产厂家应为工作的管理和实施以及评估活动（包括质量内审工作在内）提供充分的资源，包括指派经过培训的人员，以便符合本篇要求。

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.

(3) 管理者代表
最高管理者应书面任命一名管理人员，这名管理人员不论他是否承担其他职责，应具备下列权限和职责：
(i) 确保按照本篇要求有效建立并保持质量体系；并且
(ii) 向最高管理者汇报质量体系实施情况供其评审。

(c) 管理评审
最高管理者应根据所建立的程序定期多次对质量体系适用性和有效性进行评估，确保质量体系满足本篇所规定的要求和生产厂家所建立的质量方针和目标。质量体系的评审日期和结果应有文件记录。

(d) 质量策划
各生产厂家应制定质量计划，确定与所设计和生产的器械有关的质量实践、资源和活动。生产厂家应为如何达到质量要求制订出措施。

(e) 质量体系程序
各生产厂家应建立质量体系程序和指导书。在适当的时候，应制定出质量体系中所使用文件的结构纲要。

Sec. 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 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.

Sec. 820.25 Personnel.

(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.

(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.
(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.

820.22 质量审核

各生产厂家应建立质量审核程序并实施这种审核工作，以确保其质量体系符合已建立的质量体系要求，并确定质量体系是否有效。应由与受审事件无直接责任的人员实施质量审核。如有必要，应采取纠正措施，包括对不符合要求事件的复审工作。应对每一次质量审核及复审作总结报告，对受审事件负责的管理者应审阅该报告。质量审核及复审的日期和结果应有文件记录。

820.25 人员

(a) 总则

各生产厂家应有足够的人员，这些人员应具备相关学历、背景、受过培训并有一定经验，以确保能正确实施本篇所要求的所有活动。

(b) 培训

各生产厂家应建立程序，以确定培训需求并确保所有人员都受过必要培训能够充分履行其职责。培训应有文件记录。

(1) 员工应意识到他们在专职工作中的不正确行为可能会导致器械故障，这应成为他们培训的一部分。

(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.

Subpart C--Design Controls

Sec. 820.30 Design controls.

(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 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.

(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.

(2) 负责验证和确认活动的职员应认识到他们工作职责中可能遇到的过失和错误。

C- 设计控制

820.30 设计控制

(a) 总则
(1) 为了确保到达指定的设计要求，生产第三类或第二类器械以及本部分(a)(2)段中提到的第一类器械的生产厂家应建立并保持相应的程序来控制器械的设计。
(2) 下述第一类器械需要进行设计控制：
(i) 用计算机软件自动控制的器械；以及
(ii) 以下列出的器械。

章节	器械
868.6810	气管、支气管吸入导管
878.4460	外科手套
880.6760	不自主运动患者辅助保护器械
892.5650	放射性核素人工给药系统
892.5740	治疗用放射性核素源

(b) 设计和开发的策划
各生产厂家应建立和保持计划以说明或指明设计和开发活动并明确实施责任。这些计划应指出并说明那些向设计和开发过程提供或产生输入的不同部门或活动直接的接□工作。在设计和开发的进展过程中，须对这些计划进行评审、更新和批准。

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.

(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.

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

（c）设计输入
各生产厂家应建立和保持专门程序来确保与器械有关的设计要求是适用的并符合器械的预期用途，包括使用者和病人的需要。
这些程序应包括当要求不完整、含糊不清或矛盾时应如何解决的机制。设计输入要求应形成文件并应经过指定人员评审和审批。审批应形成文件，包括审批人员的签名和日期。

（d）设计输出
各生产厂家应建立和保持专门程序来明确设计输出并以文件形式记录设计输出，这样就能够充分评估其是否符合设计输入要求。设计输出程序应含有或指明验收准则，并应确保那些对器械运行起重要作用的关键设计输出已经得以明确。设计输出在获准发放之前应形成文件、经过评审和审批。审批应形成文件，包括设计输出人员的签名和日期。

(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).

(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.

(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

(e) 设计评审

各生产厂家应建立和保持设计评审程序，确保在器械设计开发的适当阶段对设计成果进行正式评审并作记录。

设计评审程序应确保参加每一次设计评审的人员，这些人员包括与被评审的设计阶段有关的所有职能部门的代表，与被评审的设计阶段无直接责任的个人，以及所需的任何专家。设计评审报告包括设计名称标识、日期和实施评审人员，应形成文件，归档在设计历史文档（DHF）中。

(f) 设计验证

各生产厂家应建立和保持程序来验证器械的设计。

设计验证应证明设计输出符合设计输入的要求。设计验证报告应包括设计的标识、方法、日期、执行设计验证人员，并应以文件形式存在 DHF 中。

(g) 设计确认

各生产厂家应建立和保持程序来确认器械的设计。

设计确认应对最初几台或几批生产装置或它们的等同物在规定的操作条件下进行。设计确认应确保器械符合规定的用户要求和预期的用途，并应包括在实际或模拟使用条件下生产装置的测试情况。在适当的时候，设计确认应包括软件的确认和风险分析。设计确认结果应包括设计名称的标识、方法、日期、实施确认人员，并应形成文件存在 DHF 中。

conditions. Design validation shall include software validation and risk 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.

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

(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.

(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.

(h) 设计转化
各生产厂家应建立和保持程序来确保器械的设计正确地转化到生产规范中去。

(i) 设计更改
各生产厂家应建立和保持设计更改程序，包括：设计更改的标识、文件记录、确认或在适当时候（在设计更改实施之前）进行的验证、评审和审批工作。

(j) 设计历史文档 (DHF)
各生产厂家应对每一类器械建立和保持设计历史文档 (DHF)。DHF 文件中应包含或指明所有必要的文件记录，以表明设计开发是按照批准的设计计划和本篇要求进行的。

Subpart D--Document Controls

Sec. 820.40 Document controls.
Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:
(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 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.

(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.

D-文件控制

820.40 文件控制

各生产厂家应建立和保持文件控制程序来控制本篇所要求的所有文件。程序应提供以下内容：

(a) 文件审批和分发

对于所有为达到本篇要求而建立的文件，各生产厂家应指定一名或多名人员检查其完整性并进行审批。审批应有文件记录，包括日期和审批人员的签名。对于所有为达到本篇要求而建立的文件，应在所有指定的地方、需使用该文件的地方或其它必要的地方都能找到，所有作废文件应迅速从各使用地方撤消或用其他方法防止其被无意使用。

(b) 文件修改

除非有其他特别指定，文件的修改应由原来进行评审和审批的相同职能部门或组织机构中的人员进行评审和审批。

修改批准后应及时通知有关人员。各生产厂家应保留文件修改的记录。修改记录应包括对修改的说明、指出受影响的文件、审批人员的签名、审批日期以及修改的生效时间。

Subpart E--Purchasing Controls

Sec. 820.50 Purchasing controls.

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

(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:

(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

E- 采购控制

820.50 采购控制

各生产厂家应建立和保持程序来确保所有采购产品或通过其他方式收到的产品和服务符合规定要求。

(a) 对供货商、分包商和顾问的评估

各生产厂家应建立和保持相关要求，包括对供货商、分包商和顾问必须达到的质量要求。各生产厂家应：

(1) 根据潜在供货商、分包商和顾问达到指定要求（包括质量要求）的能力，对其进行评估和选择。评估过程应形成文件。

(2) 根据评估的结果，确定控制类型和控制范围对产品、服务、供货商、分包商和顾问进行控制。

(3) 建立和保持合格供货商、分包商和顾问的记录。

(b) 采购资料

各生产厂家应建立和保持数据资料，这些数据资料应明确地说明或指明对采购产品或通过其它方式收到的产品和服务的规范要求，包括质量要求。

如果可能的话，采购文件中应包括一份供货商、分包商和顾问同意通知生产厂家有关产品或服务上变动的协议，以便生产厂家可以确定这些变动是否可能影响最终器械的质量。采购资料应根据 820.40 要求进行审批。

may affect the quality of a finished device. Purchasing data shall be approved in accordance with 820.40.

Subpart F--Identification and Traceability

Sec. 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.

Sec. 820.65 Traceability.
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.

Subpart G--Production and Process Controls

Sec. 820.70 Production and process controls.

(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

F- 标识和可追溯性

820.60 标识

为了在进货、生产、销售和安装各阶段识别产品以防混淆，各生产厂家应建立和保持专门程序。

820.65 可追溯性

外科植入人体或为了支持或维持生命的器械，在按照标签说明合理使用时发生的器械故障可能会对使用者造成重大伤害的，其生产厂家应建立和保持程序，用控制号对每台、每批最终器械及（必要时）有关部件加以识别。
这些程序应促进纠正措施的实施。这种识别应在 DHR 文件中作记录。

G-生产和过程控制

820.70 生产和过程控制

(a) 总则
各生产厂家应开发、实施、控制、监控生产过程确保器械符合其规范。如果制造过程有可能引起器械与规范有偏差，生产厂家应建立和保持过程控制程序，说明为确保符合规范必须进行的任何过程控制。必须进行过程控制时，该控制应包括：

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:
(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;
(2) Monitoring and control of process parameters and component and device characteristics during production;
(3) Compliance with specified reference standards or codes;
(4) The approval of processes and process equipment; and
(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

(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.

(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

(1) 指导性文件、标准操作程序（SOP）以及确定和控制生产方式的方法；
(2) 生产期间过程参数、部件和器械的特性的监控和控制；
(3) 符合指定的参考标准或法规；
(4) 过程和过程设备的审批；以及
(5) 以文件化标准或有标识的、批准的代表性样品来阐明规定技艺评定准则。

(b) 生产过程的修改
各生产厂家应对规范、方法、过程或程序的修改建立和保持程序。
这些修改在实施之前应根据 820.75 规定进行验证或在必要时进行确认，这些活动应有文件记录。所作的修改应根据 820.40 规定进行审批。

(c) 环境控制
当环境条件对产品质量可能有相应的负面影响时，生产厂家应建立和保持程序适当控制这些环境条件。
须定期检验环境控制系统，以验证系统（包括所需设备）是否齐备并能正常运转。这些活动应有文件记录并经过审批。

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.

(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.

(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.

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

(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

（d）人员
如果职工与产品或环境接触可能会对产品质量产生负面影响，各生产厂家应建立和保持有关职工健康、清洁、个人行为和服装的要求。生产厂家应确保在特殊环境条件下工作的保养人员和其他临时工经过适当的培训或在经过培训人员的监督下工作。

（e）污染物控制
各生产厂家应建立和保持程序以避免设备或产品受到可能对其质量有负面影响的物质的污染。

（f）建筑物
建筑物应设计合理，并保留足够的空间进行必要的经营活动。避免混淆并确保井井有条。

（g）设备
各生产厂家应确保所有在制造过程中使用的设备符合规定的要求，合理设计、合理制造、合理安放和安装以便进行保养、调整、清洁和使用。

maintenance, adjustment, cleaning, and use.
(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.
(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.
(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.

(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.

(i) *Automated processes.* When computers or automated data processing systems are used as part

(1) 保养计划
各生产厂家应对设备的调整、清洁和其它保养工作建立和保持计划以确保符合生产制造规范。保养活动（包括日期和执行保养活动的人员）应有文件记录。
(2) 检验
各生产厂家应根据建立的程序定期进行检验以确保遵循适用的设备保养计划。检验工作（包括日期和检验人员）应有文件记录
(3) 校正
各生产厂家应确保在需要定期校正的设备上或旁边都清晰地贴上其限制范围或允许的公差，或使校正人员可以马上查到这些数据。

(h) 生产材料
如果某一生产材料可能会对产品质量产生相应的负面影响，生产厂家应对这种生产材料的使用和撤销建立和保持专门的程序，以确保这一材料得以撤销或限制在一定数量使得器械的质量不受负面影响。对这种生产材料的消除或限制应有文件记录。

(i) 自动过程
当计算机或自动数据处理系统作为生产或质量系统的一部分使用时，生产厂家应根据制订的方案对计算机软件的预期用途进行确认。所有软件的修改应在批准和发放之前进行确认。这些确认活动和结果应有文件记录。

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.

Sec. 820.72 Inspection, measuring, and test equipment.

(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, 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.

820.72 检验、测量和试验设备

(a) 对检验、测量和试验设备的控制

各生产厂家应确保所有的检验设备、测量设备和试验设备包括机械设备、自动设备或电子检验和试验设备适合其预期用途并且能够产生有效的结果。

各生产厂家应建立和保持程序确保设备得到常规校正、检验、审查和保养。程序中应包括设备搬运、保存和存储规定，以便保持设备精确完好。这些活动应有文件记录。

(b) 校正

校正程序应包括对设备精确度的具体说明和规定范围。如果不符合此精确度范围，应该有规定说明如何制订补救措施重新恢复精确度范围，并评估这是否对器械质量有任何负面影响。这些活动应有文件记录。

(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.

Sec. 820.75 Process validation.

(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.

(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.

(1) 校正标准
对于检验设备、测量设备和试验设备的校正标准应遵循国家或国际上的标准。如果国家或国际标准不实用或没有，生产厂家应使用可再现的独立标准。如果不存在可适用的标准，生产厂家应建立和保持内部标准。
(2) 校正记录
设备标识、校正日期和各校正人员以及下一次校正日期应以文件形式做好记录。这些记录应显示在各单件设备上或附近，或设备使用者和设备校正人员可以马上查到这些记录。

820.75 过程确认

(a) 当过程结果不能通过后来的检验和试验得到充分验证时，应进行过程确认以确保其高度可靠性，并根据已建立的程序进行审批。过程确认活动和结果应有文件记录，包括审批确认人员的签名和日期，以及在适当的地方标明经确认的主要设备。

(b) 各生产厂家应建立和保持程序，监控和控制确认后过程的过程参数以确保其一直符合规定的要求。

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

(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.

Subpart H--Acceptance Activities

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

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

(b) *Receiving acceptance activities.* Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.

(c) *In-process acceptance activities.* Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that

(1) 各生产厂家应确保由合格人员来操作经确认后的过程。
(2) 对于确认后的过程，其监控和控制方法及数据、实施日期，必要时，包括那些过程实施人员或使用的主要设备均应有文件记录。

(c) 当发生变化或过程有偏差时，生产厂家应对过程进行评审和评估，并在必要时，进行再次确认。这些活动应有文件记录。

H- 验收活动

820.80 进货、在制品和最终器械的验收

(a) 总则
各生产厂家应对验收活动建立和保持专门程序。验收活动包括检验、试验或其它验证活动。

(b) 进货验收活动
各生产厂家应对进货验收建立和保持程序。进货产品必须通过检验、试验或其它方式验证为符合规定要求。接受或退回应有文件记录。

(c) 在制品的验收活动
必要时，各生产厂家应建立和保持验收程序，确保在制品符合规定的要求。这些程序应确保，只有在所需的检验和试验或其它验证活动完成之后，或在得到必要的批准之后，并且这一切活动都已形成文件之后，才能结束对在制品控制。

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.

(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:
(1) The activities required in the DMR are completed;
(2) the associated data and documentation is reviewed;
(3) the release is authorized by the signature of a designated individual(s); and
(4) the authorization is dated.

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

(d) 最终验收活动

各生产厂家应对最终器械的验收建立和保持程序以确保每一轮生产的最终器械或每一批最终器械符合验收标准。最终器械在获准发放之前必须隔离存放或以其它方式进行充分控制。最终器械只有完成以下活动后才可以获准发运:

(1) 完成 DMR 文件中所要求的活动;
(2) 已完成对相关数据和文件的评审;
(3) 已得到指定人员的签名批准发放; 并且
(4) 标明批准日期。

(e) 验收记录

各生产厂家应以文件形式记录本篇所要求的验收活动。这些记录应包括:

(1) 所进行的验收活动;
(2) 验收活动完成日期;
(3) 验收结果;
(4) 验收人员的签名;
(5) 必要时, 标明所使用的设备。这些记录将是 DHR 文件的组成部分。

Sec. 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

Sec. 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 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

820.86 验收状态

各生产厂家应以合适的方法对产品状态加以标识，标明产品是否符合验收标准。在产品生产、包装、贴标签、安装和维修的整个过程中，应保持产品的验收状态标识，以确保只有通过验收合格后的产品才可以发运、使用或安装。

I- 不合格品

820.90 不合格品

(a) 不合格品的控制

各生产厂家应建立和保持程序，对不符合规范要求的产品加以控制。
程序中应说明对不合格品的标识、记录、评估、隔离和处置。
不合格品的评估应包括确定是否有必要进行调查和指定专门的不合格品负责人员或机构。评估和任何调查工作应有文件记录。

(b) 不合格品的评审和处置

(1) 各生产厂家应建立和保持程序，确定不合格品评审职责和处置权限。程序中应阐明评审和处置过程。对不合格品的处置应有文件记录。文件中应包括使用不合格的理由以及批准其可以使用的人员签名。

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

Sec. 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. 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;

(2) 各生产厂家应对产品返工建立和保持程序，包括返工后对不合格品的重新试验和重新评估以确保产品符合经批准的当前规范。返工和重新评估活动包括确定产品返工后带来的任何负面影响，应在 DHR 文件中作记录。

J- 纠正和预防措施

820.100 纠正和预防措施

(a) 各生产厂家应对纠正和预防措施的实施建立和保持程序。这些程序应包括以下要求：
(1) 分析过程、操作、让步、质量审核报告、质量记录、维修记录、抱怨、退回产品以及其它来源的质量数据，确定产生不合格品或其它质量问题的现有及潜在的原因。必要时，应采用适当的统计方法发现重复出现的质量问题；
(2) 有关产品、过程和质量体系不合格原因的调查；

(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

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

(3) 指出纠正和预防不合格品和其它质量问题再次出现所需的措施;
(4) 验证或确认纠正和预防措施以确保这些措施是有效的以及不会对最终器械带来负面影响;
(5) 为了纠正和预防已发现的质量问题，对程序和方法进行修改并以文件形式加以记录;
(6) 确保产品质量保证直接负责人或预防措施实施人员了解有关质量问题或不合格品信息；并且
(7) 将相关质量问题以及纠正和预防措施的信息提交给有关部门作管理评审。

(b) 本章所要求的所有活动及其结果应有文件记录。

K- 标签和包装控制

820.120 器械标签

各生产厂家应建立和保持程序来控制标签标识活动。

(a) 标签的完整性
在通常条件下的加工、存储、搬运、发运以及某些使用情况下，标签的印制和应用必须注意保持清晰并且始终粘贴牢固。

(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 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.

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

(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.

(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.

Sec. 820.130 Device packaging.

Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

(b) 标签检验
指定人员须对标签的正确性进行检查，包括正确的有效期、控制号、存放指导、搬运说明以及其它任何处理说明，然后才可以批准其存储或使用。标签的批准、包括检查日期和检查人员的签名，应在 DHR 文件中作记录。

(c) 标签的存储
各生产厂家存放标签时应做好标记加以鉴别以防混淆。

(d) 标签操作
各生产厂家应对标签和包装的操作进行控制以避免标签互相混淆。应在 DHR 文件中记录贴在各个产品上的标签。

(e) 控制号码
如若根据 820.65 中规定须有控制号的，该控制号应贴在器械上发运或随机发运。

820.130 器械包装

各生产厂家应确保所设计和制造的器械包装箱和集装箱在一般加工、存储、搬运和发运条件下能使器械免遭损坏或变化。

Subpart L--Handling, Storage, Distribution, and Installation

Sec. 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.

Sec. 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.

Sec. 820.160 Distribution.

(a) Each manufacturer shall establish and maintain procedures for control and distribution of finished

L- 搬运、存储、发运和安装

820.140 搬运

各生产厂家应建立和保持程序确保产品在搬运期间不会发生混淆、损坏、退化、污染或其它负面影响。

820.150 存储

(a) 各生产厂家应建立和保持程序来控制产品的存储区域和仓库，避免发生混淆、损坏、退化、污染或其它不利于产品使用和发运的负面影响，并且确保废弃的产品、次品或退化的产品不会被使用或发运。如果产品质量会随存放时间而发生变化的，那就必须以合理的库存流转方式存放产品，并根据需要，对其情况进行评定。

(b) 各生产厂家应建立和保持程序说明从存储区域和仓库中领料和发料的审批方法。

820.160 发运

(a) 各生产厂家应对最终产品的控制和发运建立和保持程序，确保只有经审批获准发放后的器械才可以发运，以及购买合同必须经过评审以确保不明确的地方和出错地方在器械获准发运之前已经得以解决。
如若器械的适用性或质量会随时间延续而发生变化，所建立的程序应确保过期的器械或因质量变化而不适合使用的器械不被发运。

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. 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.

(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.

Sec. 820.170 Installation.

(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.

(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

(b) 各生产厂家应保留发运记录，该记录须包括或指明以下各项：
(1) 最初收件人的姓名和地址；
(2) 被发运器械的名称标识和数量；
(3) 装运的日期；以及
(4) 任何所使用的控制号。

820.170 安装

(a) 对于需安装的器械，各生产厂家应制订和维护全面的安装和检验指导书，并且在必要时，制定测试程序。该指导书和程序应包括确保合理安装的说明，以使得器械在安装后能正常工作。生产厂家应随机发运器械的指导书和程序，或以其它方式确保安装人员能获取这些指导书和程序。

(b) 安装人员应确保器械的安装、检验和所需的测试都是按照生产厂家的指导书和程序执行的，并且应以文件形式记录检验和测试结果，表明其是合理安装的。

inspection and any test results to demonstrate proper installation.

Subpart M—Records

Sec. 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

M- 记录

820.180 一般要求

本篇要求的所有记录应保存在生产场所或其它地方以便生产厂家负责人员以及 DFA 指定的检查人员可以合理得到这些记录。FDA 官员应该可以方便地获得这种记录，包括未存放在受检场地的记录，进行评审并复印。记录应清晰易读、尽可能保存完好并避免丢失。存在数据自动处理系统中的那些记录须作备份。

(a) 保密性
生产厂家认为是机密性的记录，应作好标记，以便 FDA 根据本章第 20 节有关公共信息管理规定，决定是否可以公布这些记录。

(b) 记录的保存期限
本篇所要求的所有记录应保留一段时间，相当于设计和预期的产品寿命，但不能少于从生产厂家批准商品发运日期起的 2 年时间。

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 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.

Sec. 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:

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

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

(c) 豁免

本小节不适用于 820.20(c) 管理评审，820.22 质量审核中要求的报告，以及 820.50(a)供货商、分包商和顾问评估所要求的供货商审核报告，但适用于在这些规定下建立的程序。根据 FDA 指派人员的要求，最高管理者应以书面形式证明本篇所要求的管理评审、质量审核以及必要时的供货商评审都已完成并已形成文件，注明完成日期，并且已采取必要的纠正措施。

820.181 产品制造性文档

各生产厂家应保持产品制造性文档(DMR)。各生产厂家应确保各 DMR 文件按照 820.40 要求进行准备和审批。各种类型器械的 DMR 文件应包括以下信息或指明这些信息所在地的地方:

(a) 器械规范包括相应的图纸、结构、公式、部件规范和软件规范;

(b) 生产过程规范包括相应的设备规范，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;

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

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

Sec. 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

(c) 质量保证程序和规范包括验收标准和所用的质量保证设备;

(d) 包装和标签规范，包括所用的方法和过程;

(e) 安装、保养、维修程序和方法。

820.184 产品历史文档

各生产厂家应保持产品的历史文档 (DHR)。各生产厂家应建立和保持程序，以确保保持每一批或每一台器械 DHR 文件，表明器械是根据 DMR 文件和本篇的要求生产制造的。
DHR 文件应包括以下信息或指明这些信息所在的地方:

(a) 生产日期;

(b) 生产数量;

(c) 获准发运的数量;

(d) 表明器械是根据 DMR 文件生产的验收记录;

(e) 各生产部件最初使用的标签; 以及

(f) Any device identification(s) and control number(s) used.

Sec. 820.186 Quality system record.

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.

Sec. 820.198 Complaint files.

(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:
(1) All complaints are processed in a uniform and timely manner;
(2) Oral complaints are documented upon receipt; and
(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting.

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the

(f) 使用的器械的标识和控制号。

820.186 质量体系记录

各生产厂家应保持质量体系记录（QSR）。在本篇中不针对特殊类型器械所要求的各项活动的程序和文件应包含在 QSR 中，或 QSR 应指出其所存放的地方，这包括但不仅限于 820.20 中要求的记录。各生产厂家应确保根据 820.40 中规定准备和审批 QSR。

820.198 抱怨文档

(a) 各生产厂家应保留抱怨文档。各生产厂家应建立和保持程序，对正式指定部门接受抱怨、评审抱怨和评估抱怨作出规定。这种程序应确保：
(1) 统一并及时处理所有抱怨；
(2) 收到的口头抱怨要记录下来；并且
(3) 评估抱怨，并根据本部法规 803 篇或 804 篇中的医疗器械汇报制度确定该抱怨中是否有需要向 FDA 汇报的事故。

(b) 各生产厂家应评审和评估所有抱怨以便决定是否有必要进行调查。当不进行调查时，生产厂家应保留有关记录，包括不进行调查的原因以及作出不调查决定的负责人的姓名。

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.

(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 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;

(c) 有关器械、标签或包装不符合规范的抱怨，必须经过评审、评估和调查，除非是对类似抱怨已经进行过这种调查而且没有必要再作调查。

(d) 凡抱怨涉及到必须向 FDA 汇报的事件，（本部法规第 803 篇或第 804 篇规定有必须汇报的事件），则应由指定人员迅速进行评审、评估和调查，并且，这类抱怨应在抱怨文件中单独存档或以其他方式作明显标识。除了 820.198(e)中要求的信息之外，本段提到调查记录还应包括确定以下几点：

(1) 器械是否不符合规范；

(2) 器械是用于治疗还是诊断；并且

(3) 如果有的话，器械与所汇报事故或不良事件之间的关系。

(e) 如果根据本节要求进行了调查，应由本节(a)中提到的正式指定部门保存调查记录。调查记录应包括：

(1) 器械的名称；
(2) 收到抱怨的日期；

(3) Any device identification(s) and control number(s) used;
(4) The name, address, and phone number of the complainant;
(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]

Subpart N—Servicing

Sec. 820.200 Servicing.

(a) Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions

(3) 器械使用的标识和控制号;
(4) 抱怨者的姓名、地址和电话号码;
(5) 抱怨的性质和具体内容;
(6) 调查日期和结果;
(7) 所采取的纠正措施;以及
(8) 给抱怨者的答复。

(f) 如果生产厂家正式指定的抱怨处理部门与生产场地不一处,那么应作安排使得生产场地上也能合理获取这些调查的抱怨文件和调查记录。

(g) 如果制造商正式指定的抱怨处理部门在美国以外,本部分所要求的记录应在美国可以获得,可以是:
(1) 保留有生产厂家记录的美国某地方;或
(2) 最初分销商所在地。
[参考 61 FR 52654, 1996 年 10 月 7 日, 修订后的 69 FR 11313,2004 年 3 月 10 日]

N- 服务

820.200 服务

(a) 如果对服务有要求,各生产厂家应建立和保持指导书和程序以实施和验证服务是否符合指定的要求。

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 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]

Subpart O--Statistical Techniques

Sec. 820.250 Statistical techniques.

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing,

(b) 各生产厂家应根据 820.100 的规定，用适当的统计学方法分析服务报告。

(c) 如果生产厂家收到的服务报告含有本部法规第 803 篇规定的必须向 FDA 汇报的事件，应该将此服务报告视为一项抱怨并应根据 820.198 中的要求进行处理

(d) 服务报告应形成文件，并应包括:
(1) 所维护器械的名称;
(2) 器械标识和所使用的控制号码;
(3) 维护日期;
(4) 维护的人员;
(5) 所进行的维护工作；以及
(6) 测试和检验数据。
[参考 61 FR 52654,1996 年 10 月 7 日，修订后的 69 FR 11313,2004 年 3 月 10 日]

0- 统计技术

820.250 统计技术

(a) 必要时，各生产厂家应建立和保持程序，对建立，控制和验证过程能力和产品特性的可接受性确定有效的统计技术。

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.

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.

(b) 使用抽样计划应有书面记录，并应根据有效的统计基本原理进行。各生产厂家应建立和保持程序，以确保抽样方法足以适合其预期用途，还应确保当发生变化时，评审该抽样计划。这些活动应有文件记录。

权威著作：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.
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